



Patient-Centered Outcomes Research Institute

Funding Announcement:

Communication and Dissemination

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Opportunity Snapshot

Michelle considers herself to be an intelligent and well-informed person, but figuring out options for her health can be a challenge. She is 48 years old and generally healthy, but she is noticing changes associated with menopause. Some of her friends tell her they are thrilled they are taking hormone replacement therapy (HRT), while others completely avoid medications and want to use natural remedies. She has gone online and seen stories in the news about HRT and heart disease and cancer, but the bottom line is not clear for her—especially when considering family risk because her parents had cancer and heart disease, and her aunt had a hip fracture. When she asks her doctors, they also give differing opinions. Michelle is concerned that if she cannot find a reliable and trustworthy source of information for a basic health decision like this, where can she go for information on more serious decisions if she or her family members become seriously ill?

Purpose

Every day, patients and their caregivers are faced with crucial health care decisions while lacking key information that they need. The needed information does not deliver verdicts or tell people what to do, but informs them of the trade-offs associated with the options they have—and helps them make better decisions for themselves in collaboration with their clinicians—based on the facts, perhaps even personalized for them, and their own values, preferences, and goals.

We at the Patient-Centered Outcomes Research Institute (PCORI) are entrusted by the public to fund research that will matter to patients and their caregivers, and we now turn to you to help us. We have designed five national priorities and a research agenda for the projects we will fund that is focused on producing knowledge that is useful to patients, their caregivers, and clinicians. This knowledge is also expected to be useful to health system leaders, payers, and regulators who make decisions that impact patients. We have not specified the questions or the conditions. We believe that the important gaps in knowledge are pervasive and that, rather than dictate which conditions and questions are more important than others, we have chosen to seek wisdom from around the country in the form of applications for funding in the five priority areas. We also have identified some areas, such as rare conditions, and the needs of patients with multiple chronic conditions that are often neglected to be sure they are covered among our funded projects.

In this PCORI Funding Announcement (PFA), we seek 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. This knowledge will provide insight about how to communicate and disseminate evidence on the comparative benefits and harms of available options.

We are seeking to change how research is done by emphasizing the role of strong research teams that include varying perspectives. PCORI seeks to distinguish itself by supporting research in which patients, caregivers, and practicing clinicians are actively engaged in generating the research questions, conducting

the research, and using the results of that research to truly understand and address patient needs. In the end, PCORI will be held accountable for whether this model succeeds in producing knowledge that patients need and use. We hope that you—patients, caregivers, clinicians, health plans, product manufacturers, policy makers, and researchers from around the country—will join us in producing an unprecedented portfolio of truly patient-centered outcomes research that will transform the ability of patients, their caregivers, and clinicians to seek, find, and use practical information in the decision making process.

Funds Available

We anticipate that approximately 14 contracts totaling up to \$12 million in total costs may be funded under this PFA in this funding cycle, assuming receipt of a sufficient number of high quality applications. PCORI anticipates additional funding cycles related to this announcement. However, funds available may vary, and PCORI reserves the right to modify or terminate this announcement at any time.

Budget and Project Periods

Direct project costs are limited to a maximum of \$500,000 per year.

Organizational Eligibility

Applications may be submitted by:

- Any private sector research organization, including any:
 - Non-profit organization
 - For-profit organization
- Any public sector research organization, including any:
 - University or college
 - Hospital or healthcare system
 - Laboratory
 - Unit of state or local government

All US applicant organizations must be recognized by the Internal Revenue Service. Foreign organizations and nondomestic components of organizations based in the United States 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. Individuals may not apply.

In addition, investigators may serve as Principal Investigator (PI) on only one application for any individual PFA per cycle. An individual who is a PI may, however, participate in other applications (from the same or other organizations) in a different role, such as co-investigator or consultant.

Table of Contents

Opportunity Snapshot.....	2
Purpose	2
Funds Available	3
Budget and Project Periods.....	3
Organizational Eligibility.....	3
Step 1: Review the Program Detail	6
Overview	6
Research Areas of Interest	6
Background	7
Clinician Engagement With CER.....	7
Translating Research, Decision Support Interventions, and Risk Communication	7
Distribution of CER	8
Definition of Patient-Centered Outcomes Research	8
Example Questions.....	9
Deadlines and Submission	10
Funding and Project Period Limits	10
Step 2: Consider the Components.....	10
Organizational Eligibility.....	10
Characteristics of PCORI-Funded Research.....	11
Relevance to Patients.....	13
Patient and Stakeholder Involvement	13
Dissemination and Implementation Assessment.....	14
Reproducibility and Transparency of Research.....	14
Inclusiveness of Different Populations.....	14
Protection of Human Subjects	14
Step 3: Develop Your Application	15
Step 4: Know the Review Criteria	15
Step 5: Submit Your Application	15
PCORI Review Criteria	16
About PCORI.....	17

Communication and Dissemination

If you are interested in applying for an award under this program, follow PCORI's five-step process.



- ✓ **Review the Program Detail:** Get familiar with the program announcement and PCORI's areas of interest. Look at the example questions.
- ✓ **Consider the Components:** Consider the applicant eligibility requirements and PCORI's specific requirements to see if your organization, your interests, and your project fit within this program.
- ✓ **Develop Your Application:** Design the project. Determine and document who will be involved, the research strategy, and the budget needs. To see the Application Guidelines, go to <http://www.pcori.org/assets/PFAGuidelines.pdf>.
- ✓ **Know the Review Criteria:** Understand the PCORI merit-review assessment criteria. The criteria are provided at the end of this document.
- ✓ **Submit Your Application:** Compile and submit your application. To see the Application Guidelines go to <http://www.pcori.org/assets/PFAGuidelines.pdf>. You can register for the online system and submit a Letter of Intent (LOI) beginning September 17, 2012. . A link to the online system will be available on the PCORI Funding Announcements (PFAs) Web page at <http://www.pcori.org/funding-opportunities/funding-announcements/>.



Step 1: Review the Program Detail Overview

We seek studies that evaluate and compare new and alternative approaches to the communication, dissemination, and uptake of patient-centered research to patients, their caregivers, and clinicians. Studies must address a critical gap in knowledge, and the potential of the research to benefit patients and their caregivers must be clear and important.

Research Areas of Interest

We are interested in the following broad topical areas:

- Research that compares alternative communication, dissemination, health literacy and/or implementation strategies that aim to improve patients' health outcomes, by increasing patient, caregiver, and/or provider awareness of health care options in clinical or community-based settings.
- Research that compares the effectiveness of alternative approaches, across a range of patient-centered outcomes, to increase or encourage effective patient, caregiver, or clinician participation in care decisions and in shared decision making.
- Studies to develop and compare alternative methods and tools to elicit and include patient-desired outcomes in the health care decision making process.
- Studies comparing alternative approaches, including use of public health strategies or social media, for providing new information to patients, caregivers, or clinicians, with attention to differences in effectiveness in different populations.
- Research that compares innovative approaches in the use of existing electronic clinical data and other electronic modalities from the healthcare system or from a network of systems to enhance clinical decision making by patients and providers.

In order to explain clinical effectiveness, they are going to have to communicate it in a sensible fashion that the normal person could read.

—Patient with arthritis

Being more informed will be better than what I am now, being more educated, more informed, and having more information to go in and talk to the doctor about it. To sound more intelligent so that the doctor is aware that, "Hey, this guy has done his research, he knows a little bit more about what's out there." So any extra information we can have access to will benefit our situations.

—Parent of pediatric patient

That's the same thing going on with when you start mammograms, when you do cervical cancer screenings. Everything, things that we learned when we graduated, there were these guidelines. Now everything is changing. Patients come in and they're questioning what you're doing. "According to what I read, I don't need a pap smear anymore."

—Primary care physician

Strategies may focus on patient populations with a single condition or involve patients with a range of conditions. Strategies addressing care for patients with rare conditions are of 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. The term *low prevalence* is defined as meaning conditions that affect fewer than 200,000 individuals in the United States or have a prevalence of less than 1 in 1,500 persons.

Background

Because many patients and caregivers are not aware that they may have more than one viable option for prevention, diagnosis, or treatment decisions, the value of comparative clinical effectiveness research (CER) may not be immediately recognized. However, strategies can be developed to increase patient and clinician awareness of the uncertainty associated with specific health care interventions, with the goal of increasing knowledge about, and the use of, 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 prefers an active role in clinical decision making, the reasons some do not want to participate are not 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 health care providers are an important issue for the effective use of CER results. Research on doctor-patient communication has focused primarily on the doctor-patient dyad, but still little is known about the potential role of the patient's family members or significant others in shaping the decision making process.

Clinician Engagement With CER

Changes in practice on the part of providers in response to CER has 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' 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 health care resources are engaging, if at all, with CER findings.

Translating Research, Decision Support Interventions, and Risk Communication

Translating existing scientific research into accessible and useable formats that clearly outline the risks and benefits of preventive, diagnostic, and treatment options for patients, caregivers, and health care providers is another important area of research in both clinical and community-based settings. In clinical care, decision support intervention is one of the primary ways in which medical evidence is translated into a format that is usable by patients, families, and caregivers. 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 research is needed about how decision support interventions perform using different media, what level of information and detail they require, and how they perform in patient populations with lower levels of literacy and numeracy. A further 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 health care 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 health care providers, with the goals of sustained changes in clinical practice *and* effective distribution of results to patients in order to enable changes in behavior (for example, adherence and self-care). Research is also needed to identify trusted intermediaries and trusted 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 distributing 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.

Definition of Patient-Centered Outcomes Research

PCORI has defined patient-centered outcomes research, posted the definition for public comment, and incorporated these comments into the revised definition. Applications for research projects to PCORI must align with this definition, which is provided here and available at www.pcori.org/what-we-do/pcor/.

Patient-centered outcomes research (PCOR) helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as:

1. “Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”
2. “What are my options and what are the potential benefits and harms of those options?”
3. “What can I do to improve the outcomes that are most important to me?”
4. “How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?”

To answer these questions, PCOR:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes 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, function, 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
- Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, availability of services, technology, and personnel, and other stakeholder perspectives

Example Questions

The following research questions are meant as examples of the types of questions that your research may help answer. The list is by no means exhaustive.

- 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?
- How do methods for distributing comparative effectiveness research findings to patients, caregivers, or health care 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?
- How, and how effectively, can strategies using social media be deployed to distribute CER to patients and/or their caregivers and to their clinicians?
- How do patient outcomes compare when patient preferences around screening, diagnosis, treatment, and management strategies have been elicited and accounted for in the decision making process?
- How do strategies compare in their ability to effectively engage patients with lower levels of literacy and/or numeracy in clinical decision making?
- How do strategies for training health care providers in imparting information about risk to patients and their caregivers compare in their ability to improve patient outcomes?
- How do interventions to promote shared decision making compare in their ability to influence patients’ health behaviors and self-care (eg, adherence to medication) or patients’ behavior in the clinical encounter?

Deadlines and Submission

This is a standing announcement, with three application deadlines per year. For this round, applicants must submit a Letter of Intent to PCORI no later than 5:00 PM EST on the due date shown in the Key Dates table (<http://www.pcori.org/funding-opportunities/funding-announcements/apply/>) via PCORI's online system. Full applications must be submitted to PCORI no later than 5:00 PM EST on the due date shown in the Key Dates table via the PCORI online system.

Funding and Project Period Limits

We expect to fund approximately 14 projects totaling up to \$12 million in total costs under this PFA. Because the nature and scope of the proposed research is expected to vary widely from application to application, it is anticipated that the size and duration of each award will also vary.

Projects may not exceed three years in duration. Budgets may not exceed \$500,000 in direct costs per year. It is expected that, within these limitations, project budgets and duration will vary substantially, depending on the study design, needs for recruitment and/or primary data collection, required length of follow-up, and analytic complexity. To that end, PCORI will reserve a portion of funding for smaller (less than \$500,000 in total costs) and intermediate sized projects (less than \$1 million in total costs). PCORI encourages studies that can deliver findings promptly, including studies that take advantage of research infrastructure already in place and of longitudinal studies already underway. Currently funded CER studies may be considered for PCORI funding to support distinctive work related to extending follow-up, adding additional outcomes, or examining outcomes in key patient subgroups. Efficient use of research resources is a criterion that will be considered by merit reviewers and will also be reviewed by PCORI staff. The total amount awarded and the number of awards will depend on the quality, duration, and costs of the applications received.

Applicants wishing to propose prospective randomized trials or other complex studies that they believe will require more funding or longer duration may contact PCORI before the required deadline for the Letter of Intent to request permission to increase the budget beyond \$500,000 in direct costs in any project year or to extend the study duration beyond three years. PCORI does not guarantee that permission will be granted, and applicants should expect that the deliberative process may result in delaying the submission for one or more cycles.



Step 2: Consider the Components

Now that you understand the research focus and priorities, you will need to determine if your organization and approach meet PCORI's other eligibility requirements. To do that, please consider the following important issues.

Organizational Eligibility

Applications may be submitted by:

- Any private sector research organization, including any:



- Non-profit organization
- For-profit organization
- Any public sector research organization, including any:
 - University or college
 - Hospital or healthcare system
 - Laboratory
 - Unit of state or local government

All US applicant organizations must be recognized by the Internal Revenue Service. Foreign organizations and nondomestic components of organizations based in the United States 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. Individuals may not apply. Foreign organizations should consult the PCORI Application Guidelines because there is an extra step for such organizations to register within the PCORI online system.

In addition, investigators may serve as Principal Investigator (PI) on only one application for any individual PFA per cycle. An individual who is a PI may, however, participate in other applications (from the same or other organizations) in a different role, such as co-investigator or consultant.

Characteristics of PCORI-Funded Research

Successful applicants for PCORI funds must:

1. Have a research team that includes patients and/or caregivers, as well as clinicians, health system managers, or other potential end-users of the study findings, along with researchers—each contributing the expertise that they have and participating actively in the design and implementation of the study and the dissemination of its results. A key concept here is ensuring that the research remains true to the interests of those who would use it.
2. Be familiar with the four questions of our patient-centered outcomes research definition, which can also be found at <http://www.pcori.org/what-we-do/pcor/>:
 - a. “Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?”
 - b. “What are my options, and what are the potential benefits and harms of those options?”
 - c. “What can I do to improve the outcomes that are most important to me?”
 - d. “How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?”

These questions articulate the needs of people as they make health care decisions. Applicants must clearly explain how their proposed research aligns with one or more of these questions.

3. Demonstrate that the proposed research question and project has the potential to provide truly important information that patients need to make decisions but that is not currently available.

Think about what kind of or support patients, clinicians, or health systems may need to effect changes that will bring us closer to the elimination of disparities—or about interventions that may make it feasible to adopt this information widely. What information would make the biggest difference to those who seek this change?

4. Propose to use PCORI resources efficiently in producing new knowledge. We aim to stretch our resources as far as possible because we recognize the vast information needs of patients. Research budgets will be used as one component to evaluate the use of resources, as detailed in Review Criterion #8 (see PCORI Review Criteria on pages 17-18). We are looking for approaches that are highly efficient without sacrificing methodological rigor. We are also interested in the potential for findings to be applied in multiple areas, independent of the disease studied.
5. Make clear how you are accounting for individual differences among patients and patient groups. Average results are useful, but we are also very interested in providing evidence that can be tailored to patient subgroups and individuals based on their clinical and demographic characteristics. We want products of the research that are scalable and generalizable—and can be customized for sites. We recognize that there are challenges in seeking evidence at these levels, but we hope that many applications will seek to provide insights about how individual patients may make use of the products of the research.

PCORI is interested in research that can be rapidly disseminated and implemented into clinical and community settings, yielding prompt improvements in patients' decisions and the outcomes experienced. To that end, projects of shorter duration and projects that take advantage of existing research infrastructure and data are of great interest. Applications must include a dissemination and implementation assessment that discusses prospects for dissemination and considers possible barriers as well. For projects that produce important findings deserving dissemination, PCORI will consider subsequent applications that evaluate additional dissemination and implementation efforts.

A variety of study designs and analytic methods may contribute valid new knowledge. These include evidence syntheses, randomized comparisons at either the individual or cluster level, or various observational approaches (eg, quasi-experimental studies). Qualitative methods may also be employed, either in mixed methods approaches or, potentially, as qualitative comparative studies. Evidence syntheses should follow rigorous standards accepted in the field, such as those published by the Agency for Healthcare Research and Quality (AHRQ) or the Institute of Medicine (IOM). Issues of possible heterogeneity of treatment effects must be considered and discussed. Any planned analyses of subpopulations should be discussed. Inclusion of previously understudied population groups, including the elderly, children (if appropriate), and vulnerable populations, is particularly important. Randomized evaluations must be generalizable either by virtue of considering entire populations or by efficiently recruiting highly representative study populations rather than selected volunteers. Observational comparisons must employ study designs and analytic methods that convincingly protect against selection bias and other threats to validity. Applicants should specifically discuss the need to measure factors such as differential adherence to chosen treatments that could create apparent differences in effectiveness in clinical populations. Regardless of the particular methods employed, proposals are expected to use rigorous

methodology. Applicants are encouraged to refer to the contents of the PCORI draft Methodology Report, which is posted at <http://pcori.org/assets/MethodologyReport-Comment.pdf>, in developing their research plan. However, since the draft report will not have been finalized with feedback from public comment before the December 17th 2012 application deadline, applications for this funding cycle are not required to adhere to the Report's standards. Adherence to the finalized Methodology standards will be required in future funding cycles.

Comparisons must be to relevant alternatives—such as other interventions or clinical policies designed to address the same need in the same or a different healthcare system, to the previous approach used within the same system, or to “usual care.” The research will ideally provide information about the range of outcomes that are experienced by and important to patients. These outcomes may include quality of life, ability to participate in desired activities, degree of suffering from pain or other symptoms, ability to live independently, and satisfaction with health care.

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 (e.g. the elderly; children, if appropriate; patients with multiple chronic conditions; patients with rare conditions) and other vulnerable populations, including those of low socioeconomic status: low literacy and/or numeracy; and patient groups known to experience disparities in health care and outcomes, such as racial/ethnic minorities. Alternatively, the study may focus primarily on comparative strategies for communicating, disseminating, or implementing in one or more of these populations of interest.

Please note that your application will be organized by and scored against the eight PCORI review criteria found at the end of this document.

Relevance to Patients

Research proposals should clearly identify the relevant patient population, the health decision(s) examined in the proposed study, and the patient outcomes that will be affected by the research, as outlined in PCORI Review Criterion #4. As patient-centered research, the focus should be on the identification of the primary concerns and questions of patients and their caregivers.

Details of the required plan for patient and stakeholder engagement are described in the Application Guidelines (<http://www.pcori.org/assets/PFAguidelines.pdf>).

Patient and Stakeholder Involvement

Persons representative of the population of interest, referred to here as patients, their caregivers, and clinicians, should be engaged in all phases of the research process, as outlined in PCORI Review Criterion #7: Research Team and Environment. Patients may include individuals who have or had the condition or who are at risk of the condition under study; it may also include patient surrogates or caregivers. In some instances, representatives of patient advocacy organizations may be appropriate research collaborators. Clinicians who face these decisions in collaboration with their patients are also relevant team members. Engagement should include participation in formulation of research questions; defining essential

characteristics of study participants, comparators, and outcomes; monitoring of study conduct and progress; and dissemination of research results. In essence, patients and stakeholders must be important contributors throughout the research enterprise.

A key goal of patient engagement in research is to present information that best supports health decisions through generation of evidence relevant to patients, their caregivers, and clinicians. Patients and other key stakeholders should be meaningfully involved in the research team. The specific members of the team will vary from study to study.

Details of the required plan for patient and stakeholder engagement are in the Application Guidelines (<http://www.pcori.org/assets/PFAguidelines.pdf>).

Dissemination and Implementation Assessment

PCORI is interested in funding studies that produce findings that can be readily disseminated and implemented—and are highly likely to be valued by patients and caregivers. To that end, it is important that potential facilitators and barriers to dissemination and incorporation into practice be assessed and anticipated. Applicants must provide a dissemination and implementation assessment as described in the PCORI Application Guidelines (<http://www.pcori.org/assets/PFAguidelines.pdf>).

Reproducibility and Transparency of Research

The ability to replicate potentially important findings from PCORI-funded studies in other datasets and populations is essential to building confidence in the accuracy of these findings. To that end, we will support policies to promote sharing of study documentation (e.g. study protocol, programming code, data definitions) so that other researchers may replicate the findings in other populations. For large studies—those with direct costs greater than \$500,000 in any year—we will also require that applicants propose a plan for sharing of de-identified data, so that results may be reproduced by others in the same dataset. Whether data sharing is ultimately requested will depend on study findings and the availability of funds to support the process. Details of both requirements are in the Application Guidelines (<http://www.pcori.org/assets/PFAguidelines.pdf>).

Inclusiveness of Different Populations

PCORI seeks to fund research that includes diverse populations with respect to age, gender, race, ethnicity, geography, or clinical status. PCORI recognizes that some proposed studies may represent important PCOR opportunities even in the absence of a broadly diverse population. However, the burden is on the applicant in such cases to justify the importance of the study given the absence of diversity. 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.

Protection of Human Subjects

PCORI adopts, by reference, the Human Subjects requirements of 45 CFR Part 46.

3

Step 3: Develop Your Application

There are three main parts of designing your project: (1) defining your research question and research strategy, including the study population and analytic approach; (2) describing the people who will comprise your research team and the institutions, organizations, and locations that will be involved; and (3) determining the budget. To better understand each of these steps and to find and complete the application forms, please see the PCORI Application Guidelines (<http://www.pcori.org/assets/PFAguidelines.pdf>).

4

Step 4: Know the Review Criteria

It is PCORI's goal to make its funding decisions in a way that best supports our mission of improving patient-centered outcomes and in the most fair and transparent way possible. Below is an overview of PCORI's review and decision making process.

The PCORI review process includes four stages:

- Completeness, Compliance, and Eligibility Check
- Merit Review
- PCORI Deliberations
- Business Review

You should carefully read and thoroughly understand the PCORI review criteria, at the end of this document, before applying.

5

Step 5: Submit Your Application

To apply with PCORI, you must register with PCORI's online system and submit both a timely Letter of Intent and a timely application. To learn more about the application process, go to the Application Guidelines at <http://www.pcori.org/assets/PFAguidelines.pdf>.

PCORI Review Criteria

PCORI Criteria	Brief Description
RESEARCH STRATEGY: Background and Significance	
1. Impact of the condition on the health of individuals and populations	Refers to the current impact of the condition on the health of individuals and populations. 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? A particular emphasis is on patients with chronic conditions, including those patients with multiple chronic conditions.
2. Innovation and potential for improvement	Refers to the potential that the proposed research may lead to meaningful improvement in patient health, well-being, or quality of care. 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 change practice? Does the research question address a critical gap in current knowledge as noted in systematic reviews, guidelines 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? Do preliminary studies indicate potential for a sizeable benefit of the intervention relative to current practice? How likely is it that positive findings could be disseminated quickly to effect changes in current practice?
3. Impact on health care performance	Refers to the potential that the proposed research could lead to improvements in the efficiency of care for individual patients or for a population of patients. Does the research promise potential improvements in convenience or elimination of wasted resources, while maintaining or improving patient outcomes?
RESEARCH STRATEGY: Relevance to Patients	
4. Patient-centeredness	Is the proposed research focused on questions and outcomes of specific 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? Is the absence of any particularly important outcomes discussed?
RESEARCH STRATEGY: Approach	
5. Rigorous research methods	Refers to the use of appropriate and rigorous research methods to generate patient-centered evidence, including appropriate choice of study design and of analytic methods. How likely is it that the proposed study population, study design, and available sample size will yield unbiased, generalizable information with sufficient precision to be useful and reliable for patients, their caregivers, and clinicians
RESEARCH STRATEGY: Inclusiveness of Different Populations	
6. Inclusiveness of different populations	Does the proposed study include a diverse population with respect to age, gender, race, ethnicity, geography, or clinical status? Alternatively, does it include a previously understudied population for whom effectiveness information is particularly needed?



	Does the study have other characteristics that will provide insight into a more personalized approach to decision making based on a patient’s unique biological, clinical, or sociodemographic characteristics.
PEOPLE AND PLACES	
7. Research Team and Environment	The research team must be appropriately trained and experienced to carry out the planned studies. Does the study team have complementary and integrated research expertise in implementing the study? Are relevant patients and other key users of the study information (eg, caregivers, clinicians, health system, community, or policy makers) appropriately included on the team? Will the research environment contribute to the probability of success? Are features of the research environment, such as health system or community involvement or collaborative arrangements, described? Are institutional and community investment in the success of the research described?
BUDGET	
8. Efficient use of research resources	Does the budget appear to be reasonable in relation to the potential contribution of the research? Does the justification address the efficiency with which PCORI resources would be used? Are there opportunities to make the study more efficient? Are there additional benefits to a PCORI investment in this study through the creation of common data or infrastructure that could support future research?

About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed health care decisions and improve health care delivery. PCORI will commission research that is guided by patients, caregivers, and the broader health care community and will produce high integrity, evidence-based information.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI will use a variety of forums and public comment periods to obtain public input throughout its work.

Our Mission: PCORI helps people make informed health care decisions and improves health care delivery and outcomes by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader health care community.

Our History: PCORI was created by the Patient Protection and Affordable Care Act of 2010 as a non-profit, 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."

The statutory language defining PCORI is broad and authorizes research that will support a strong patient-centered orientation, inform better choices among alternative treatment and prevention strategies, and direct attention to individual and system differences that may influence strategies and outcomes. PCORI was designed to produce knowledge through the analysis and synthesis of existing research or the support of new research.