



Cycle 3 2017 Funding Cycle

**PCORI Funding Announcements:
Addressing Disparities; Assessment of Prevention,
Diagnosis, and Treatment Options; Communication and
Dissemination Research; and Improving Healthcare
Systems**

Published October 3, 2017

This PCORI Funding Announcement (PFA) applies to the funding cycle that closes February 6, 2018, at 5 p.m. (ET). Application Guidelines, templates, and other resources are available at <https://www.pcori.org/funding-opportunities/announcement/broad-pcori-funding-announcements-cycle-3-2017>.



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	October 3, 2017																
Letter of Intent Deadline	October 31, 2017, by 5 p.m. (ET) Letters of Intent (LOIs) will be screened for responsiveness to this PCORI Funding Announcement (PFA) and for fit to program goals. Only those selected will be permitted to submit full applications. Notification of denial or approval to submit a full application will occur no later than November 28, 2017.																
Applicant Resources	See https://www.pcori.org/funding-opportunities/announcement/broad-pcori-funding-announcements-cycle-3-2017																
Key Dates	<table border="0"> <tr> <td>Online System Opens:</td> <td>October 3, 2017</td> </tr> <tr> <td>Town Hall:</td> <td>October 19, 2017, 12–1 p.m. (ET)</td> </tr> <tr> <td>LOI Deadline:</td> <td>October 31, 2017, by 5 p.m. (ET)</td> </tr> <tr> <td>LOI Status Notification:</td> <td>November 28, 2017</td> </tr> <tr> <td>Application Deadline:</td> <td>February 6, 2018, by 5 p.m. (ET)</td> </tr> <tr> <td>Merit Review:</td> <td>April 2018</td> </tr> <tr> <td>Awards Announced:</td> <td>August 21, 2018</td> </tr> <tr> <td>Earliest Project Start Date:</td> <td>October 2018</td> </tr> </table>	Online System Opens:	October 3, 2017	Town Hall:	October 19, 2017, 12–1 p.m. (ET)	LOI Deadline:	October 31, 2017, by 5 p.m. (ET)	LOI Status Notification:	November 28, 2017	Application Deadline:	February 6, 2018, by 5 p.m. (ET)	Merit Review:	April 2018	Awards Announced:	August 21, 2018	Earliest Project Start Date:	October 2018
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Maximum Project Budget (Direct Costs)	\$2 million (Addressing Disparities; Assessment of Options; Communication and Dissemination Research; Improving Healthcare Systems—small studies) \$5 million (Improving Healthcare Systems—large studies)																
Maximum Research Project Period	Three years (Addressing Disparities; Assessment of Options; Communication and Dissemination Research; Improving Healthcare Systems—small studies) 5 years (Improving Healthcare Systems—large studies)																
Funds Available Up To	Addressing Disparities: \$8M; Assessment of Options: \$32M; Communication and Dissemination Research: \$8M; Improving Healthcare Systems: \$16M																
Eligibility	Applications may be submitted by any private-sector research organization, including any nonprofit or for-profit organization, and any public-sector research organization, including any university or college hospital or healthcare system; laboratory or manufacturer; or 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 U.S. 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 applications for funding. Individuals are not permitted to apply.																
Review Criteria	<ol style="list-style-type: none"> 1. Potential for the study to fill critical gaps in evidence 2. Potential for the study findings to be adopted into clinical practice and improve delivery of care 3. Scientific merit (research design, analysis, and outcomes) 4. Investigator(s) and environment 5. Patient-centeredness 6. Patient and stakeholder engagement 																
Contact Us	<p>Programmatic Inquires: Please contact the PCORI Helpdesk via email (sciencequestions@pcori.org), phone (202-627-1884), or online (http://www.pcori.org/PFA/inquiry). PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed in two business days prior to an LOI or application deadline.</p> <p>Administrative, Financial, or Technical Inquiries: Please contact the PCORI Helpdesk at pfa@pcori.org. PCORI will respond within two business days. Please note that during the</p>																

	week of a deadline, response times may exceed two business days. Applicants may also call the PCORI Helpdesk (202-627-1885). Applicants are asked to plan accordingly; 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.

New or Revised for the Cycle 3 2017 Funding Cycle:

- Addressing Disparities:
 - The maximum project budget has increased from \$1.5 million to \$2 million.
 - There are no changes since the prior announcement (Cycle 1 2017).
- Assessment of Options:
 - There are no changes since the prior announcement (Cycle 1 2017).
- Communication and Dissemination Research:
 - The maximum project budget has increased from \$1.5 million to \$2 million.
 - The Greater than Budget and/or Time Request Template has been retired.
 - Revised criteria for the use of “usual care” comparators have been added.
- Improving Healthcare Systems:
 - The maximum project budget for small studies has increased from \$1.5 million to \$2 million.
 - The Improving Healthcare Systems (IHS) Program is currently not interested in funding applications whose primary aim is to compare the use of community health workers (CHWs) or navigators with “usual care” or care delivered by other healthcare personnel. PCORI will consider interventions focused on CHWs and patient or peer navigators if they are part of a larger multicomponent intervention, are integrated with multidisciplinary healthcare teams, or are compared with other non-personnel-based efficacious interventions.

Application Guidelines & PCORI Online

- Under the Budget tab in PCORI Online, applicants will enter a Detailed Budget for each project year for prime contractors only. The Federally Negotiated or Independently Audited Indirect Cost Rate Letter (prime contractor) and the Fringe Benefit Rate Policy Verification Document (prime contractor) will be combined and uploaded with the Budget Justification.
- Applicants must complete the (new) [PCORI Methodology Standards Checklist](#) and upload it as a single PDF with the Research Plan Template to PCORI Online.
 - Applicants are no longer required to cite the PCORI Methodology Standards in the Research Design/Approach (Section D) of the Research Strategy Template.
 - Applicants must adhere to the updated PCORI Methodology Standards, which now include 48 standards in 12 categories.
- The Research Plan Template has been updated.
 - The Research Strategy page limit is now 12 pages instead of 20.
 - The Research Strategy questions have been updated.
 - The Research Team and Environment section is new.

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I. Introduction

The Patient-Centered Outcomes Research Institute (PCORI) funds patient-centered outcomes research (PCOR), a type of comparative clinical effectiveness research (CER) that focuses on outcomes that matter to patients, their caregivers, and their families. The studies that PCORI funds must include the perspectives of patients and other healthcare stakeholders.

To be considered responsive, applications must describe research that compares at least two alternative approaches. Approaches may address diagnostic methods, screening strategies, interventions for prevention or treatment of disease, or strategies to improve the healthcare system. Through its various funding announcements, PCORI is interested in studies of interventions that may include:

- Specific drugs, devices, and procedures
- Medical and assistive devices and technologies
- Psychological therapies
- Organizational models and policies within and across healthcare systems (e.g., patient-centered medical homes, clinical protocols, and pathways)

PCORI is seeking applications designed to provide information to inform critical decisions facing patients and caregivers, clinicians, policy makers, and healthcare system leaders. These decisions must be consequential and occurring now in the absence of sound evidence about the comparative effectiveness of alternative approaches. There must be substantial potential for patients and caregivers to benefit from the new knowledge in ways that are important to them. The premise of this research is that the new knowledge will inform critical choices of patients and stakeholders in health care. This knowledge will provide insight about the comparative benefits and harms of the options, and also provide information about outcomes that are important to patients.

The public entrusts PCORI to fund research that matters to patients, their caregivers, and other stakeholders (defined as clinicians and clinician societies; hospitals and health systems; payers [insurance]; purchasers [business]; industry; researchers; policy makers; and training institutions). PCORI seeks to change the way in which research is conducted by emphasizing the role of diverse research teams that include varying perspectives. PCORI distinguishes itself by supporting research in which patients, caregivers, practicing clinicians, and the broader stakeholder community are actively engaged in generating research questions, reviewing research applications, conducting research, disseminating research findings, promoting the implementation of research findings, and using the results to understand and address patient and other stakeholder needs.

The Broad PCORI Funding Announcements (PFAs) seek investigator-initiated applications for patient-centered CER projects aligned with our five priority areas for research. This PFA covers the following four priority areas: Addressing Disparities; Assessment of Prevention, Diagnosis, and Treatment Options; Assessment of Prevention, Diagnosis, and Treatment Options; Communication and Dissemination Research; and Improving Healthcare Systems.

II. Addressing Disparities

PCORI invites applications CER designed to evaluate and compare interventions intended to reduce or eliminate disparities in health and health care. Patients and other stakeholders often lack the appropriate evidence required to make the best choices regarding prevention, screening, diagnosis, monitoring, or treatment. Applications to the Addressing Disparities Program should focus on overcoming barriers that may disproportionately affect health outcomes or focus on identifying best practices for reducing disparities in target populations (racial and ethnic minority groups; low-income groups; residents of rural areas; individuals with special healthcare needs, including individuals with disabilities; patients with low health literacy, numeracy, or limited English proficiency; and lesbian, gay, bisexual, transgender, and questioning [LGBTQ] persons).

Background

The health disparities literature has largely been devoted to describing disparities, including identifying their potential sources and drivers. Previous research has identified pervasive disparities in access to high-quality health care and worse health outcomes for specific populations across multiple conditions and multiple settings—outcomes that are based on race or ethnicity, gender, geographic location, socioeconomic status, disability, and other factors. These disparities have been well-documented. Thus, PCORI's Addressing Disparities Program is seeking applications that compare evidence-based interventions to improve health outcomes and reduce disparities for target populations. (See the section below on [Addressing Disparities Targeted Populations](#).)

Research of Interest

PCORI seeks to fund studies that provide evidence to help guide decisions about how to eliminate disparities in health and health care, as well as how to ensure that people receive care according to their needs and have the opportunity to achieve the best-possible health outcomes.

The Addressing Disparities Program is interested in funding CER of evidence-based interventions aimed at reducing and eliminating disparities in health and health care. Interventions to reduce persistent disparities have been understudied and are multifactorial, complex, and context-specific. Often, evidence-based interventions have been shown to be effective in the general population, but lack evidence for effectiveness in populations at risk for disparities. The Addressing Disparities Program is interested in studies that tailor and test these types of interventions in these populations.

PCORI's Addressing Disparities Program seeks to fund investigator-initiated research that:

- Compares evidence-based interventions to reduce or eliminate disparities in patient-centered outcomes (PCOs), including health, health care, and patient-reported outcomes—e.g., by accounting for possible differences at the patient, provider, or systems level. We are interested in research to determine which interventions can be most effective for eliminating disparities in outcomes.
- Compares benefits and risks of treatment, diagnostic, prevention, or service options, with a focus on eliminating disparities.
- Compares and identifies practices for tailoring evidence-based interventions to patient



populations at risk for disparities.

PCORI strongly encourages applicants to review the funded research on our website to ensure that their proposed research is not duplicative of projects we have already funded.

Addressing Disparities Targeted Populations

PCORI's Addressing Disparities Program is interested in studies focusing on previously understudied populations for whom effectiveness information is needed. Proposed research must focus on at least one of the following groups:

- Racial and ethnic minority groups
- Low-income groups
- Residents of rural areas
- Individuals with special healthcare needs, including individuals with disabilities
- Patients with low health literacy, numeracy, or limited English proficiency
- LGBTQ persons

Addressing Disparities Priority Areas

The Addressing Disparities Program is interested in applications that include team-based care or strategies to enhance family and caregiver involvement in patient care to reduce disparities and improve patient-centered and clinical outcomes. The Addressing Disparities Program is also interested in funding comparative effectiveness studies that focus on:

- Interventions to address disparities in human immunodeficiency virus (HIV) prevention and treatment
- Interventions to reduce sleep disorder disparities among racial and ethnic minorities
- Pharmacologic and non-pharmacologic treatments for Alzheimer's disease and other forms of dementia
- Interventions to improve communication between clinicians and people with disabilities

Applications that cover any of these high-priority areas must also focus on one or more of the following Addressing Disparities target populations: racial and ethnic minority groups; low-income groups; residents of rural areas; individuals with special healthcare needs, including individuals with disabilities; patients with low health literacy, numeracy, or limited English proficiency; and LGBTQ persons.

Community Health Worker and Navigator Projects

The Addressing Disparities Program has funded many projects focusing on community health worker (CWH) and navigator interventions. Applications aiming to study these types of interventions must focus on one of the following areas, which are based on existing evidence gaps:

- Comparing different CHW and patient navigator program models, worker functions, training and certification levels, and implementation approaches across different settings, conditions, and

populations¹

- Examining the integration of CHW and patient navigators into the care team, determining specifically the organizational strategies and components that are essential to well-functioning teams and the factors that increase acceptance by care teams²

Applications that propose research focusing on CHW or navigators as a primary component of interventions being studied will undergo substantial scrutiny to ensure that the studies do not overlap significantly with previously funded studies or concurrent applications, and that they fill a gap within the program's portfolio. PCORI encourages applicants to review the current portfolio to avoid redundancy with funded projects.

III. Assessment of Prevention, Diagnosis, and Treatment Options

Research of Interest: Comparative Clinical Effectiveness

Patients, caregivers, and clinicians often lack the appropriate evidence required to make the best choices regarding prevention, screening, diagnosis, monitoring, or treatment. Where therapies or technologies have been approved and marketed, there are often gaps in research comparing their effectiveness with that of other clinical options, and prior research may not have included outcomes that are important to patients and their caregivers. In addition, the existing evidence base might not be relevant for certain patient populations, such as those at the extremes of age or with multiple comorbid conditions.

For this particular PFA on the Assessment of Prevention, Diagnosis, and Treatment Options, PCORI seeks to fund investigator-initiated research that:

- Compares the effectiveness of two or more strategies for prevention, treatment, screening, diagnosis, or management that are known to be efficacious but have not been adequately compared in previous studies; interventions without sufficient evidence of efficacy will be considered only when they are in reasonably common use. PCORI is particularly interested in studies that are conducted in typical clinical populations and that address the full range of relevant PCOs.
- Addresses a high-priority evidence gap, as identified by prior systematic reviews, clearly defined gaps in clinical guidelines, or other credible evidence reviews.
- Investigates, among compared groups, factors that account for variation in treatment outcomes, with attention paid to demographic, biological, clinical, social, economic, or geographic factors; comorbidities; and other factors that may influence those outcomes. Strategies may focus on patient populations with a single condition or involve patients with a range of conditions.

For this PFA, proposed projects should address the comparison of specific clinical services or strategies

¹ Institute for Clinical and Economic Review. [2013]. A review of program evolution, evidence on effectiveness and value, and status of workforce development in New England. Retrieved April 8, 2015 from Comparative Effectiveness Public Advisory Council: <http://cepac.icer-review.org/wp-content/uploads/2011/04/CHW-Draft-Report-05-24-13-MASTER1.pdf>.

² McDonald KM, Sundaram V, Bravata DM, et al. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies (Vol. 7: Care Coordination). Rockville (MD): Agency for Healthcare Research and Quality (US); 2007 Jun. (Technical Reviews, No. 9.7.) 4, Review of Systematic Reviews of Care Coordination Interventions. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK44016/>.

that are defined clearly and can be replicated in other clinical settings with minimal adaptations or changes. PCORI does not encourage projects that have the primary goal of developing and testing decision aids or testing the use of lay personnel who perform ancillary services in healthcare settings.

This funding opportunity is broad-based and is not confined to specific clinical services or patient populations. However, the program's goal is to expand the evidence base that pertains to clinical services that would be chosen by clinicians, patients, and caregivers in usual clinical delivery settings. The services of interest include:

- Prescription drugs and biologics
- Surgical and other interventional procedures
- Techniques for disease screening
- Vaccinations and other interventions to prevent diseases
- Counseling and behavioral interventions
- Complementary and integrative services
- Rehabilitative services
- Diagnostic tests and procedures

IV. Communication and Dissemination Research

Summary of Program and Objectives

There is a need for greater knowledge about how to best communicate and facilitate the effective use of PCOR and CER findings by patients, caregivers, and healthcare professionals. Well-documented barriers exist to the rapid transfer of evidence. Informed healthcare decisions require innovative and effective strategies to make existing PCOR/CER evidence available to patients and providers in real-world settings. Moreover, the information needs to be understandable to improve decision making.

The Communication and Dissemination Research Program invites applications that study the comparative effectiveness of communication and dissemination strategies. We are looking for strategies aimed at informing and empowering patients, caregivers, and other healthcare decision makers so that they know what questions to ask and have the information they need to provide support in shared decision making.

This announcement is designed to solicit applications that include:

- The direct comparison of two or more health communication and dissemination interventions or strategies, each of which has established efficacy or is in widespread use
- Research conducted in real-world, clinical care settings and situations
- Proposed research questions and health outcomes that will matter to the patient population, their caregivers, and family members under study, and that will help to guide their healthcare decisions

Research appropriate for this PFA includes:

- Communication strategies to promote the use of health and healthcare CER evidence by patients and clinicians
- Dissemination strategies to promote the use of health and healthcare CER evidence by patients and clinicians
- Explanation of uncertain health and healthcare CER evidence to patients and clinicians

Note: *If the proposed research includes “usual care” as the control condition or one arm of an intervention trial, applicants must provide a clear definition of “usual or standard care” and a rationale for why “usual care” is a compelling and appropriate comparator. Applicants must also provide a description of the diversity in existing regimens or modalities in “usual care.” The study also should measure how “usual care” varies by setting and time.*

Research not appropriate for this PFA includes:

- Applications that focus on the development, testing (establishing efficacy), and validation of individual decision aids and tools
- Applications that include a formal cost-effectiveness analysis
- Applications that directly compare the costs of care of two or more alternative approaches to providing care
- Applications that include creation of clinical practice guidelines or clinical pathways

See [Categories of Non-responsiveness](#) for a more detailed explanation and examples of topics that PCORI will consider nonresponsive.

Background

Making an informed healthcare choice requires critically assessing the potential benefits and harms of the options within the context of the patient’s personal characteristics, conditions, and preferences.^{3,4} The environment in which patients, caregivers, and their providers communicate is also evolving rapidly to include a wide array of available health information and communication applications. These tools can help fill critical information gaps, but are often confusing and difficult to use. The type of healthcare decisions being made is an important determinant of the appropriate information needed and of the best vehicle for providing it. (For example, the informational needs of a patient weighing options for treating high blood pressure will differ from those of a patient facing a terminal cancer diagnosis with complicated treatment options.) Furthermore, patients and caregivers want information that does not necessarily deliver decisions or tell them what to do, but instead informs them of the relevant trade-offs and facilitates improved decision making in collaboration with their healthcare team.

Clear communication approaches and active dissemination of PCOR/CER research findings to all

³ Barry, M.J. and Edgman-Levitan, S. (2012). Shared decision making—The pinnacle of patient-centered care. *NEJM* 366(9), 780–781.

⁴ National Research Council. (2001). *Crossing the quality chasm: A new health system for the 21st century*. Washington, DC: The National Academies Press.

audiences (in easy-to-understand formats) are critical to increasing the awareness, consideration, adoption, and use of these data by patients, caregivers, and healthcare providers.⁵ *This PFA focuses on three key areas: (1) communication strategies, (2) dissemination strategies, and (3) explaining uncertainty.*

Communication strategies to promote the use of health and healthcare CER evidence by patients and clinicians

Translating existing scientific research into accessible and usable formats that clearly outline the risks and benefits of various healthcare options for patients, caregivers, and healthcare providers is an important research area in clinical and community-based settings. In clinical care, shared decision making and decision-support interventions are two of the primary ways in which medical evidence is translated into a usable format for patients, families, and caregivers. Understanding the best ways to communicate, while addressing numeracy and health literacy, is fundamental to communicating PCOR/CER effectively via shared decision making.^{6,7,8} For example, the integration of patient decision support, electronic health records, and associated patient systems holds considerable promise, but little evidence is available to guide best practices.

Research gaps identified in a systematic review included the need for more head-to-head comparisons of communication strategies.³ For example, more CER is needed to determine how shared decision making and decision-support interventions perform using different media, what level of information and detail they require, how they perform in different patient subpopulations, and how they can reflect new evidence and remain current. In addition, CER is needed to determine whether using efficacious applications of newer conceptual approaches to decision making—such as use of gist representation approaches in evidence communication or using behavioral economic strategies to improve healthcare decisions—can improve patients’ and clinicians’ use of evidence in decision making compared to more traditional methods.⁹ Furthermore, most of the CER research to date consists of comparisons of communication strategies relative to “usual care.” In most cases, it is difficult to determine what “usual care” is or how it differs from “standard of care.” **Therefore, proposed research that includes “usual care” as the control condition or one arm of an intervention trial must provide a clear definition of “usual or standard care” and measure the actual communications services that patients receive in this condition.**

Effective communication skills of patients and healthcare providers are important for the optimal use of CER results. Research on doctor-patient communication has focused primarily on the doctor-patient

⁵ McCormack, L., Sheridan, S., Lewis, M., Boudewyns, V., Melvin, C.L., Kistler, C., Lux, L.J., Cullen, K., and Lohr, K.N. (2013, November). *Communication and dissemination strategies to facilitate the use of health-related evidence*. Evidence report/technology assessment No. 213. (Prepared by the RTI International-University of North Carolina Evidence-Based Practice Center under Contract No. 290-2007-10056-1.) AHRQ Publication No. 13(14)-E003-EF. Rockville, MD: Agency for Healthcare Research and Quality.

⁶ Nielsen-Bohlman, L., Panzer, A., and Kindig, D. (2004). *Health literacy: A prescription to end confusion*. Washington, DC: The National Academies Press.

⁷ Lipkus, I.M. and Peters, E. (2009). Understanding the role of numeracy in health: Proposed theoretical framework and practical insights. *Health Educ Behav* 36(6), 1065–1081.

⁸ Sorensen, K., Van den Broucke, S., Fullam, J., Doyle, G., Pelikan, J., Slonska, Z., and Brand, H., for Consortium Health Literacy Project European (HLS-EU). (2012). Health literacy and public health: A systematic review and integration of definitions and models. *BMC Public Health*, 12(8).

⁹ Treiman, K, Swinson, Evans T, and Wagner, L. (2015, October). Expert Panel Meeting on Advancing Medical Decision Making: Final Report. Available at: <http://www.pcori.org/sites/default/files/PCORI-Advancing-Medical-Decision-Making-Expert-Panel-Report.pdf>.

dyad, but little is known about other health professionals who communicate with patients and play a critical role in the patient care experience. Moreover, additional information is needed on how family involvement and family dynamics affect communication and the decision-making process. Applicants should consider broadening their focus beyond the patient-clinician dyad by recognizing that patient-centered care and communication are characterized by a complex web of communication among patients, caregivers, and a variety of healthcare professionals with whom the patients interact during different stages of the care continuum (pre-diagnosis to end-of-life).¹⁰

Dissemination strategies to promote the use of health and healthcare CER evidence by patients and clinicians

The dissemination of CER information and evidence-based practices to patients, caregivers, and providers (in clinical and community-based settings) is an area that has not received sufficient research attention. Dissemination is defined as *the active and targeted approach of spreading evidence-based interventions to potential adopters and the target audience through determined channels using planned strategies*.¹¹ The goals of dissemination are to (1) increase the reach of information; (2) increase adoption of information by patients, caregivers, and providers to use and apply evidence; and (3) scale up and sustain evidence-based interventions. The goals of dissemination research are to make such efforts more effective in accomplishing these aims.³ Dissemination research is the scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience or to individual patients. The intent is to understand how best to spread and sustain knowledge and the associated evidence-based interventions, as well as how and why health information may or may not reach different groups of patients and stakeholders.

Although more research is needed to identify the most effective approaches for disseminating CER information and evidence-based practices to healthcare providers, with the goals of sustained changes in clinical practice *and* effective dissemination to patients of results that enable behavior changes (e.g., adherence and self-care), CER includes evaluation of alternative strategies for dissemination and implementation itself. In other words, dissemination can be the subject of CER and not just an approach to publicize the CER findings. This area has continued to evolve and includes the development and application of new study designs. *Effectiveness-implementation hybrid designs blend the design components of clinical effectiveness trials (e.g., proven interventions introduced in real-world settings) and the implementation strategy.* **Dissemination studies using such hybrid designs have the potential to speed and improve the translation of clinical intervention uptake; identify more effective implementation strategies; and provide more useful information for patients, stakeholders, researchers and decision makers.**^{12,13} Three types of hybrid designs have been identified, and they vary according to the emphasis placed on testing the intervention versus the implementation. Hybrid Type 1

¹⁰ Epstein, R.M. and Street, R.L., Jr. (2007). *Patient-centered communication in cancer care: Promoting healing and reducing suffering*. National Cancer Institute, NIH Publication No. 07-6225. Bethesda, MD.

¹¹ Rabin, B.A. and Brownson, R.C. (2012). Developing a terminology for dissemination and implementation research. In Brownson, R.C., Colditz, G.A., and Proctor, E.K. (Eds.), *Dissemination and implementation research in health: Translating science into practice* (pp. 23–51). Oxford University Press: New York, NY.

¹² Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. 2012. Effectiveness-implementation hybrid designs: Combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical Care*. 50(3):217-226.

¹³ Bernet AC, Willens DE, Bauer MS. 2013. Effectiveness-implementation hybrid designs: Implications for quality improvement science. *Implementation Science*. 8(Suppl 1):S2.

tests the effects of a clinical intervention on relevant outcomes while observing and gathering information on its potential for implementation in a real-world situation; Hybrid Type 2 balances attention to the effectiveness of the clinical intervention with the implementation strategy that supports the interventions; and Hybrid Type 3 tests an implementation intervention and strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.¹² Given the range of expertise needed for conducting dissemination and implementation research, applicants are encouraged to form interdisciplinary teams of scientists, stakeholders, and patients from diverse community, practice, and patient populations.

Explaining uncertain health and healthcare CER evidence to patients and clinicians

Risk and uncertainty are ubiquitous in health care. Like most decisions, many healthcare decisions have consequences and involve uncertainties and trade-offs. A significant gap exists in the limited research on risk communication generally, and with underserved individuals and those with limited health literacy and numeracy in particular. Research is also lacking in methods for communicating risk to healthcare providers and enabling them to use the information effectively. A seminal publication on patient-centered communication from the National Cancer Institute identified managing uncertainty as a core function of patient-clinician communication.⁷ Uncertainty creates many challenges, including (1) determining whether preventive services and treatments should be implemented in clinical practice; (2) determining for whom and in what settings services and treatments should be implemented; and (3) communicating evidence so that consumers can make informed decisions.³ A systematic review identified research gaps that revealed a need for analyses that identify and prioritize uncertainties that should be communicated; methods that measure and provide a better understanding of uncertainties as they pertain to risks, practice recommendations, and other types of evidence; and standardized language used to communicate uncertainties in clinical evidence. The systematic review also revealed a need for formal systems used to rate uncertainty arising from clinical evidence that incorporates the patient perspective to ensure comprehensibility, meaningfulness, and appropriate use.¹⁴

Research of Interest

The Communication and Dissemination Research Program seeks to fund investigator-initiated studies that include, but are not limited to, the following:

Communication Strategies

- Compare strategies that increase knowledge of how to communicate complex information to patients and caregivers.
- Identify and compare practices that increase understanding of the tension between strongly held beliefs and contrary evidence, and those practices' impact on the shared decision-making process.
- Compare strategies meant to generate conversations between patients and providers about what is appropriate and necessary treatment (e.g., [Choosing Wisely](http://www.choosingwisely.org/)¹⁵)—based on patients'

¹⁴ Han, P.K. (2013). Conceptual, methodological, and ethical problems in communicating uncertainty in clinical evidence. *Med Care Res Rev* 70(1 Suppl.), 14S–36S.

¹⁵ Available at <http://www.choosingwisely.org/>.

preferences and conditions—to improve patient satisfaction with their decision process and enable them to use the best available evidence.

- Compare strategies and methods that optimize communication among the patient, family/caregiver, and healthcare team (e.g., role of the family member or caregiver in patient-provider, patient-caregiver, and healthcare team interactions).
- Evaluate how patients can best incorporate the influence of family, friends, and other patients into healthcare decisions that occur outside of the healthcare setting.
- Compare strategies in situations where there is not a single “right” choice (e.g., preference-sensitive decisions) to improve patients’ satisfaction with their decision process and to enable them to use the best-available evidence.

Dissemination Strategies

- Compare CER dissemination strategies while evaluating the potential for implementation in real-world settings (e.g., hybrid effectiveness-implementation design trial).
- Compare and identify best practices of dissemination and translation techniques to facilitate shared decision making in everyday practice.
- Identify the most effective approaches to disseminating CER results to healthcare providers, with the goals of sustained changes in clinical practice and effective dissemination to patients of results that enable behavior changes (e.g., self-care).
- Understand how strategies used in public health communication and social marketing can be adapted to disseminate CER results and to identify creative ways of combining multiple communication channels to increase CER exposure.

Explaining Uncertainty

- Compare strategies for conveying uncertainty associated with health and healthcare evidence that increase the likelihood that patients and caregivers will understand the information, incorporate it into decision making, and evaluate personal trade-offs.
- Compare strategies to reduce the cognitive burden required to understand complex numeric and risk-related information, and to improve understanding of the potential outcomes and decision making.
- Compare the effectiveness of health literacy- and numeracy-sensitive health communication strategies that relay risks and benefits of health decisions so that individuals can make sound healthcare decisions.
- Compare interventions that help patients and families or caregivers facing difficult medical decisions in which the outcomes are ambiguous or uncertain to improve their understanding of the outcomes and facilitate their decision making.

PCORI is interested in understanding the role of shared decision making and established, effective decision aids in communicating and implementing PCOR/CER. PCORI will consider applications



focused on developing, testing (establishing efficacy), and validating individual decision aids and tools to be nonresponsive to this PFA.

PCORI expects the efficacy or effectiveness of each intervention to be known. Applicants may use interventions that have documented efficacy or effectiveness in similar situations with some adaptation if necessary— if the efficacy is well documented (e.g., with multiple trials or with a systematic review) and sufficiently strong rationale for why the intervention would be expected to be efficacious in the proposed new setting(s) and/or population(s) is provided. If an intervention is to be adapted, PCORI expects the majority of the proposed time and budget to aim at establishing comparative effectiveness rather than adapting and validating the interventions.

PCORI's Evidence to Action Networks

PCORI is interested in ensuring communication and engagement between awardees with similar needs and interests and end-users to help refine and improve the research and to facilitate dissemination of research findings that will help patients and the public make better-informed healthcare decisions. To meet this goal, PCORI has set up Evidence to Action Networks (E2AN), whereby we facilitate engagement among awardees and cross-learning between projects and teams composed of researchers, patients, caregivers, and other stakeholders. PCORI also facilitates exchanges between awardees and end-users (e.g., patients; caregivers; and other stakeholders, such as payers, employers and purchasers, clinicians, professional societies, policy makers, and training institutions) for disseminating and implementing important research findings.

PCORI encourages awardees to participate in E2ANs if they become available on a specific topic relevant to their research.

V. Improving Healthcare Systems

Summary of Program

The Improving Healthcare Systems (IHS) Program within the PCORI invites applications for research that studies the comparative clinical effectiveness of alternative features of healthcare systems (e.g., innovative technologies, incentive structures, or healthcare service delivery designs) that are intended to optimize the quality, outcomes, and efficiency of patient care and that have the greatest potential for sustained impact and replication within and across healthcare systems. Healthcare systems encompass multiple levels (e.g., individual patients, family and social supports, providers and care teams, organizations or practice settings, local community resources, and the state- and national-level policy environments) and include entities organized to deliver, arrange, purchase, or coordinate health services. Healthcare delivery models (e.g., integrated health systems and patient-centered medical homes) and care settings (e.g., hospitals, physician practices, nursing homes, community health clinics, or patients' homes) also define healthcare system operations. PCORI seeks studies that will affect healthcare delivery by determining which system features lead to improved PCOs and which provide valuable knowledge to patients, their caregivers and clinicians, as well as other key stakeholders, including payers and employers. The diagram below is intended to illustrate this summary. Please note that the shading of two levels—National Health Environment and State Health Environment—indicates that

although they clearly influence and shape the broader health policy environment, PCORI does not include them as specific targets for research interventions.

The Healthcare System

Figure adapted from: Taplin, S. H., Clauser, S., et al. (2012) Introduction: Understanding and Influencing Multilevel Factors Across the Cancer Care Continuum. *Journal of the National Cancer Institute*, 44, 2–10.



Background

Healthcare organizations are under constant pressure from competing sources to improve aspects of care, but they often lack the critical information needed to guide decisions related to system-level change. Research could help develop a body of evidence supporting effective interventions that would enable organizations to provide higher quality care that is more accessible, coordinated, effective and efficient, and that would ultimately improve PCOs.

The public entrusts PCORI with funding research that will matter to patients, their caregivers, and other stakeholders (defined as clinicians and their professional societies; hospitals; health systems administrators; payers [insurance]; purchasers [business]; industry [pharmaceutical and medical device companies]; researchers; policy makers; and training institutions). PCORI seeks to change the way in which research is conducted by emphasizing the role of diverse research teams that reflect the varying perspectives of such key stakeholders. PCORI distinguishes itself by supporting research that actively engages patients, caregivers, and other stakeholders in all phases of the research process—from inception to conclusion—including generating research questions, reviewing research applications, conducting research, disseminating research findings, promoting the implementation of research findings, and using the results to understand and address patient and other stakeholder needs.

Over the past two decades, the Institute of Medicine (IOM) and others have sharpened the focus on ensuring that healthcare systems are designed and oriented to achieve the health outcomes most desired by individual patients—that is, to become more patient-centered. In particular, the IOM has



addressed key aspects of systems improvement, including making care:

- Accessible
- Effective
- Patient-centered
- Timely
- Efficient
- Safer
- Equitable
- Coordinated

IHS seeks to fund comparative CER that addresses the same areas as those addressed by IOM.

Interventions designed to achieve the IOM aims listed above may target:

- Technology (e.g., interoperative electronic health records, telemedicine, and patient-accessible health records)
- Patient incentives (e.g., free or subsidized preventive care and automatic enrollment in certain follow-up programs)
- Provider incentives (e.g., free continuing medical education units for certain courses, reduced paperwork, provision of key comparative quality performance information). Only non-financial incentives are acceptable for providers.
- Organizational models and policies within and across healthcare systems (e.g., patient-centered medical homes and standing orders)
- Personnel (e.g., multidisciplinary teams, peer navigators, and CHWs)

Although a focus on personnel is a key intervention area supported by IHS, the IHS portfolio already includes many projects that evaluate interventions focused on CHWs and patient or peer navigators. IHS is currently not interested in funding additional applications whose primary aim is to compare the use of CHWs or navigators with “usual care” or care delivered by other healthcare personnel. PCORI will consider interventions focused on CHWs and patient or peer navigators if they are part of a larger multicomponent intervention, are integrated with multidisciplinary healthcare teams, or are compared with other non-personnel-based efficacious interventions.

In addition, PCORI may consider applications proposing to compare the use of CHWs and patient or peer navigators with “usual care” or care delivered by other healthcare personnel if there is a strong rationale supporting the need for additional research (e.g., studies target a rare disease or an understudied population or setting). PCORI encourages applicants to discuss such proposals with the IHS Program before submitting a Letter of Intent.

Innovation and changes in healthcare systems and in the behavior of healthcare system participants are

often driven by economic, political, and social needs to improve access to care or quality of care, to attract patients or enrollees, and to contain costs. The effects of all such innovations may vary considerably among subgroups of the general population, but this Heterogeneity of Treatment Effect (HTE) is often inadequately measured. PCORI and the IHS Program are particularly interested in studies that include adequately powered subgroup analysis and address understudied or underrepresented patient populations in research. See the [Populations Studied](#) section.

Research of Interest

PCORI seeks to fund investigator-initiated research on the effects of system changes on the broad outcomes listed below. We are especially interested in studies that conduct head-to-head comparisons with or without “usual care” as a comparator. (See the [Requirements for PCORI Research](#) section for more information on “usual care.”) Such studies may include:

- Patients’ access to care, high quality of care, support for self-care, and coordination of care across healthcare settings
- Professional decision making on the basis of patients’ personal values
- Experiences that are important to patients and their caregivers, such as overall health, functional ability, health-related quality of life, stress, severity of symptoms, survival, and unanticipated healthcare utilization, such as unexpected hospital stays or visits to the Emergency Department
- The efficiency of healthcare delivery, as measured by the amount of ineffective, duplicative, or wasteful care provided to patients

The IHS Program is also interested in funding studies that:

- Leverage existing research resources, such as adding patient-centered outcomes research to an existing large clinical trial, using established practice-based research networks, or analyzing large databases that contain valuable, relevant information that may be used to answer important CER questions.
- Leverage healthcare system resources in support of some or all of the intervention requirements. Especially attractive is the possibility of broader and sustained impact through potential adoption by participating or supporting healthcare organizations and stakeholders (e.g., payers), should the intervention prove effective.
- Test practices that combine evidence-based guidelines (such as Choosing Wisely, <http://www.choosingwisely.org/>) with patient incentives, provider incentives, or patient and provider incentives combined to elicit patient preferences and reduce harms faced by patients simultaneously.

Sample Research Questions

The following are examples of the types of questions that patients, clinicians, or healthcare administrators might ask and that your research might help answer. This is not an exhaustive list.

- An 84-year-old woman in a rural community and with multiple chronic diseases is having

increasing difficulty managing at home alone, but does not want to leave her home or neighborhood to live in a nursing home. What are the benefits and drawbacks of a new care management program designed to help her stay at home and remain safe and independent, compared to a program that links her to comprehensive community services?

- A 27-year-old Hispanic man with diabetes, chronic back pain, and depression has been invited by his public hospital-based clinic to participate in a group-visit program for patients with chronic conditions that is led by a behavioral care specialist and a health educator. How likely is it that he will benefit from this program compared with the “usual care” he has been receiving (defined by quarterly visits with his primary-care practitioner punctuated by referrals to specialists as needed)? What is the nature of the benefit? Are there any risks? What should his physician recommend?
- A 50-year-old African-American man has frequent exacerbations of his chronic obstructive pulmonary disease that trigger recurrent emergency department visits and acute-care hospitalizations. Does regularly scheduled home-based respiratory care reduce his emergency department utilization and hospital readmissions compared to physician office visits that he or his caregiver must schedule? Does it improve functional status, health-related quality of life, or other PCOs?

Below is one research question of interest that the IHS Program seeks to support through this PFA. The IHS advisory panel identified this topic as an evidence gap in need of further research.

Care Coordination for High-Cost/High-Need Patients

High-cost/high-need (HCHN) patients make up 5 percent of the patient population in the United States, yet consume 50 percent of all healthcare resources. HCHN patients include children with complex needs; adults less than 65 years old with disabilities; frail older adults; and patients with multiple or complex chronic conditions, which may be complicated by functional limitations, behavioral and substance abuse challenges, and social needs.

HCHN patients require regular primary care consultation and at least one additional specialty consultation multiple times a year. Despite frequent contact with various healthcare providers, their physical, social, and behavioral needs often remain unmet due to low-quality and uncoordinated care. The traditional primary care model is not designed to meet this population’s unique needs because these patients require constant and effective communication among healthcare providers. Studies suggest that this group could benefit from a more holistic approach to care delivery achieved through effective care coordination (<https://nam.edu/wp-content/uploads/2016/09/Tailoring-Complex-Care-Management-Coordination-and-Integration-for-High-Need-High-Cost-Patients.pdf>).

CER on care coordination for HCHN patients is of interest to all stakeholders, including payers who need evidence of effective and scalable care coordination strategies for these high healthcare utilizers. Thus, the IHS Program seeks to fund CER that addresses an adapted version of a first-quartile IOM CER topic: Compare the effectiveness of comprehensive care coordination programs—such as the medical home— and “usual care” in managing children and adults with severe chronic disease,

especially in populations with known health disparities.

The adapted IOM comparative clinical effectiveness question of interest in this PFA is:

- **What is the comparative clinical effectiveness of different comprehensive care coordination models on improving PCOs for HCHN patients?**
 - HCHN population of interest: Patients with multiple chronic conditions
 - Care coordination models may include, but are not limited to:
 - Expanded primary care teams
 - Home-based primary care
 - Patient-centered medical homes
 - Outcomes should be measured at more than one level of the healthcare system, such as the patient, caregiver, clinician, or healthcare organization.

Evidence to Action Networks

PCORI is interested in connecting PCORI-funded investigators who are studying similar research topics and populations to help strengthen the body of research and to facilitate collaborative learning and dissemination of research findings. To meet this goal, PCORI has set up Evidence to Action Networks (E2AN), whereby we facilitate engagement among awardees and cross-learning between projects and teams composed of researchers, patients, caregivers, and other stakeholders. In addition, PCORI facilitates exchanges between awardees and end-users (e.g., patients; caregivers; and other stakeholders, such as payers, employers and purchasers, clinicians, professional societies, policy makers, and training institutions) for disseminating and implementing important research findings.

PCORI encourages awardees to participate in such E2AN as they become available.

VI. Requirements for PCORI Research

This section includes language that is specific to PCORI’s requirements for applications for funding. Applicants should use this section as guidance when preparing their applications.

Research Priorities

To be considered responsive, applications must:

- *Describe comparators.* Regardless of the approach being studied, all proposed research projects must compare at least two alternatives. If the applicant proposes “usual care” as a rational and important comparator in the proposed study, then it must be described in detail, coherent as a clinical alternative, and properly justified as a legitimate comparator (e.g., “usual care” is guidelines-based). It must also be accompanied by an explanation of how the care given in the “usual care” group will be measured in each patient, and how appropriate inferences will be drawn from its inclusion. “Usual care” must be described as mentioned above to ensure that it accounts for geographic and temporal variations, and it has wide interpretability, applicability,

and reproducibility.

- *Describe research that compares two or more alternatives, each of which has established efficacy.* PCORI expects the efficacy or effectiveness of each intervention to be known. If the efficacy or evidence base is insufficient, then data need to be provided to document that the intervention is used widely. The application must provide information about the efficacy of the interventions that will be compared; pilot data might be appropriate. Projects aiming to develop new interventions that lack evidence of efficacy or effectiveness will be considered out of scope.
- *Describe research that studies the benefits and harms of interventions and strategies delivered in real-world settings.* PCORI is interested in studies that provide practical information that can help patients and other stakeholders make informed decisions about their health care and health outcomes.
- *Describe consultation with patients and other stakeholders about how the study is answering a critical question.* Explain the pertinent evidence gaps and why the project questions represent decisional dilemmas for patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders. Describe why project outcomes are especially relevant and meaningful endpoints to patients and other stakeholders.

Categories of Non-responsiveness

PCORI discourages proposals in the following categories, and will likely deem them nonresponsive:

- Instrument development, such as new surveys, scales, etc.
- Developing, testing and validating new decision aids and tools, or clinical prognostication tools
- Pilot studies intended to inform larger efforts
- Comparing patient characteristics rather than clinical strategy options
- For Assessment of Prevention, Diagnosis, and Treatment Options (APDTO) and Improving Healthcare Systems (IHS) program applicants ONLY: Comparing interventions for which the primary focus is the role of community health workers or patient navigators

Consistent with PCORI's [authorizing law](#),¹⁶ PCORI does not fund research whose findings will include:

- Coverage recommendations
- Payment or policy recommendations
- Creation of clinical practice guidelines or clinical pathways
- Establishment of efficacy for a new clinical strategy
- Pharmacodynamics
- Study of the natural history of disease

¹⁶ Available at http://www.pcori.org/sites/default/files/PCORI_Authorizing_Legislation.pdf.

- Basic science or the study of biological mechanisms

Studies of Cost-Effectiveness

PCORI will consider an application nonresponsive if the proposed research:

- Conducts a formal cost-effectiveness analysis of alternative approaches to providing care
- Directly compares the costs of care between two or more alternative approaches to providing care

Proposals that include studies of these issues may measure and report utilization of any or all health services, but may not employ direct measurements of care costs. For further information, please reference our [cost-effectiveness analysis FAQs](#).

PCORI does have an interest, however, in studies addressing questions about conditions leading to high costs to the individual or to society. This interest is reflected in our review criterion on the condition's impact on the health of individuals and populations. Thus, PCORI is interested in studies that:

- Examine the effect of costs on patients, such as patients' out-of-pocket costs, hardship or lost opportunity, or costs as a determinant of or barrier to access to care
- Address cost-related issues, such as the resources needed to replicate or disseminate a successful intervention
- Evaluate interventions to reduce health system waste or increase health system efficiency

Avoiding Redundancy

PCORI encourages potential applicants to review funded research at pcori.org. We intend to balance our funded portfolio to achieve synergy and avoid redundancy where possible.

Methodological Considerations

Regardless of study design, applications must adhere to all relevant [PCORI Methodology Standards](#). These include 48 individual standards that fall into 12 categories. The first five categories are cross-cutting and relevant to most PCOR studies. Researchers should refer to all of these standards when planning and conducting their research projects. These cross-cutting categories are:

1. Standards for Formulating Research Questions
2. Standards Associated with Patient-Centeredness
3. Standards on Data Integrity and Rigorous Analyses
4. Standards for Preventing and Handling Missing Data
5. Standards for Heterogeneity of Treatment Effect (HTE)

In addition to these five sets of standards, the first standard of "Standards for Causal Inference Methods" -(CI-1)- is cross-cutting and applicable to all PCOR studies.

The seven other standards categories will be applicable to particular study designs and methods. Applicants should use the standards in each of these categories as guidance when they are relevant to a

study. These categories are:

1. Standards for Data Registries
2. Standards for Data Networks as Research-Facilitating Structures
3. Standards for Causal Inference Methods
4. Standards for Adaptive and Bayesian Trial Designs
5. Standards for Studies of Medical Tests
6. Standards for Systematic Reviews
7. Standards for Research Designs Using Clusters

Most of these standards are minimal. The PCORI Methodology Standards reflect practices that applicants should follow in all cases, and all deviations need to be explained and justified. Applicants should address additional best practices—including relevant guidelines for conducting clinical trials developed by other organizations—in the application for PCORI funding. To help reviewers quickly identify adherence to a particular standard, applicants must cite each relevant [PCORI Methodology Standard](#) within the [Methodology Standards Checklist](#), following the instruction in the checklist itself and in the [Application Guidelines](#). Program staff use the checklist to evaluate applications.

Applicants should specifically discuss their capacity to measure such factors as differential adherence to chosen treatments (or participation in intervention programs) that could create or explain apparent differences in the effectiveness of the alternative interventions being compared in clinical populations.

Patient-Centered Outcome Measures

PCORI encourages investigators to design their research using validated outcome measures. Include preliminary data that support using the proposed measures in the study population. We encourage investigators to consider those measures described in the [Patient-Reported Outcomes Measurement Information System¹⁷](#) (PROMIS).

Leveraging Existing Resources

PCORI encourages investigators to propose studies that leverage existing resources, such as adding PCOR to an existing large clinical trial or analyzing existing large databases that contain valuable, relevant information that may be used to answer important CER questions. PCORI is interested in studies that leverage existing research network or consortia, as well as established data resources such as patient outcomes registries especially when such patient outcomes registries can be linked to electronic medical record (EMR) data from healthcare delivery systems or administrative claim data from public or commercial insurers to facilitate the conduct of comparative clinical effectiveness research. PCORI does not intend for this PFA to support the development of new patient registries, but rather to support the effective utilization of established patient registries where comprehensive data on patient characteristics and patient outcomes have been collected and/or can be linked to the EMR data or claims data to evaluate treatment outcomes in the proposed CER studies. In circumstances where

¹⁷ Available at <http://www.nihpromis.org/>.

randomized control trials are not practical or ethically acceptable, studies leveraging established patient outcomes registries can have meaningful and complementary roles in evaluating patient outcomes.

Studies in Rare Diseases

PCORI is interested in the investigation of strategies addressing care for patients with rare diseases. These conditions are defined as “life-threatening” or “chronically debilitating.” They are of such low prevalence (affecting fewer than 200,000 in the U.S. [i.e., less than 1 in 1,500 persons]) that special efforts—such as combining data across large populations—might be needed to address them.

Patient and Stakeholder Engagement

PCORI encourages all applicants to outline how patients and other stakeholders will participate as partners in various phases of the proposed research. Before completing this section of the Research Strategy, applicants are encouraged to review the [Engagement Rubric](#)¹⁸, which can be found in the PCORI Funding Center. Applicants should also review the PCORI Methodology Standards Associated with Patient-Centeredness and [PCORI’s Sample Engagement Plans](#).¹⁹ The rubric and Sample Engagement Plans are not intended to be comprehensive or prescriptive; instead, they provide a variety of examples to incorporate engagement, where relevant, into the research process.

Applicants are expected to consult with patients and other stakeholders on their decisional dilemma and evidence needs, or to reference previously documented decisional dilemmas in preparation for the submission of Letters of Intent (LOIs) and applications. To describe the decisional dilemma, state the specific clinical decision(s) or treatment choice(s) confronted by the decision makers and explain how the findings from the proposed research will inform those decisions. State why this decision—such as choosing a specific medication, surgical approach, or care delivery strategy to treat a condition or manage a specific population—is important to patients. Document the uncertainty patients and other stakeholders face in making this decision. Identify the patients and other stakeholders you consulted in determining that the proposed study addresses their evidentiary needs for decision making, and indicate your commitment to continue engaging them actively in the conduct of the study. Similarly, applicants should document how the project outcomes are especially relevant and meaningful endpoints to patients and other stakeholders.

Populations Studied

PCORI seeks to fund research that includes diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status, so that possible differences in outcomes may be examined in defined subpopulations, otherwise known as HTE. PCORI recognizes that some proposed studies might represent important PCOR opportunities, even in the absence of a broadly diverse study population. However, the burden is on the applicant to justify the study’s importance in the absence of diversity; to discuss which subgroups are most important; and to discuss how the subgroups will be analyzed, including whether or not the study will be powered to examine the question of effectiveness in subgroups. PCORI is particularly interested in including previously understudied populations for whom effectiveness information is especially needed, such as hard-to-reach populations or patients with

¹⁸ Available at <http://www.pcori.org/sites/default/files/Engagement-Rubric.pdf>.

¹⁹ Available at <http://www.pcori.org/sites/default/files/PCORI-Sample-Engagement-Plans.pdf>

multiple conditions. Thus, comparisons should examine the impact of the strategies in various subpopulations, with attention to the possibility that the strategy's effects might differ across subpopulations. PCORI has developed the following list of populations of interest to guide our efforts in research and engagement. (Note that the Addressing Disparities Program requires that proposed research focus on at least one of the groups indicated by an asterisk below.)

- 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, transgender, and questioning (LGBTQ) persons*
- Veterans and members of the Armed Forces and their families

Protection of Human Subjects

This component (up to five pages) is included in the Research Plan Template. Describe the protection of human subjects involved in your proposed research. 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](#),²⁰ which is issued by the U.S. Department of Health and Human Services (HHS). In referencing the HHS Supplemental Grant Application Instructions, note that PCORI does not require that applicants comply with sections of that policy that refer to requirements for federal-wide assurance and the inclusion of women, minorities, and children in the proposed studies. Instead PCORI expects applicants to address diversity in study participants in the research plan, through a focus on subpopulations, as described in the above section on ‘Populations Studied.’ Awardees must also comply with appropriate state, local, and institutional regulations and guidelines pertaining to the use of human subjects in research.

PCORI requires awardees to ensure that there is a Data and Safety Monitoring Plan, which may include

²⁰ See <http://grants.nih.gov/sites/default/files/supplementalinstructions.docx>

the need to appoint a Data and Safety Monitoring Board, as provided in the [PCORI Policy on Data and Safety Monitoring Plans for PCORI-Funded Research](#).²¹

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](#)²²). Reviewers' comments on human subject research are not reflected in the overall application score, but PCORI staff might use them during potential funding negotiations. Final determinations about the adequacy of human subject protections rest with the Institutional Review Board or international equivalent that have jurisdiction for the study.

The Awardee Institution, 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

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](#).²³

Data Management and Data-Sharing Plan

PCORI encourages openness in research and making research data available for purposes of replication and reproducibility. Although not required to be submitted as a component of the research application, if an award is made, the awardee is required to develop and maintain a plan that addresses data management and data sharing of research project data in a manner that is appropriate for the nature of the research project and the types of research project data, and that is consistent with applicable privacy, confidentiality, and other legal requirements.

Recruitment

Proposals should include information about the size and representativeness of the potential pool of patients from which recruitment will occur, and describe the means by which this size estimate was determined. Likewise, proposals should provide evidence-based estimates of how many participants are expected in the study, based on expected recruitment; applying the study's inclusion and exclusion criteria; anticipated acceptance (or refusal) rates; and other factors, such as failure to follow up. Such estimates must be discussed in the application, specified in the milestones, reviewed by merit reviewers and PCORI staff, and monitored by PCORI in the funded research.

Peer Review and Release of Research Findings

PCORI has a legislative mandate to ensure the scientific integrity of the primary research it supports and to make study findings widely available and useful to patients, clinicians, and the general public within a specific timeframe. Accordingly, the PCORI Board of Governors (Board) adopted the [Process for Peer Review of Primary Research and Public Release of Research Findings](#).²⁴

²¹ See <http://www.pcori.org/sites/default/files/PCORI-Policy-Data-Safety-Monitoring-Plans.pdf>

²² See <http://www.pcori.org/sites/default/files/PCORI-Checklist-for-Evaluating-Human-Subjects-Protections.pdf/>.

²³ See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-054.html>.

²⁴ See <http://www.pcori.org/sites/default/files/PCORI-Peer-Review-and-Release-of-Findings-Process.pdf>

In summary, Awardee Institutions are required to submit to PCORI for peer review a draft final research report that provides the methodological details, describes the main study results, and interprets the findings in clinical or other decisional contexts. Subject matter experts; individuals with expertise in research methodology or biostatistics; and patients, caregivers, and other healthcare stakeholders will review the draft final research report. After Awardee Institutions have responded to reviewers' comments to PCORI's satisfaction, the report will be accepted and considered final. PCORI will then prepare a 500-word standardized abstract summarizing the study results for patients and the general public, which the Awardee Institution will review and approve.

PCORI will post the following materials on its website no later than 90 days after the draft final research report is accepted: (1) a 500-word abstract for medical professionals; (2) a 500-word standardized abstract summarizing the study results for patients and the general public; (3) a link to the study record on [ClinicalTrials.gov](https://clinicaltrials.gov) (as applicable); and (4) ancillary information, including conflict of interest disclosures. The final research report, along with anonymized reviewer comments, will be made publicly available on the PCORI website no later than 12 months after its acceptance, except by prior mutual agreement with the Awardee Institution.

VII. How To Submit an Application

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.

Letter of Intent (LOI)

Applicants should download the [LOI Template](#) from the [PCORI Funding Center](#). They must complete the document and convert it to a PDF file. The LOI is limited to two pages, excluding references. PCORI suggests including all references as in-text citations using American Medical Association citation style, but other citation styles are accepted. Do not upload additional documents as part of your LOI, including Letters of Endorsement or Letters of Support, because they are not requested at this stage. Their inclusion will result in LOI rejection without review. Please visit the [PCORI Funding Center](#) for additional applicant resources, including the PFA and required templates.

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

- Title of the proposed study that preferably captures the comparative nature of the study
- Specific aims (clearly stated)
- How the study will improve the quality and relevance of evidence available to help patients and stakeholders make informed health decisions
- Knowledge gap addressed by research question(s)
- Concise description of study design
- Study population (description of participants and participating study sites)



- Outcomes (identification and description of why they are important to patients)
- Sample size
- Comparators (described and listed clearly, with demonstrated efficacy specified for each and details on how the strategies will be delivered in real-world settings)
- Patient and other stakeholder engagement (involvement through planning, conducting, and disseminating)

The LOI Template provides guidance on responding to each item. Please refer to the [Application Guidelines](#) for due dates and information on how to submit an LOI via [PCORI Online](#). **The deadline for LOI submission is October 31, 2017, by 5 p.m. (ET).**

LOI Review

LOIs are evaluated based on the following:

- Importance and relevance of the topics to PCORI priorities, as evidenced by critical gaps identified by clinical guidelines developers and recent systematic reviews
- Clarity and credibility of responses to the LOI questions
- The investigators' prior relevant experience
- Programmatic fit and balance, considering whether the application overlaps with previously funded studies or concurrent applications to a significant degree or, conversely, whether the application fills a gap in the portfolio with certain characteristics, including disease category, topics, priority population, methodologies, and other variables

Only applicants whose LOIs are deemed most responsive to this PFA will be invited to submit a full application. A minimum of two PCORI staff review the LOIs, which are not scored during review. Notification of the request to submit a full application will occur no later than November 28, 2017.

Applicants are invited to submit an application based on the information provided in the LOI. Any changes to the following require PCORI's approval:

- Research question(s)
- Specific aims
- Study design
- Comparators
- Principal Investigator (PI)
- Institution

If you need to change any of this information or have questions, please email pfa@pcori.org.

Note: A PI can only submit one LOI per PFA. However, an individual listed as a PI on one LOI may be listed as and serve in another non-PI role (e.g., co-investigator or consultant) on other LOIs within the



same PFA, during the same cycle. A PI can submit multiple LOIs to different program PFAs in a cycle, but the PI must ensure that the research topics and projects are not similar. If a PI submits an LOI to multiple program PFAs, LOIs that exhibit scientific overlap or that appear to be duplicate submissions will be disqualified. PCORI will contact the PI and provide him or her with an opportunity to choose which PFA he or she would like to apply to. This applies to single and dual-PI submissions.

Project Budget and Duration

The maximum budget and research period of performance for the Broad PFAs can be found in the Overview section. At the time of contract execution, PCORI sets aside all of the funds associated with an awarded project to be made available throughout the contract's period of performance. The maximum budget includes all research- and peer-review-related costs. Refer to the [Application Guidelines](#) for additional details. Appendix 2 within the guidelines provides a complete list of allowable and unallowable costs. This PFA does not consider exceptions to the budget or to period-of-performance limits. PCORI will not review requests exceeding the stated maximum budget or period of performance. Note that although subcontractor indirect costs are included in the prime applicant's direct-cost budget, subcontractor indirect costs are not factored when determining adherence to the PFA's direct-cost limit.

Note: If your proposed budget is more than \$2 million in direct costs and is a head-to-head comparison of two or more interventions or strategies (and not an evidence synthesis study or a project to develop and evaluate a decision support tool), you may wish to apply under PCORI's [Pragmatic Studies To Evaluate Patient-Centered Outcomes Funding Announcement](#), which will open on October 3, 2017.

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 an LOI and an application for each cycle to which you are applying.

Applicant Resources

PCORI Funding Center	https://www.pcori.org/funding-opportunities/announcement/broad-pcori-funding-announcements-cycle-3-2017
PCORI Online System	https://pcori.force.com/engagement
PCORI Funding Awards	http://www.pcori.org/research-results-home

VIII. 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; the review panel’s preliminary review of full applications; an in-person panel discussion of a subset of full applications (identified by PCORI’s Research Priority Area Program staff and based on the preliminary review and program priorities); the Selection Committee’s recommendation of applications for funding; and, finally, Board award 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., non-responsiveness). 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. An application can be scientifically withdrawn if it is not responsive to the guidelines described in this PFA, describes research that is not comparative, includes a cost-effectiveness analysis, or otherwise does not meet PCORI programmatic requirements.

PCORI Merit Review Officers (MROs) recruit each review panel based on the number of invited LOIs and topic areas represented by the 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.

The table below is designed to help applicants understand how the PCORI merit review criteria align with criteria from other funding organizations with which applicants might be familiar (e.g., NIH). Though PCORI’s criteria do map to most NIH criteria, there are areas where we ask for different information (i.e., PCORI does not include a criterion that tracks to NIH’s innovation criterion, but does include criteria evaluating patient-centeredness and engagement) reflecting PCORI’s unique approach.

Crosswalk of PCORI Merit Review Criteria with NIH Criteria	
SIGNIFICANCE	<ol style="list-style-type: none"> 1. Potential for the study to fill critical gaps in evidence 2. Potential for the study findings to be adopted into clinical practice and improve delivery of care
APPROACH	<ol style="list-style-type: none"> 3. Scientific merit (research design, analysis, and outcomes)

	4. Investigator(s) and environment
PCORI-only Merit Review Criteria	
PATIENT-CENTEREDNESS/ENGAGEMENT	5. Patient-centeredness 6. Patient and stakeholder engagement

Below are PCORI’s merit review criteria. PCORI’s merit review panels use these criteria during the preliminary and in-person review phases to evaluate and score all submitted applications, and to ensure consistency and fairness in how applications are evaluated.

Criterion 1. Potential for the study to fill critical gaps in evidence:

The application should address the following questions:

- Does the application convincingly describe the clinical burden?
- Does the application identify a critical gap in current knowledge as noted in systematic reviews, guideline development efforts, or previous research prioritizations?
- Does the application identify a critical gap in current knowledge, evidenced by inconsistency in clinical practice and decision making?
- Would research findings from the study have the potential to fill these evidence gaps?

Criterion 2. Potential for the study findings to be adopted into clinical practice and improve delivery of care

The application should describe how evidence generated from this study could be adopted into clinical practice and delivery of care by others. The application should also address the following questions:

- Does the application identify who will make the decision (i.e., the decision maker) or use (i.e., the end-user) the study findings (not the intervention) this study produces, such as local and national stakeholders?
- Does the application identify potential end-users of study findings—such as local and national stakeholders—and describe strategies to engage these end-users?
- Does the application provide information that supports a demand for this kind of a study from end-users?
- Would this study’s research findings have the potential to inform decision making for key stakeholders? If so, provide an example. How likely is it that positive findings could be reproduced by others, resulting in improvements in practice and patient outcomes? Identify the potential barriers that could hinder adoption of the intervention by others.
- Does the application describe a plan for how study findings will be disseminated beyond publication in peer-reviewed journals and at national conferences?

Criterion 3. Scientific merit (research design, analysis, and outcomes)

The application should show sufficient technical merit in the research design to ensure that the study goals will be met. The application should also address the following questions:

- Does the application describe a clear conceptual framework anchored in background literature which informs the design, key variables, and relationship between interventions and outcomes being tested?
- Does the Research Plan describe rigorous methods that demonstrate adherence to the PCORI Methodology Standards?
- Is the overall study design justified?
- Are the patient population and study setting appropriate for the proposed research question?
- Does the application provide justification that the outcome measures are validated and appropriate for the population?
- Are each of the comparators (e.g., active intervention arm and comparator arm) described clearly and well-justified? If “usual care” is one of the arms, is it adequately justified and will it be sufficiently measured?
- Are the sample sizes and power estimates appropriate? Is the study design (e.g., cluster randomized design, randomized controlled trial, or observational study) accounted for and is the anticipated effect size adequately justified?
- Is the study plan feasible? Is the project timeline realistic, including specific scientific and engagement milestones? Is the strategy for recruiting participants feasible? Are assumptions about participant attrition realistic, and are plans to address patient or site attrition adequate?

Criterion 4. Investigator(s) and environment

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

The application should also address the following questions:

- How well-qualified are the PIs, collaborators, and other researchers to conduct the proposed activities? Is there evidence of sufficient clinical or statistical expertise (if applicable)?
- Does the investigator or co-investigator have demonstrated experience conducting projects of a 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 PI roles and areas of responsibility?
- Is the level of effort for each team member appropriate for successfully conducting the proposed work?
- Does the application describe adequate availability of and access to facilities and resources

(including patient populations, samples, and collaborative arrangements) to carry out the proposed research?

- Is the institutional support appropriate for the proposed research?

Criterion 5. Patient-centeredness

The application should demonstrate that the study focuses on improving patient-centered outcomes and employs a patient-centered research design (i.e., a design informed or endorsed by patients). *(Note: The study can be patient-centered even if the end-user is not the patient, as long as patients will benefit from the information.)*

The application should also address the following questions:

- Does the application include a thorough description about which outcomes (both benefits and harms) are important to patients, and are those outcomes included in the study plan?
- Does the application provide information that indicates that closing the evidence gap is important to patients and other stakeholders?
- Are the interventions being compared in the study available to patients now, and are they the best options for comparison (including whether they would be chosen by patients and their healthcare providers for managing the condition being studied)?

Criterion 6. Patient and stakeholder engagement

The application should demonstrate the engagement of relevant patients and other stakeholders (e.g., patients, caregivers, clinicians, policy makers, hospitals and health systems, payers [insurance], purchasers [business], industry, researchers, and training institutions) in the conduct of the study. Quality of engagement should be evaluated based on scope, form, and frequency of patient and stakeholder involvement throughout the research process.

The application should also address the following questions:

- Does the application provide a well-justified description of how the research team incorporates stakeholder involvement? Does the study include the right individuals (e.g., researchers, patients, caregivers, clinicians, policy makers and other healthcare system stakeholders) to ensure that the projects will be carried out successfully?
- Does the application show evidence of active engagement among scientists, patients, and other stakeholders throughout the research process (e.g., formulating questions, identifying outcomes, monitoring the study, disseminating, and implementing)? Is the frequency and level of patient and stakeholder involvement sufficient to support the study goals?
- Is the proposed Engagement Plan appropriate and tailored to the study?
- Are the roles and the decision-making authority of all study partners described clearly?
- Are the organizational structure and resources appropriate to engage patients and stakeholders throughout the project?

In-Person Review

During preliminary review, all administratively and scientifically compliant applications are evaluated and scored by panels of external reviewers based on PCORI's merit review criteria, including evaluation of adherence to the PCORI Methodology Standards. After preliminary review, 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 forward to in-person review.

During the in-person review, merit reviewers meet to discuss applications and to clarify further the merits of the proposed research. They also identify areas for improvement. 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. Program staff members then recommend projects to a Selection Committee, which includes members of the Board. The Selection Committee considers recommendations and works with staff to identify a slate of applications for possible funding based on merit review scores, programmatic balance and fit, and PCORI's strategic priorities. This slate is then proposed to the Board for consideration and approval.

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 which will include:

- In-person panel discussion notes
- Final average overall score
- Preliminary reviewer critiques
- Application quartile, to help applicants understand how they did relative to other discussed applications

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 while adhering to the PCORI Methodology Standards. Programs also consider the funds allotted for the current funding announcement when deciding which applications to recommend to the Board 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 September 2018.