PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Cycle 3 2016 Funding Cycle

Limited PCORI Funding Announcement: Dissemination and Implementation of PCORI-Funded Patient-Centered Outcomes Research Results and Products in Real-World Settings

Published August 15, 2016
Updated May 19, 2017

This limited PCORI Funding Announcement (PFA) applies to the funding cycle that closes on December 19, 2016, at 5 p.m. (ET). Application Guidelines, templates, and other resources are available at http://www.pcori.org/Cycle-3-2016-dissemination-implementation/.

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."

Overview

Published	August 15, 2016
Updated	May 19, 2017
Letter of Intent Deadline	September 14, 2016, by 5 p.m. (ET) A Letter of Intent (LOI) is required to submit a full application. Notification of denial or approval to submit a full application will occur no later than October 21, 2016
Summary	PCORI seeks to fund projects aiming to disseminate and implement patient-centered outcomes research/comparative clinical effectiveness research (PCOR/CER) results obtained from PCORI-funded studies. This announcement is designed to help close the gap between evidence development and implementation of that evidence in practice. PCORI recognizes that generating research evidence will be useful only if there is a commitment and strategic plan for dissemination and implementation. PCORI seeks projects designed to actively disseminate and implement the research results and products of PCORI-funded studies using creative strategies consistent with best practices in the context of established dissemination and implementation models and frameworks in real-world settings.
Applicant Resources	See http://www.pcori.org/Cycle-3-2016-dissemination-implementation/
Key Dates	Online System Opens: August 15, 2016 LOI Deadline: September 14, 2016, by 5 p.m. (ET) Screening Notification October 21, 2016 Application Deadline: December 19, 2016, by 5 p.m. (ET) Merit Review: March 2017 Awards Announced: August 15, 2017 Earliest Project Start Date: October 2017
Maximum Project Budget (Direct Costs)	$300,000
Maximum Project Period	Two years
Budget/Time Limits	If the proposed project exceeds the $300,000 budget and two-year period, applicants must submit a Greater Than Time/Budget Request with their LOI.
Funds Available Up to	$2,000,000 per cycle

Eligibility	*PCORI Research Awardees:* Recipients of PCORI research awards, including Broad PCORI Awards, Pilot Projects Program Awards, Targeted PCORI Awards, Pragmatic Clinical Study Awards, and PCORI-funded demonstration projects occurring within the National Patient-Centered Clinical Research Network (PCORnet) infrastructure (e.g., ADAPTABLE, obesity trials) are eligible to respond to this announcement. Applications associated solely with Eugene Washington PCORI Engagement Awards and Pipeline to Proposal Awards are not eligible for this limited PCORI Funding Announcement (PFA). *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 U.S. applicant organizations. Nondomestic components of organizations based in the United States and foreign organizations may apply, as long as there is demonstrable benefit to the U.S. healthcare system and U.S. efforts in the area of patient-centered research can be shown clearly. Organizations may submit multiple funding applications. Individuals are not permitted to apply. *Personnel:* A Letter of Support is required from the Principal Investigator (PI) of the original PCORI-funded research project if he or she is not the proposed PI of the current application. *Timing:* Applicants are required to submit a draft final research report pertaining to their PCORI research award before submitting a full application to this announcement. Applicants may submit the mandatory LOI before submitting their draft final research report. Applications submitted prior to the receipt of the draft final research report pertaining to the PCORI research award will be administratively withdrawn. Applicants will be eligible to submit their application up to two years after submitting their draft final research report.
Review Criteria	Please note that the merit review criteria for this announcement are different from those used when reviewing PCORI research applications. 1. Importance of research results and products in the context of the existing body of evidence 2. Readiness of the research results and products for dissemination 3. Technical merit 4. Project personnel and environment 5. Patient-centeredness 6. Patient and stakeholder engagement
Contact Us	**Programmatic Inquires:** Please contact the PCORI Dissemination Helpdesk via email disseminationpfa@pcori.org. PCORI will provide a response within three business days. However, we cannot guarantee that all questions will be addressed in three 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 provide a response 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 p.m. (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.

Table of Contents

I. Introduction

Summary of Program

The Patient-Centered Outcomes Research Institute (PCORI) is launching this funding initiative to support the dissemination and implementation of patient-centered outcomes research/comparative clinical effectiveness research (PCOR/CER) results obtained from PCORI-funded studies. This limited PCORI Funding Announcement (PFA) provides awardees the opportunity to apply for funds to support dissemination and implementation of their research. PCORI recognizes that generating research evidence will be useful only if there is a commitment and strategic plan to disseminate and implement it within the context of other evidence. Through this funding announcement, PCORI seeks to fund projects designed to actively disseminate and implement the results of PCORI-funded studies that are informed and guided by established dissemination and implementation models and frameworks, in the context of real-world settings. This limited PFA is designed to help close the gap between evidence development and implementation of that evidence in practice.

PCORI's objectives underlying this limited PFA are:

- To provide PCORI awardees the opportunity to disseminate the important findings pertaining to the original PCORI research that can improve practice on a timely basis

- To stimulate the development, application, and evaluation of dissemination and implementation approaches that will increase the use and application of PCOR/CER research results—as well as products derived from PCORI-funded studies—by diverse populations of end-users, including patients, caregivers, providers, policy makers and other relevant stakeholders

- To gain and apply generalizable knowledge from feedback and evaluation of dissemination and implementation strategies to better understand the barriers and facilitators of evidence dissemination and uptake, and to inform improvements in future dissemination and implementation efforts and ensure applicability to a wide range of audiences

- To explore the development, application, and evaluation of mechanisms for incorporating CER findings in decision making by diverse groups of stakeholders. This includes identifying best practices for approaching dissemination and implementation in PCORI priority areas and with priority populations.

Background

U.S. healthcare organizations and agencies in the public and private sectors spend billions of dollars on research and service delivery programs each year, yet patients and stakeholders often lack sufficient information to make decisions regarding the most effective treatment strategies for their particular circumstances.[1] Compared to the investment in research and service delivery in the United States, considerably less is spent on ensuring the availability and use of evidence-based information and approaches in real-world settings. As such, the gap between what we know can optimize healthcare

---

[1] Grimshaw JM, Eccles MP, Lavis JN, Hill SJ, Squires JE. Knowledge translation of research findings. Implementation Science 2012, 7:50.

delivery and what actually gets implemented in everyday practice remains one of the most important issues hindering the healthcare system and public health.[2,3] In the context of PCOR/CER, wherein end-users (e.g., patients and stakeholders) are actively partnering with researchers to identify and answer important and timely comparative research questions, and evidence is being generated as to the optimal approaches and interventions for use in real-world practice, it is even more critical that healthcare settings and personnel be equipped and engaged to effectively and efficiently integrate evidence into practice. Dissemination and implementation science seeks to address this gap by understanding how to create, evaluate, report, disseminate, and integrate evidence-based strategies to improve health and prevent disease in clinical and public health practice settings.[4] Finding ways to enhance awareness and knowledge of useful and relevant information (dissemination) to help people and organizations make decisions and put it into practice (implementation) is vital to the use of evidence in the healthcare system.

The concepts of dissemination and implementation are sometimes used interchangeably to characterize the complete process of bringing evidence into practice. For the purposes of this limited PFA, we make the following distinction between dissemination and implementation:

- *Dissemination* is the intentional, active process of identifying target audiences and tailoring communication strategies to increase awareness and understanding of evidence and to motivate its use in policy, practice, and individual choices.[5] The purpose of dissemination is to spread and sustain knowledge and the associated evidence-based interventions. *Passive dissemination*, sometimes called *research diffusion*, is an untargeted dissemination process whereby new evidence is absorbed and acted upon by a small body of highly motivated recipients.[6] **This limited PFA will not support projects primarily dependent on passive dissemination strategies, such as untargeted mass mailing, publication of study findings, and untargeted presentations to heterogeneous groups.**

- *Implementation* is the deliberate, iterative process of integrating evidence into policy and practice through adapting evidence to different contexts and facilitating behavior change and decision making based on evidence across individuals, communities, and healthcare systems.[4]

Dissemination and implementation share the ultimate goal of encouraging the use of evidence in individual decision making, policy, and practice; both involve stakeholder engagement and partnerships with people and organizations, and are enhanced through ongoing evaluation. For the current announcement, successful applications will propose context-appropriate strategies that address how research results and products are packaged, transmitted, interpreted, and delivered to diverse patient and stakeholder groups. Additional resources related to dissemination and implementation science and relevant terminology can be accessed at http://www.pcori.org/sites/default/files/PCORI-Dissemination-

---

[2] Meissner HI, Glasgow RE, Vinson CA, et al. The US training institute for dissemination and implementation research in health. Implementation Science: IS. 2013:8-12. Doi: 10.1186/1748-5908-8-12.

[3] Green LW, Ottoson JM, Garcia C, Hiatt RA. Diffusion theory and knowledge dissemination, utilization, and integration in public health. Annu Rev Public Health. 2009;30:151–174. doi: 10.1146/annurev.publhealth.031308.100049. [PubMed] [Cross Ref]

[4] Brownson RC, Colditz GA, Proctor EK. Dissemination and implementation research in health: translating science to practice. New York: Oxford University Press, Inc.; 2012.

[5] Mathematica Framework: http://www.mathematica-mpr.com/~/media/publications/pdfs/health/pcori%20di%20framework%20draft.pdf.

[6] Lomas J. Diffusion, dissemination, and implementation; who should do what? *Ann N Y Acad Sci.* 1993;703:226-35; discussion 235-7.

Implementation-Framework.pdf.

Priority Areas of Interest

PCORI is seeking projects that are proposing creative and well-informed strategies for actively disseminating and implementing PCOR results aimed at increasing their use, implementation and impact among diverse populations of patients, caregivers, healthcare providers, policy makers, and other relevant stakeholders.

Strategies proposed for disseminating and implementing PCORI results will vary based on the evidence being disseminated, the population(s) being targeted, and the goals of the dissemination and implementation effort. Below is a list of examples, which are intended to illustrate potential approaches. This list is not exhaustive or prescriptive. As such, a wide range of active strategies may be considered for supporting dissemination and implementation efforts, including but not limited to:

- Paper-based products that are adapted in design, format, or language to target lay audiences, cultural groups, and low health literacy or numeracy

- Electronic or web-based tools, such as Internet, TV, radio, cell phone, social networking sites, listservs, health avatars, and others

- Adaptation of electronic health records, personal health records, electronic medical records, or clinical decision aids attached to these systems

- Personal interactions occurring through targeted one-on-one or group discussions or in real-world settings, such as work, school or healthcare clinics

PCORI is interested in a number of diverse dissemination and implementation areas. It is expected that investigators and their partners will identify unique and creative opportunities for active dissemination and implementation of their work outside of the outlined areas of interest. **Examples of interest areas include, but are not limited to the following:**

- Translation and adaptation of the content or delivery mechanism of CER research results and products found effective to improve their penetration and use at the policy, health systems, clinical practice, caregiver, and patient levels

- Development, demonstration, and evaluation of processes or products to incorporate PCORI research results and products into decision-making settings for patients, providers, policy makers, and other stakeholders

- Translation, adoption, and dissemination of PCORI research results and products within the context of the existing body of evidence in the topic area targeted to one or more defined audiences of stakeholder groups with specialized needs (PCORI priority populations)

- Demonstration of the capacity and ability to take research results and products found effective through PCORI research studies "to scale" in diverse settings and populations

- De-implementation of or reduction in the use of strategies and procedures that are not evidence-based, have been prematurely widely adopted, or are harmful or wasteful, in place of

evidence-based approaches

Funds Available

PCORI has devoted up to $6 million in total annual costs under this limited PFA to fund projects designed to disseminate and implement PCOR/CER results attained from PCORI-funded studies. The proposed budget for individual studies may go up to $300,000 in direct costs as appropriate. The maximum project period is up to two years. However, if the proposed project's budget or duration exceeds limits specified in this announcement, applicants must submit a Greater Than Time/Budget Request with their Letter of Intent (LOI) to be considered for additional time or budget. Because the nature and scope of projects will vary, it is anticipated that the size and duration of awards will also vary. The amount awarded and the number of awards will depend upon the quality, duration, and costs of the applications received.

II.   Guidance for Preparing Applications

In developing a dissemination and implementation strategy and corresponding PCORI application, applicants should pay attention to three fundamental concepts, which the literature has identified as being instrumental to effective dissemination and implementation.[7,8,9,10,11] These concepts are Context, Engagement, and Evaluation.

- *Context* involves incorporating the dissemination and implementation plan into the bigger picture. Although the focus of dissemination efforts should be the results and products associated with PCORI-funded research projects, the findings must be considered within the context of (1) the existing body of evidence in the topic area, and (2) the setting in which the dissemination will take place (e.g., health system, organization, community, and so on), as well as the relationships with the stakeholders within the setting. Applicants should provide assurances of how the context of other research will be incorporated with the current findings when disseminating the evidence. Applicants should justify the strategy being proposed in the context of their PCORI findings, the broader knowledge related to the findings, and the goal of their dissemination and implementation efforts.[6]

- *Engagement* involves incorporating the perspectives and experiences of pertinent patients and stakeholders, including individuals living with the disease or condition of interest, as well as the host delivery systems and settings in which applicants intend to disseminate and implement their work. Dissemination and implementation efforts will not succeed without ongoing stakeholder engagement to provide the context needed to tailor dissemination and

---

[7] Pentland, D., K. Forsyth, D. Maciver, M. Walsh, R. Murray, L. Irvine, and S. Sikora. "Key Characteristics of Knowledge Transfer and Exchange in Healthcare: Integrative Literature Review." Journal of Advanced Nursing, vol. 67, no. 7, July 2011, pp. 1408–1425.

[8] Greenhalgh, T., G. Robert, F. Macfarlane, P. Bate, and O. Kyriakidou. "Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations." Milbank Quarterly, vol. 82, no. 4, 2004, pp. 581–629.

[9] Glasgow, R.E., C. Vinson, D. Chambers, M.J. Khoury, R.M. Kaplan, and C. Hunter. "National Institutes of Health Approaches to Dissemination and Implementation Science: Current and Future Directions." American Journal of Public Health, vol. 102, no. 7, July 2012, pp. 1274–1281.

[10] Brownson, R.C., G.A. Colditz, and E.K. Proctor. "Dissemination and Implementation Research in Health: Translating Science to Practice." New York: Oxford University Press, 2012.

[11] Neta, G. R.E. Glasgow, C.R. Carpenter, J.M. Grimshaw, B.A. Rabin, M.E. Fernandez, and R.C. Brownson. "A Framework for Enhancing the Value of Research for Dissemination and Implementation." American Journal of Public Health, vol. 105, no. 1, January 2015, pp. 49-57.

implementation activities. Ongoing support for engagement can help activate stakeholders and encourage capacity building among partners.[7,8] Applicants should ensure that patients and stakeholders are appropriately engaged in planning and executing their dissemination and implementation strategy and that the principles of reciprocal relationships, co-learning, partnership, trust, transparency, and honesty are reflected in their plans to engage with patients and stakeholders.

- *Evaluation* involves understanding how and why dissemination and implementation activities are or are not successful. Evaluation should be included as soon as planning for dissemination and implementation activities begins. Evaluation should focus on measurable processes and short-term outcomes that provide timely information on the effectiveness of the proposed activities. Ongoing feedback based on assessment of processes and short-term outcomes can inform future dissemination and implementation efforts.[9,10] PCORI expects that projects will be evaluated in terms of measuring issues such as reach, uptake, and adoption of the research findings.

Specific Requirements

The proposed project should meet the following requirements:

- Use active dissemination and implementation strategies in real-world contexts and settings.

- Center dissemination and implementation efforts around research findings or products emerging from PCORI-funded research awards.

- Receive endorsement from relevant patient organizations, clinician organizations, payer or purchaser consortia, and other stakeholders with significant influence upon the targeted end-users of this dissemination and implementation effort.

- Address an important research gap that is being filled with the research results and products of PCORI-funded research awards.

- Have strong interest from and support of the host delivery systems and settings.

Nonresponsiveness

LOIs and applications will be considered nonresponsive to this limited PFA and may be administratively withdrawn if the proposed project:

- Proposes a dissemination plan that is dependent upon passive dissemination strategies (publications or presentations to heterogeneous audiences) as its primary dissemination method.

- Aims to develop or validate a new tool or system for patients or clinicians without the primary purpose of actively disseminating or implementing evidence. Tools and systems proposed as the primary mechanism for actively disseminating and implementing evidence will be considered.

PCORI Populations of Interest

PCORI is particularly interested in identifying best practices for disseminating and implementing PCOR

research results and products to hard-to-reach populations or patients with multiple conditions. PCORI has developed a list of priority populations to guide our research and engagement efforts, which includes:

- Racial and ethnic minority groups

- Low-income groups

- Women

- Children (age 0–17 years)

- Older adults (age 65 years and older)

- Residents of rural areas

- Individuals with special healthcare needs, including individuals with disabilities

- Individuals with multiple chronic diseases

- Individuals with rare diseases

- Individuals whose genetic makeup affects their medical outcomes

- Patients with low health literacy, numeracy, or limited English proficiency

- Lesbian, gay, bisexual, and transgender (LGBT) persons

- Veterans and members of the armed forces and their families

Protection of Human Subjects

If applicable, applicants should describe the protection of human subjects involved in their proposed research. If human subject protection is not applicable, applicants should provide a justification in the event that 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 titled, "Human Subjects Research Policy" in the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports,[12] which was issued by the U.S. Department of Health and Human Services. PCORI does not require that applicants comply with sections of this policy that refer to requirements for federal-wide assurance or that refer 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.

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[13]). 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 (IRB) or IRBs that have jurisdiction for the

---

[12] See http://grants.nih.gov/sites/default/files/supplementalinstructions.docx.
[13] See http://www.pcori.org/sites/default/files/PCORI-Checklist-for-Evaluating-Human-Subjects-Protections.pdf/.

study.

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

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

For those projects requiring human subject protection, PCORI requires that all applicants adhere to the National Institutes of Health (NIH) policy on education in the protection of human subject participants in the conduct of research. This applies to all individuals listed as key personnel in the application. The policy and FAQs are available on the NIH website.[14]

III.   How To Submit an Application

Letter of Intent

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

- Clear identification and description of the research results and products to be disseminated

- Objective and specific aims

- Clear identification and description of the setting in which dissemination will take place and the end-users

- Identification of the evidence gap the research results and products fill, and the significance of the finding in the context of existing literature

- Clear description of the methodological approach for disseminating the research finding or product

- Description of the dissemination evaluation plan, including measurable indicators of success

---

[14] See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html.

- Patient and other stakeholder engagement in the planning and implementation of this dissemination effort

Please address all categories in the LOI Template, and then upload the document into PCORI Online. **The deadline for LOI submission is September 14, 2016, by 5 p.m. (ET).**

Letter of Intent Review

LOIs are noncompetitive and will not be scored during LOI review. A minimum of two PCORI staff members will screen LOIs for nonresponsiveness and to ensure compliance with administrative guidelines. Nonresponsive LOIs and those not adhering to administrative guidelines will be removed from the full application process. Notification of denial or approval to submit an application will occur no later than October 21, 2016. Please refer to the Application Guidelines for information on how to submit your LOI via PCORI Online.

Submission Dates

LOIs and applications must be submitted in accordance with the published dates and times listed in the Overview section of this document and in the PCORI Funding Center.

PCORI Online

To submit an application, you must register with PCORI Online and submit both an LOI and an application for each cycle to which you are applying.

Applicant Resources

PCORI Funding Center	http://www.pcori.org/Cycle-3-2016-dissemination-implementation/
PCORI Online	https://pcori.fluxx.io
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 PFA development; staff evaluation of LOIs; preliminary review of full applications by review panels; in-person panel discussion of a subset of full applications (identified by PCORI's Research Priority Area Program staff, based on the preliminary review and program priorities); and programmatic review and recommendation to the Office of the Chief Engagement and Dissemination Officer (OCEDO) 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 administrative or scientific reasons (e.g., nonresponsiveness). An application may be administratively withdrawn if it is incomplete; 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 panel based on the number and 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 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 announcement are different from those used when reviewing PCORI research applications.**

Criterion 1. Importance of research results and products in the context of the existing body of evidence
- Does the application sufficiently identify and describe the original evidence gap that the PCORI-funded research addressed? Does the application sufficiently demonstrate that the evidence gap identified at the time of the funding of the original PCORI research award still persists and is important?

- Does the application sufficiently describe the PCORI research results in the context of the relevant body of existing evidence? How will dissemination of research findings improve practice and outcomes?

Criterion 2. Readiness of the research results and products for dissemination
- Does the application sufficiently describe the strength of the evidence and address the generalizability of the research results and products being disseminated?

- Does the application provide sufficient information to indicate a willingness or readiness of healthcare settings in which dissemination will occur to use and embrace these research results and products?

Criterion 3. Technical merit (project design, evaluation, and outcomes)

- Does the application sufficiently describe the targeted end-users and settings of the described research results and products? Are these users and settings generalizable?

- Does the application describe a clear dissemination and implementation framework or model to anchor and inform the design, outcomes, and evaluation plan?

- Does the application provide a clear methodological approach for disseminating the described research results and products?

- Does the application describe the plan for evaluating success in sufficient detail?

- Does the application consider factors that may help or hinder the use of research results and products, as well as barriers of user implementation and how to mitigate them, within the context of the proposed project?

- Is the project timeline realistic, including specific scientific and engagement milestones?

NEW 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., Principal Investigators [PIs], collaborators, and other stakeholders) to conduct the proposed activities?

- 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?

  o (Dual-PI Option Only) Does the Leadership Plan adequately describe and justify roles and areas of responsibility of the PIs?

- Is 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

- Does the application provide sufficient information to indicate a willingness or readiness of relevant patients and their caregivers to use and embrace the research results and products of the original PCORI research award?

Criterion 6. Patient and stakeholder engagement

- Does the application demonstrate that people representing the population of interest and other

relevant stakeholders are engaged in ways that are appropriate and necessary given the dissemination plan's scope and setting?

- Are relevant patient organizations, clinician organizations, payer/purchaser consortia, and other stakeholders with significant influence on the targeted end-users or setting of this dissemination and implementation effort adequately engaged and committed?

- Does the application demonstrate the principles of reciprocal relationships, co-learning, partnership, trust, transparency, and honesty?

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 research, 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. Science and Engagement/Dissemination Program staff members then recommend projects to the OCEDO for funding approval. The Dissemination and Implementation Program, including funded projects portfolio, is governed by the Engagement, Dissemination, and Implementation Committee, which is 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 the overdue reports have been submitted to PCORI.**

Summary Statements and Funding Recommendations

Summary statements are provided to applicants 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:

- In-person panel discussion notes, reviewed by PCORI Science staff

- 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. Programs also consider the funds allotted for the current PFA when deciding which applications to recommend to PCORI's Board of Governors 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 August 2017.