PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Fall 2014 Funding Cycle

PCORI Funding Announcement:
Communication and Dissemination Research

Published August 6, 2014

This PCORI Funding Announcement applies to the funding cycle that closes November 4, 2014, at 5:00 p.m. (ET). Application guidelines, templates, and other resources are available at http://www.pcori.org/fall-2014-communication/.

About PCORI

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, caregivers, and the broader healthcare community.

PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a nonprofit, nongovernmental organization. PCORI's purpose, as defined by the law, is to help patients, clinicians, purchasers, and policy makers 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."

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

Follow us on Twitter: @PCORI

Overview

Published	August 6, 2014
Letter of Intent Due	September 5, 2014, by 5:00 p.m. (ET)
Summary	PCORI seeks to fund projects that address critical knowledge gaps in the communication and dissemination process—both the communication and dissemination of research results to patients, their caregivers, and clinicians, as well as the communication between patients, caregivers, and clinicians in the service of enabling patients and caregivers to make the best possible decisions in choosing among available options for care and treatment.
Applicant Resources	See http://www.pcori.org/fall-2014-communication/
Key Dates	Online System Opens: August 6, 2014 Letter of Intent (LOI) Deadline: September 5, 2014, by 5:00 p.m. (ET) Applicant Town Hall Sessions: August 14, 2014, 12:00 p.m. (ET) August 15, 2014, 12:00 p.m. (ET) LOI Status Notification: September 19, 2014 Application Deadline: November 4, 2014, by 5:00 p.m. (ET) Merit Review: February 2015 Awards Announced: April/May 2015 Earliest Project Start Date: July/August 2015
Maximum Project Budget (Direct Costs)	$1.5 million
Maximum Project Period	Three years
Funds Available up to	$8 million
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 US applicant organizations. Nondomestic components of organizations based in the US and foreign organizations may apply, as long as there is demonstrable benefit to the US healthcare system and US efforts in the area of patient-centered research can be clearly shown. Organizations may submit multiple applications for funding. Individuals are not permitted to apply.

Review Criteria	1. Impact of the condition on the health of individuals and populations 2. Potential for the study to improve healthcare and outcomes 3. Technical merit 4. Patient-centeredness 5. Patient and stakeholder engagement
Budget/Time Limits	Applicants must submit a Greater than Time/Budget Request with their Letter of Intent if the proposed project's budget or duration exceed limits specified in this funding announcement.
Contact Us	**Programmatic Inquires:** Please contact the PCORI Helpdesk via email (pfa@pcori.org), phone (202-627-1884), or online (http://www.pcori.org/PFA/inquiry). PCORI will provide a response within three business days. However, we cannot guarantee that all questions will be addressed three business days prior to a Letter of Intent or application deadline. **Administrative, Financial, or Technical Inquiries:** Please contact the PCORI Helpdesk at pfa@pcori.org. PCORI will provide a response within two business days. Please note that during the week of the application deadline, response times may exceed two business days. One week prior to an application deadline, 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 5:00 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 Fall 2014 Funding Cycle:

- The research areas of interest have been revised to include more specific information on the broad topical areas the Communication and Dissemination Research program is interested in funding.
- New/updated sections: Evidence to Action Networks, Non-responsive and Non-priority Research Areas, and Replication and Reproducibility of Research and Data Sharing Plan
- Revised and expanded "Letter of Intent" section and added instructions
- New "LOI Review" section; this is now a competitive screening process. Only Letters of Intent deemed most responsive to this PCORI Funding Announcement will be invited to submit a full application.
- New "IV. Merit Review" section and updated Criterion 3

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I. Introduction

Summary of Program

Knowledge about how to optimally communicate and facilitate the effective use of patient-centered outcomes research (PCOR) and comparative effectiveness research (CER) findings by patients, caregivers, and healthcare professionals needs to be strengthened. There are well-documented barriers to the rapid transfer of evidence that could be useful for identifying healthcare options and facilitating informed decision making. For healthcare decisions to be informed, innovative and effective strategies are needed to make existing PCOR/CER evidence available to patients and providers, and the knowledge must be applicable in real-world settings. Moreover, the information needs to be in understandable language in order to improve personalized and shared decision making.

The Communication and Dissemination Research program at PCORI invites applications that study the comparative effectiveness of alternative approaches aimed at informing and empowering patients, caregivers, and other healthcare decision makers to ask for, understand, and use information to support shared decision making between patients and their healthcare providers in order to make the best possible decisions with the goal of increasing knowledge about, and the use of, CER results.

CER is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition, or to improve the delivery of care. The purpose of CER is to assist patients, consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.[1-2] *This announcement is designed to include the direct comparison of effective health communication interventions or strategies, and patients along with caregivers and providers in the context of real-world clinical care settings and situations.*

Background

Health care in the US has changed dramatically over the past several decades. Today, patients have more treatment options than ever. Making the right choices requires a critical assessment of the potential benefits and harms of the options, within the context of the patient's personal characteristics, conditions, and preferences. Every day, patients and their caregivers are faced with crucial healthcare decisions while lacking key information. This information would not necessarily deliver decisions or tell people what to do, but inform them of the trade-offs associated with the options they have and enable them to make better decisions for themselves in collaboration with their healthcare team based on the evidence and their own values, preferences, and goals.

PCORI is entrusted by the public to fund research that will matter to patients, their caregivers, and other

[1] Sox HC and Greenfield S. Comparative effectiveness research: A report from the Institute of Medicine. *Ann Intern Med.* 2009;151(3):203-205.
[2] Institute of Medicine. Initial national priorities for comparative effectiveness research. Washington, DC. Institute of Medicine of the National Academies. 2009.

stakeholders (defined as clinicians, clinician societies, hospitals, and health systems; payers [insurance]; purchasers [business]; industry; researchers; policymakers; and training institutions). PCORI seeks to change how 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 the research questions, reviewing the proposals, conducting the research, disseminating the findings, promoting the implementation of the findings, and using the results to understand and address the needs of patients and other stakeholders.*

Patient-centered care is respectful and responsive to individual patient preferences, needs, and values, and ensures that patient values guide all clinical decisions. However, when it comes to determining course of care, many patients and caregivers are not aware that they may have more than one viable option for prevention, diagnosis, or treatment decisions, and thus the value of PCOR/CER may not be immediately recognized. Strategies can be developed to increase patient and clinician awareness of the uncertainty associated with specific healthcare interventions, with the goal of increasing knowledge about, and the use of, PCOR/CER results. It should be noted that the type of healthcare decision the patient faces is an important variable affecting the information needed and how it is provided. (For example, the information needs of a patient weighing options for treating high blood pressure will be different from those of a patient facing a terminal cancer diagnosis with complicated treatment options.) Additionally, although a majority of patients prefer an active role in clinical decision making, the reasons some choose not to participate are not entirely clear. Knowledge gaps in this area include the role of cultural norms and values in shaping preferences for participation in clinical decision making.

Communication skills of both patients and healthcare providers are an important issue for the effective use of CER results. When a patient receives health care, s/he interacts with a variety of individuals who collectively comprise the healthcare team. Research on doctor-patient communication has focused primarily on the doctor-patient dyad, but little is known about other health professionals who communicate with and play a critical role in the patient care experience. Moreover, additional information is needed regarding how family involvement and family dynamics affect communication and the decision-making process.

Additional areas of inquiry relevant to the Communication and Dissemination Research program that warrant further investigation include:

Clinician Engagement with CER

Changes in practice on the part of providers in response to the availability of PCOR/CER findings have been limited. It is unclear which methods for translating CER results into clinical care will prove to be most effective in terms of reaching the greatest proportion of patients and improving patient outcomes. Further research is needed to understand clinicians' attitudes toward CER and shared medical decision making. Strategies can then be developed to increase clinicians' utilization of CER and to increase clinicians' motivation and willingness to engage their patients in the decision-making process. Little is known about how clinical decision making could be structured to reduce the potential time burden in individual clinical encounters. Additional information is also needed on how community-based healthcare resources are engaging, if at all, with PCOR/CER findings.

Translating Research, Decision Support Interventions, and Risk Communication

Another important area of research in both clinical and community-based settings is translating existing scientific research into accessible and usable formats that clearly outline the risks and benefits of preventive, diagnostic, and treatment options for patients, caregivers, and healthcare providers. In clinical care, shared decision making and decision support interventions are one of the primary ways in which medical evidence is translated into a format that is usable by patients, families, and caregivers. Understanding the most optimal ways to communicate uncertainty as well as addressing numeracy and health literacy, are fundamental to effectively communicating PCOR/CER via shared decision making and decision aids and needs to be better understood. The integration of patient decision support, electronic medical records, and associated patient systems holds considerable promise, but little if any evidence is available to guide best practices. 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 patient populations with lower levels of literacy and numeracy, and how they can reflect new evidence and remain current. Another significant gap is the limited research on risk communication, in general, and with underserved individuals and those with limited health literacy and numeracy, in particular. To date, research on effective methods for communicating risk information to healthcare providers and enabling them to use the information effectively is lacking.

Distribution of CER

The distribution of CER information to patients, caregivers, and providers (in both clinical and community-based settings) is an area that has not received sufficient research attention. Little is known about which methods and approaches are most effective or the various impacts of different approaches. More research is needed to identify effective approaches to distribute CER results to healthcare providers, with the goals of sustained changes in clinical practice *and* effective distribution of results to patients in order to enable changes in behavior (e.g., adherence and self-care). Research is also needed to identify trusted intermediaries and channels of communication most often turned to by patients, caregivers, and clinicians. Additionally, further investigation is needed to explore how strategies used in public health communication and social marketing can be adapted to distribute the results of CER, and to identify creative ways of combining multiple channels of communication and dissemination to increase exposure to CER. Further exploration is also needed to understand the disparities that may remain regarding access to social media resources to ensure that the “e-health revolution” does not widen existing health-related knowledge gaps among low-income and racial and ethnic minority populations. Finally, further research is needed to examine the reliability of any CER data currently available through social media sites and to understand how individuals evaluate and use this information in their prevention, screening, diagnosis, and treatment decision-making processes. More specifically, there is a lack of information on how these media may influence patient self-care and adherence to treatment recommendations.

Research of Interest

The Communication and Dissemination Research program seeks to fund investigator-initiated comparative effectiveness research that:

- Compares strategies that increase knowledge on how to communicate complex information to patients and caregivers.
- Compares and identifies best practices of dissemination and translation techniques to facilitate bringing shared decision making to everyday practice.
- Identifies and compares practices that increase understanding of the tension between strongly held beliefs and contrary evidence and the impact on the shared decision-making process.
- Compares strategies meant to generate conversations between patients and providers about what is appropriate and necessary treatment (e.g., Choosing Wisely) based on patients' preferences and conditions.
- Compares strategies for conveying uncertainty associated with health and healthcare evidence that increase the likelihood that patients and caregivers will understand the information and be able to incorporate it into decision making and evaluate personal trade-offs.
- Identifies and compares promising practices that address contextual factors and their impact on patient-centered communication.
- Compares 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.
- Compares strategies and methods that optimize communication between patient, family/caregiver, and the healthcare team (e.g., role of family member/caregiver in the patient-provider interaction, patient-caregiver and healthcare team interaction).
- Compares innovative approaches in the use of existing electronic clinical data and other electronic modalities (e.g., electronic health records) from the healthcare system or from a network of systems to enhance clinical decision making by patients and providers.

PCORI is interested in understanding the role of shared decision making and established, effective decision aids in communicating and implementing PCOR/CER. The development, testing, and validation of individual decision aids will be considered nonresponsive to this PCORI Funding Announcement (PFA).

Research studies may focus on patient populations with a single condition or involve patients with a range of conditions. Studies addressing care for patients with rare conditions are also of special interest. Rare diseases are defined as life-threatening or chronically debilitating diseases that are of such low prevalence in populations that special efforts, such as combining data across large populations, may be needed to address them. By "low prevalence," we mean conditions that affect fewer than 200,000 individuals in the US or have a prevalence of less than 1 in 1,500 persons.

Sample Research Questions

The following are meant as examples of the types of questions that your research may help answer. This list is by no means exhaustive. ***All questions must have a comparative component***.

- How do designs for decision support interventions compare in their ability to assist patients and/or caregivers with lower levels of literacy/numeracy, and how do strategies for communicating risk information to vulnerable populations compare?

- Which methods of dissemination are most effective in imparting useful information to patients and their caregivers to increase adoption of practices, patient outcomes, and involvement in care decisions?
- How do methods for distributing CER findings to patients, caregivers, or healthcare providers compare in their ability to improve patients' health outcomes?
- To whom are clinicians most likely to turn for trustworthy information about the effectiveness, relative effectiveness, benefits, and harms of different treatment options for a given condition, and how do they access that information?
- How do strategies learned from public health communication and social marketing compare in their ability to promote the distribution of CER to patients and/or their caregivers and to their clinicians?
- How do strategies in community-based settings compare with strategies in clinical-based settings in their ability to promote the distribution of CER to patients and/or their caregivers?

To be competitive for a PCORI contract, an application must make the case that its proposed research question(s) and outcomes will matter to patients and/or other stakeholders.

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 facilitate dissemination of research findings that will help patients and the public to make better and informed healthcare decisions. To meet this goal, PCORI has set up Evidence to Action Networks, where PCORI facilitates engagement among awardees and cross-learning between projects and teams comprising 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 dissemination and implementation of important research findings.

Awardees are encouraged to participate in these Evidence to Action Networks as they become available.

II. Guidance for Proposing Research

Research Priorities

PCORI funds patient-centered outcomes research (PCOR), a type of comparative CER. The studies PCORI supports 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, both of which are viable alternatives*. The types of interventions tested can include specific drugs, devices, and procedures, as well as other types of alternatives, such as medical and assistive devices and technologies, diagnostic testing, behavioral change, and a wide variety of strategies for improving delivery systems, but the studies must be comparative. "Usual care" (or no specific intervention) may be an appropriate

comparator if this is a realistic choice faced by patients and other stakeholders, but the clinical characteristics must be specified. Applications proposing to use usual care as the comparator must justify the choice to use usual care (e.g., usual care is guidelines-based) and should clearly describe the components of usual care that will be used or measured in the research. A clear description of usual care is necessary to enhance the reproducibility of the research in other settings.

- *Compares two or more clinical strategies that each have established efficacy.* It may be appropriate to include as a comparator a generally accepted practice that occurs with insufficient evidence of efficacy. Applications should evaluate the comparison of two or more clinical interventions. PCORI would like the efficacy of each intervention to be known prior to the initiation of the proposed project, which may include pilot data as appropriate. PCORI is also concerned about commonly accepted practices that occur with insufficient evidence of efficacy. The application must provide information about efficacy of the clinical interventions that will be compared. Projects that aim to develop new or novel interventions, which lack evidence, will be considered out of scope.
- *Studies the benefits and harms of interventions and strategies delivered in real-world clinical settings.* PCORI is interested in innovative studies that provide practical information that can help patients and other stakeholders make informed decisions about their health care and health outcomes.
- *Is based on health outcomes that are meaningful to the patient population under study and are likely to guide the decisions regarding care made by patients, caregivers, and providers.* While most PCOs directly impact the patient's quality of life, certain physiological measurements, such as blood pressure and serum cholesterol, are strongly linked to complications or other outcomes that patients care about and have become outcomes of interest to patients because of increased awareness. Therefore, an application to PCORI that proposes to conduct a study comparing two approaches to helping people control their blood pressure would be well-aligned with PCORI's focus on patient-centeredness, assuming that the study would also compare the two approaches' effects on any other relevant outcomes that are important to patients, such as treatment-related symptoms (side effects).

Non-responsiveness and Non-priority Research Areas

Applications will be considered non-responsive if the proposed research:

- Conducts a formal cost-effectiveness analysis in the form of dollar-cost per quality-adjusted life-year to compare two or more alternatives.
- Measures the relative costs of care of two or more alternative approaches as the primary criteria for choosing the preferred alternative.

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 costs of care.

PCORI does have an interest, however, in studies that address questions about conditions that lead to

high costs to the individual or to society. This is included in our review criterion on impact of the condition on the health of individuals and populations. Thus, PCORI is also 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; or
- Evaluate interventions to reduce health system waste or increase health system efficiency.

Proposals that include studies of these issues without utilizing a formal cost-effectiveness analysis or comparing the costs of alternatives are considered responsive.

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

- Study of the natural history of disease
- Instrument development
- Pharmacodynamics
- Fundamental science or study of biological mechanisms
- Developing and evaluating new decision aids or clinical prognostication tools
- Establishing efficacy for a new clinical strategy
- Pilot studies intended to inform larger efforts
- Comparisons of patient characteristics rather than clinical strategy options

Features of Patient-Centered Outcomes Research (PCOR)

PCOR helps people and their caregivers communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options. This research:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system features to inform decision making, highlighting the choices that matter to people.
- Is inclusive of an individual's preferences, autonomy, and needs, focusing on outcomes that people notice and care about, such as survival, functioning, symptoms, and health-related quality of life.
- Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination.
- Directly compares clinical interventions that are generally available in the clinical settings.
- Obtains the perspectives of stakeholders to address the burdens to individuals, availability of services, and requirements for technology and personnel.

Leveraging Existing Resources

Investigators are encouraged 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 comparative effectiveness research (CER) questions. PCORI is also interested in seeking proposals for meta-analyses that use individual participant data.

Preliminary Data and Use of Accepted Measures

PCORI encourages investigators to design their research using valid PCO measures including preliminary data that support the proposed measures. Investigators are encouraged to consider those measures described in the Patient Reported Outcomes Measurement Information System (PROMIS).

Documentation of Assumptions

PCORI specifically seeks studies that are sufficiently powered to detect clinically meaningful effects. To that end, applicants must justify the proposed sample sizes by explaining the assumptions used in all study power calculations. The application should clearly state all the necessary assumptions (i.e., the primary outcome measure, the estimated difference in the mean value of this measure between study arms, standard deviation of the measure, type I error rate, and any other assumptions). All such estimates must be justified by referring to prior published research or preliminary data.

Studies in Rare Diseases

PCORI is interested in the investigation of strategies that address care for patients with rare conditions. Rare diseases are defined as life-threatening or chronically debilitating diseases that are of such low prevalence in populations that special efforts, such as combining data across large populations, may be needed to address them. The term low prevalence is defined as conditions that affect fewer than 200,000 individuals in the US or have a prevalence of less than 1 in 1,500 persons.

Methodological Considerations

Regardless of study design, proposals must adhere to all relevant PCORI Methodology Standards. These include 47 individual standards that fall into 11 categories. The first five categories are cross-cutting and are relevant to most PCOR studies. Researchers should refer to all of these standards when planning and conducting their research projects. These categories are:

- Standards for Formulating Research Questions
- Standards Associated with Patient-Centeredness
- Standards on Data Integrity and Rigorous Analyses
- Standards for Preventing and Handling Missing Data
- Standards for Heterogeneity of Treatment Effect

Six other categories of standards will be applicable to particular study designs and methods. The standards in each of these categories should be used for guidance when they are relevant to a particular study:

- Standards for Data Registries
- Standards for Data Networks as Research-facilitating Infrastructures
- Standards for Causal Inference Methods
- Standards for Adaptive and Bayesian Trial Designs
- Standards for Studies of Diagnostic Tests

- Standards for Systematic Reviews

Most of these should be considered "minimal" standards. Additional best practices, including relevant guidelines for the conduct of clinical trials developed by other organizations, should be addressed in the application for PCORI funding.

All applicants should specifically discuss their capacity to measure factors such 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 and Stakeholder Engagement

PCORI encourages all applicants to clearly describe the patient and stakeholder engagement in their research proposals. PCORI understands that patient and stakeholder engagement in research can take many forms; it is not seeking one particular type or method of engagement. Rather, applicants should communicate how patients (those with lived experience), family members, caregivers, and the organizations that represent them, as well as any other relevant stakeholders, will be involved in study activities. Because this type of engagement in research is a relatively new concept, PCORI has developed the Engagement Rubric to guide both applicants and merit reviewers. Additionally, studies are expected to adhere to PCORI's Methodology Standards Associated with Patient-centeredness and to the PCOR Engagement Principles found within the rubric. These and additional resources are available in PCORI's Funding Center.

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 CER may be examined, otherwise known as heterogeneity of treatment effects. PCORI recognizes that some proposed studies may represent important PCOR opportunities even in the absence of a broadly diverse study population. However, the burden is on the applicant in such cases to justify the importance of the study in the absence of diversity and to discuss which subgroups are most important and how they will be analyzed, including whether there will be power to examine the question of effectiveness in subgroups. Alternatively, PCORI is interested in the inclusion of previously understudied populations for whom effectiveness information is particularly needed, such as hard-to-reach populations or patients with multiple conditions. Thus, comparisons should examine the impact of the strategies in various subpopulations with attention to the possibilities that the effects of the strategy might differ across various populations. Populations of interest include those that are less frequently studied. PCORI has developed a list of priority populations to guide our efforts in research and engagement, which includes:

- Racial and ethnic minority groups
- Low-income groups
- Women
- Children (age 0–17 years)
- Older adults (age 65 years and older)
- Residents of rural areas

- Individuals with special healthcare needs, including individuals with disabilities
- Individuals with multiple chronic diseases
- Individuals with rare diseases
- Individuals whose genetic makeup affects their medical outcomes
- Patients with low health literacy/numeracy and/or limited English proficiency
- Lesbian, gay, bisexual, and transgender (LGBT) persons

Protection of Human Subjects

PCORI adopts, by reference, the Human Subjects requirements of 45 CFR Part 46. If the proposed research will involve human subjects, refer to the Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan in Part II of the Instructions for the PHS 398 Form provided by the National Institutes of Health. Note: PCORI requires engagement in the research by patients and/or other stakeholders as research partners. Research subjects protection requirements do not apply to co-investigators, members of the research team, or research partners.

Replication and Reproducibility of Research and Data Sharing Plan

PCORI is committed to maximizing the utility and usability of data collected in our funded projects. This is essential to building confidence in the accuracy of these findings. PCORI supports policies to promote sharing of study documentation (e.g., study protocol, programming code, and data definitions) so that other researchers may replicate the findings in other populations. Please propose a method for sharing data and appropriate documentation on request.

Budget and Project Duration

If your proposed project exceeds $1.5 million in total direct costs and/or exceeds three years, please submit a Greater than Request with a justification for the increased budget and/or extended length of your study. If applicable, combine the completed Greater than Time/Budget Request with the completed Letter of Intent (LOI), save as a PDF, and upload into the PCORI Online System. The request will be reviewed by the program staff, and you will receive a notification for approval or denial of this request two weeks after the LOI deadline.

III. How to Submit a Proposal

Letter of Intent

IMPORTANT TO NOTE: With the Fall 2014 Cycle, the Communication and Dissemination Research program will be using a screening Letter of Intent. You may submit a full application only if invited to do so based on your LOI. Research questions proposed in the LOI cannot change if you are invited to submit a full application. LOIs with the primary focus of tool development, testing, and validation will be screened out and not considered.

Applicants should download the Letter of Intent template for the Communication and Dissemination

PFA from the Funding Center. Complete the document and convert it to a PDF file with a limit of 1,500 words. Letters of Intent that exceed the word limit (excluding references) will not be reviewed. References should be numbered in the text and full citation provided in the reference section of the LOI. Do not upload additional documents as part of your LOI, including letters of endorsement or support, as they are not accepted at this stage. Their inclusion will result in LOI rejection without review. Please visit the Funding Center for additional applicant resources, including the PFA and required templates.

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

- Condition burden and impact: high prevalence and/or associated with significant suffering
- Knowledge gap addressed by research question(s)
- Documentation of high-priority topic by patients, stakeholders, research, and/or clinical communities
- Specific aims: clearly stated
- Study population: clear description; representative of community practice; inclusion of PCORI priority populations
- Outcomes: primary outcomes identified; description of why they are important to patients provided
- Study design: clearly described and defended, including description of how selection bias and confounding factors will be mitigated in nonrandomized designs; use of a theoretical/conceptual framework to guide the research study
- Sample size and power calculations: sample size is adequate; assumptions clearly stated and supported
- Analytic plan: both quantitative and qualitative if appropriate
- Patient and stakeholder engagement: involvement throughout planning, implementation of the project, and dissemination of findings discussed
- Impact: plans for dissemination; how findings will be used in health decision making; anticipated overall impact of findings

Additional consideration will be given to programmatic fit and balance, taking into consideration whether the proposal significantly overlaps with previously funded studies or concurrent proposals or, conversely, whether the proposal fills a gap in the portfolio of proposals with certain characteristics, including disease category, topics, priority population, methodologies, and other variables.

Please address all categories in the Letter of Intent template. Then upload the document into the PCORI Online System. **The deadline for LOI submission is September 5, 2014, by 5:00 p.m. (ET).**

Only Letters of Intent deemed most responsive to this PFA will be invited to submit a full application. Notification of request to submit full application will occur on or before September 19, 2014.

Letter of Intent Review

Letters of Intent are evaluated on the following criteria (note that PCORI does not score the LOI):

- Importance and relevance of the topics to PCORI priorities, as evidenced by critical gaps identified by clinical guidelines developers and/or recent relevant systematic reviews
- Clarity and credibility of applicants' responses to the LOI questions
- Prior relevant experience
- Programmatic fit and balance, taking into consideration whether the proposals significantly overlap with previously funded studies or concurrent proposals or, conversely, whether the proposal fills a gap in the portfolio of proposals with certain characteristics, including disease category, topics, priority population, methodologies, and other variables.

Only Letters of Intent deemed most responsive to this PFA will be invited to submit a full application. Notification of request to submit full application will occur no later than September 19, 2014. Please refer to the Application Guidelines for due dates and information on how to submit your LOI via PCORI Online.

Note: An individual may submit only one LOI per PFA as a Principal Investigator (PI). While a PI may submit an LOI to other PFAs, the research topic/project must be distinct. Letters of Intent with scientific overlap or that appear to be duplicate submissions will be removed during the LOI screening process.

Submission Dates

Letters of Intent and applications must be submitted in accordance with the published dates and times listed in the Overview in this PFA and in the PCORI Funding Center.

PCORI Online System

To submit a proposal, you must register with the PCORI Online System and submit both a Letter of Intent and an application for each cycle in which you are applying.

Applicant Resources

PCORI Funding Center	http://www.pcori.org/fall-2014-communication/
PCORI Online System	https://pcori.fluxx.io
PCORI Funding Awards	pcori.org/pfaawards

III. Merit Review

PCORI Merit Review is a multiphase process that includes: evaluation of Letters of Intent; preliminary review of full applications by review panels; in-person panel discussion of a subset of full applications (identified by PCORI's Research Priority Area Program Staff, based on the preliminary review and program priorities); Selection Committee recommendation of applications for funding; and finally, Board of Governors award approval (no later than May 2015).

Preliminary Review

PCORI conducts rigorous merit review of the full applications it receives. Note that applications may be eliminated from the review process for administrative or scientific reasons (e.g., non-responsiveness). An application may be administratively withdrawn if it is incomplete or submitted past the stated due date and time, or it does not meet the administrative or formatting criteria outlined in the Application Guidelines, in the PCORI templates, and in the PCORI Online System. An application may be scientifically withdrawn if it is not responsive to the guidelines as described in this PFA, describes research that is not comparative, includes cost-effectiveness analysis, or otherwise does not meet PCORI programmatic requirements.

Administratively and scientifically responsive applications will be reviewed by one or more specially convened merit review panels. Each panel is recruited by PCORI Merit Review Officers, who identify the Chair; scientist reviewers who are clinical experts familiar with the clinical content of submitted applications; methodological and statistical experts familiar with pragmatic clinical trials and large database analyses; patient representatives trained in review of scientific proposals; and representatives of other stakeholder groups.

The following are PCORI's Merit Review criteria. These five criteria are used by PCORI's review panels during the preliminary and in-person phases to score and evaluate all submitted applications:

Criterion 1. Impact of the condition on the health of individuals and populations

The proposal addresses the following questions:

- Is the condition or disease associated with a significant burden in the US population, in terms of prevalence, mortality, morbidity, individual suffering, or loss of productivity?
- Alternatively, does the condition or disease impose a significant burden on a smaller number of people who have a rare disease?
- Does the proposal include a particular emphasis on patients with one or more chronic condition(s)?

Criterion 2. Potential for the study to improve health care and outcomes

The proposal has the potential to lead to meaningful improvement in the quality and efficiency of care and to improvements in outcomes important to patients. It addresses the following questions:

- Does the research question address a critical gap in current knowledge as noted in systematic reviews, guideline development efforts, or previous research prioritizations?
- Has it been identified as important by patient, caregiver, or clinician groups?
- Do wide variations in practice patterns suggest current clinical uncertainty?
- Is the research novel or innovative in its methods or approach, in the population being studied, or in the intervention being evaluated in ways that make it likely to improve care?
- Do preliminary studies indicate potential for a sizable benefit of the intervention relative to current practice? How likely is it that positive findings could be disseminated and implemented quickly, resulting in improvements in practice and patient outcomes?

Criterion 3. Technical merit

The proposal has sufficient technical merit in the research design to ensure that the study goals will be met. It addresses the following questions:

- Does the proposal describe a clear conceptual framework/theory/model that supports the validity of the identified evidence gap and informs the design, key variables, and relationships being tested?
- Does the research plan describe rigorous methods that demonstrate adherence to PCORI's Methodology Standards?
- Are the comparison interventions realistic options that exist in current practice?
- Are sample size and power estimates presented that are based on realistic and careful evaluations of the anticipated effect size?
- Is the project timeline realistic, including specific scientific and engagement milestones?
- Does the research team have the necessary expertise to conduct the project?
- Is the organizational structure and are the described resources appropriate to carry out the project?
- Is there a diverse study population with respect to age, gender, race, ethnicity, and clinical status, appropriate for the proposed research?

Criterion 4. Patient-centeredness

The proposal demonstrates patient-centeredness at every stage of the research. It addresses the questions:

- Is the research focused on questions that affect outcomes of interest to patients and their caregivers?
- Does the research address one or more of the key questions mentioned in PCORI's definition of patient-centered outcomes research?

Criterion 5. Patient and stakeholder engagement

The proposal demonstrates that people representing the population of interest and other relevant stakeholders are engaged in ways that are appropriate and necessary in a given research context. It addresses the questions:

- Are patients and other stakeholders engaged in:
    - Formulating research questions
    - Defining essential characteristics of study participants, comparators, and outcomes
    - Identifying and selecting outcomes that the population of interest notices and cares about (e.g., survival, function, symptoms, health-related quality of life) and that inform decision making relevant to the research topic
    - Monitoring study conduct and progress
    - Designing/suggesting plans for dissemination and implementation activities
- Are the roles and the decision making authority of all research partners clearly stated?

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

In-Person Review

After preliminary review is completed, panel scores and critiques are evaluated by PCORI program staff to identify a subset of applications to be discussed at the in-person review meeting. Not all submitted applications move forward to in-person review, but all applications are evaluated and scored based on PCORI's Merit Review criteria, which include evaluation of adherence to PCORI's Methodology Standards.

During the in-person review, panels meet to discuss applications and further clarify the merits of the proposed research along with identifying areas for improvement. Additionally, each application is re-scored based on the content of discussion. The in-person panel meeting is led by a Chair and a PCORI Merit Review Officer, who ensure that all applications receive a fair and thorough review informed by the standards outlined in the PFA.

Post-Panel Review

Following the in-person panel review, meritorious applications are reviewed by PCORI program staff, who review merit review scores and comments, identify duplication or synergy among funded projects, and consider the fit of applications within the programmatic vision. Program staff then recommend projects to a Selection Committee that includes members of PCORI's Board of Governors. 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 proposed to PCORI's Board of Governors for its consideration and approval.

Funding Recommendations

Factoring in the total available funds allotted for this announcement, high scoring applications that fit the programmatic needs and satisfactorily address reviewers' critiques and adhere to PCORI's Methodology Standards will be considered for funding by the PCORI Board of Governors. Applicants will receive notification of the funding status of their application no later than April/May 2015.