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Introduction
The Patient-Centered Outcomes Research Institute (PCORI) was created to conduct research to provide information about the best available evidence to help patients and their health care providers make more informed decisions. PCORI’s research is intended to give patients a better understanding of the prevention, treatment, and care options available and the science that supports those options.

PCORI awards contracts using funding announcements released at standard times throughout the year (July, November, and March). In addition, PCORI will release ad hoc, targeted funding announcements with various deadlines throughout the year. For updated funding announcements, visit our Funding Opportunities web page at www.pcori.org/funding-opportunities.

This document provides applicants with guidelines for letters of intent (LOIs) and application creation and submission. Detailed below are instructions for the content requirements of your LOI, your research plan (as part of your application), and information for use of the PCORI online system. For questions regarding any of the information contained in the document below or for help with your LOI or application, please contact us at www.pcori.org/funding-opportunities/contact/.

PCORI’s Online System
To apply for a PCORI research project, you must first register using our online system. To do so, please go to http://egstage.altum.com/Easygrants_Web_PCORI/. You will be required to enter the following information:

- Name
- Telephone number
- Mailing address
- Password
- Security answer

Note that your e-mail address will serve as your login name.

Application Instructions
If you are interested in applying for an award under a PCORI Funding Announcement (PFA), follow PCORI’s five-step process, described below:
• **Inform PCORI with the letter of intent:** Let PCORI know that you intend to apply by submitting a required letter of intent (LOI) by the deadline listed in the funding announcement to which you are responding.

• **Design the research plan:** State the specific aims of the project, the research question(s) to be studied, and how you will answer that question. Explain how the research plan aligns with PCORI review criteria. Describe the project’s study design, study population, and analytic strategy. Applicants are encouraged to refer to the contents of the PCORI draft Methodology Report posted at [www.pcori.org/methodology](http://www.pcori.org/methodology) in developing their analytic plan. Because the final version of this report will not be complete before the July 31, 2012 application deadline, the Report’s standards are not a required element, nor will they be used in the evaluation of, applications for this funding cycle. Describe plans for dissemination and implementation, as well as for supporting replication and data sharing.

• **Document the people and places:** Determine and document who will be on the research team, what their roles will be, and where the research will be conducted. Describe plans for engaging patients and other relevant stakeholders in the research project.

• **Develop the budget:** Determine, list, and justify the costs associated with the project.

• **Submit the application:** Compile and submit your application using the PCORI online system: [http://egstage.altum.com/Easygrants_Web_PCORI/](http://egstage.altum.com/Easygrants_Web_PCORI/)

**Step 1: Letter of Intent**

To be eligible to apply for PCORI funding, you must first submit a letter of intent (LOI). Submission of this letter through the PCORI online system is required before submitting a full application. No additional approval from PCORI is required to apply, unless your application is for more than $500,000 of direct costs in any given year—see section 5.1 of this document. Below is the format and process for submitting the LOI. If you do not submit a letter of intent by the deadline indicated in the funding announcement, you will not be able to submit your full application.

For each funding cycle, you must submit a new LOI to apply for the latest PFA. LOIs will be deleted from the system if you do not submit an application.

After you have registered on the PCORI online system, you will be allowed to proceed to complete an LOI. After you log in, you will land on the PCORI online page with the “Apply for funding” link. Clicking on the
“Apply for funding” link will show all PFAs currently open. You will then click on the PFA that you would like to apply for to start the submission of your LOI.

The left links allow you to navigate to all pages that you will need to complete, as described below:

1.1 LOI Format and Online Process
When completing your LOI in the PCORI online system, you will be asked to enter the following information: (All fields are required.)

- Principal Investigator (PI) Information
- Project Information
- Personnel
- Subject and Focus Area
  a. PI Information. This section allows applicants to update the information entered at registration. In addition, it requires you to add or select the following information about your organization:
    i. Name of Organization
    ii. Employer Identification Number (EIN) or Tax ID number—foreign institutions may enter Not Applicable (N/A). All US and Canadian organizations must enter an EIN.
    iii. Data Universal Numbering System (DUNS), which assigns a unique number to a business entity. If your organization does not have a DUNS number, you can get a free DUNS number at [www.dnb.com](http://www.dnb.com) under the D&B D-U-N-S Number tab.
    iv. City
    v. State
    vi. Country
    vii. Type of Organization
  b. Project Information. The following project-related information must be input:
    i. Project Title (Limit 100 Characters)
    ii. Project Start Date
    iii. Project End Date
    iv. Projected Requested Total (Direct + Indirect) Cost
    v. Technical Abstract
  c. Subject and Focus Areas. You will be required to complete the following questions:
    i. What diseases or conditions does your proposal address? Please select up to three.
ii. Does your proposal include a vulnerable and/or underserved population? Please select up to three.

iii. What specific area of the PCORI priorities does your application address? See PCORI’s National Priorities for Research (www.pcori.org/priorities) for a list of priorities. Please select from list.

iv. What study design does your research use? Please select from list.

v. Does your application include specific analytic methods? Please select from list.

NOTE: You cannot upload documents to the online LOI system. You will be required to fill in fields in the online system to provide the information described above. You may prepare this information in a word or text document, and then paste it into the LOI registration system.

Step 2: The Research Plan

The Research Plan consists of the following nine required sections, as described in the Sections table. Begin each section of the Research Plan with a section header (e.g., Research Strategy, References Cited) and follow the same order and page limits as shown in the table. Reviewers will consider all parts of your application to ensure a full understanding of your strategy and overall proposal, but it is important to understand that your application will be scored against the eight PCORI review criteria found at the end of this document, six of which apply to material contained in the Research Plan (the remaining two PCORI review criteria concern the People and Places - more information found in Step 3).

Below are the required sections of the research plan. Where applicable, maximum page limits are listed in the table for each section; a description of expected content for each section follows.

<table>
<thead>
<tr>
<th>Sections</th>
<th>Document</th>
<th>Submission Method</th>
<th>Limit</th>
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<td>1.</td>
<td>Research Plan: Specific Aims</td>
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<td>2.</td>
<td>Research Plan: Research Strategy</td>
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<td>3.</td>
<td>Research Plan: Replication and Reproducibility of Research and Data Sharing Plan</td>
<td>Upload</td>
<td>2 pages</td>
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<tr>
<td>4.</td>
<td>Research Plan: Dissemination and Implementation Assessment</td>
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<td>Research Plan: References Cited</td>
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<td>6.</td>
<td>Research Plan: Protection of Human Subjects</td>
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### 2.1 Research Plan: Section 1. Specific Aims (1 page)
In this section, concisely state the goals of the proposed research. Describe the research questions (hypotheses), the study design, the comparisons to be evaluated, the outcomes that will be studied, and the anticipated impact of study results on clinical or patient-decision making and on patient outcomes.

### 2.2 Research Plan: Section 2. Research Strategy (15 pages)
Organize the Research Strategy in the order shown below and use the instructions provided. Start each section with the appropriate section heading. Number your citations and insert them using superscript; provide the full reference in a numbered list in the References Cited section. Components of the Research Strategy are aligned with the first six PCORI review; the remaining two PCORI review criteria concern the People and Places (more information found in Step 3) and the Budget (more information found in Step 4). The required subsections of the Research Strategy section are:

- Part A: Background and Significance (Criteria 1–3)
- Part B: Relevance to Patients (Criterion 4)
- Part C: Approach (Criterion 5)
- Part D: Inclusiveness of Different Populations (Criterion 6)

Research Strategy subsections A to D are described in detail below, including the relationship of each to PCORI review criteria.

The term clinician, as used in this document, should be understood in a broad sense as referring to physicians, nurses, pharmacists, counselors, and other providers of care and support services.

#### 2.2.1 Part A. Background and Significance
The subsections in Part A correspond to PCORI Criteria 1–3. Each of these criteria will be evaluated and scored separately during the peer review process.
2.2.1.1 Impact of the Condition on the Health of Individuals and Populations
(See PCORI Review Criterion 1)

Discuss the burden of the disease(s), condition, or research area under consideration. Diseases/conditions with significant burden in the US population are of particular interest. Burden can be defined by the frequency of the disease/condition; the expected mortality and burden of suffering from symptoms; complications or other consequences of the disease/condition; the costs to the US population in terms of health care services use; the cost to individual patients in terms of out-of-pocket expenses, along with costs such as time away from paid or unpaid occupations. Emphasis is placed on patients with chronic conditions, including patients with multiple chronic conditions, but prevention and treatment of common acute events that may have long-term consequences (eg, trauma) are also relevant. Studies that address cross-cutting questions relevant to patients with different diseases/conditions are also of interest.

2.2.1.2 Innovation and Potential for Improvement Through Research
(See PCORI Review Criterion 2)

Describe why the proposed research should be expected to influence current practice and lead to meaningful improvement in patient health, well-being, or quality of care. Research involving a novel intervention, or one that employs an innovative approach in its analytic methods, study population, or research team composition, may be more likely to have an impact than study approaches that have been tried before. Research that addresses a recognized gap in knowledge may also be more likely to be noticed and, if appropriate, implemented. Evidence that patients, caregivers, clinicians, or other stakeholders have previously expressed a need for this information is highly relevant, as is a description of the frequency with which the decision under study is faced by patients. Applicants may also reference previously published priorities for comparative effectiveness research, such as those of the Institute of Medicine (IOM) or the Agency for Healthcare Research and Quality's (AHRQ) Future Research Needs projects, to demonstrate why their proposed topic is a priority and can improve patient outcomes. They should also provide a description of other research, either recently published or in progress, that is responsive to the same question.

Applicants should also discuss how likely it is that study findings may improve patient health, well-being, or quality of care and how quickly the results of their research can be disseminated to effect changes in current practice. Applicants should include a discussion of the impact of both a positive and a negative finding. Reference should be made to previous research findings and to current practice patterns as a basis for expectations of the impact of the information to be gained, in terms of the size of a clinical benefit and the prospects for prompt dissemination and adoption of findings into practice. (See also the requirement for a Dissemination and Implementation Plan below). Findings that can be leveraged across disease states, including, but not limited to, evidence on processes of care (eg, adherence, behavior change, etc.), are of particular interest. Finally, applicants are expected to demonstrate how the findings of their research could help patients, caregivers, and clinicians make health-related decisions or help other stakeholders (eg, patient-advocacy groups, community groups, researchers, health-related associations, organizational providers, payers, purchasers, policy makers, regulators, etc.) make decisions that will impact patient-centered outcomes.
2.2.1.3 Impact on Health Care Performance
(See PCORI Review Criterion 3)

This refers to the impact of the proposed research on the efficiency of patient care, for the individual patient or for patient populations. For example, the findings may improve the evidence base, allowing better outcomes for a given investment of time, personnel, or other resources; a new intervention may reduce time or resource requirements or reduce wasteful or ineffective care. Such improvements may, in turn, improve the overall quality and experience of care or reduce the need for specific subsequent services.

2.2.2 Part B. Relevance to Patients
(See PCORI Review Criterion 4)

Patient-centeredness refers to the ways in which the proposed research is focused on questions and outcomes of specific interest to patients and their caregivers; this is distinct from patient engagement. Patient-centeredness is a perspective on health that is derived from and directly relevant to the patient’s experience of illness and of care. Applicants should discuss how the research relates to one or more of the key questions mentioned in PCORI’s definition of patient-centered outcomes research (www.pcori.org/what-we-do/pcor/). Outcomes studied should have relevance for patients.

The engagement of patients and stakeholders in the design and conduct of research is a key strategy for ensuring that the research question and the conduct of the research remain patient-centered. A plan for engaging patients and other key stakeholders is required (see description in Step 3 below).

2.2.3 Part C. Approach
(See PCORI Review Criterion 5)

2.2.3.1 Rigorous Research Methods
This 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 that minimize risks of bias and enhance the potential for causal inferences from the analyses.

Applicants are encouraged to refer to the contents of the PCORI draft Methodology Report posted at www.pcori.org/methodology in developing their analytic plan. Because the final version of this report will not be complete before the July 31, 2012 application deadline, the Report’s standards are not a required element, nor will they be used in the evaluation of, applications for this funding cycle. Further recommendations concerning aspects of study design, analytic methods, reports, and dissemination are provided below.

2.2.3.2 Study Design
- **Research question:** PCORI will fund comparative studies with a focus on outcomes that are experienced by and important to patients. The application’s research question should be clearly stated and should compare two (or more) relevant alternatives faced by patients, their caregivers, or clinicians; healthcare systems; or policymakers. (See PCORI draft Methodology Report.) Applicants should explain why the proposed comparison is relevant to patients.
- **Choice of comparators:** The rationale for the choice of comparators must be explicitly justified (see PCORI draft Methodology Report). Comparator treatment(s), interventions, strategies, or policies must be chosen to enable accurate evaluation of effectiveness or safety compared to other viable options for similar patients. Researchers should focus on clearly describing how the chosen comparator(s) defines the causal question, reduces the potential for biases, and allows direct comparisons between two or more choices faced by patients. The potential that differential adherence between the comparators could bias outcomes comparisons should be addressed in all studies, regardless of study design.

- **Choice of study design:** The choice of study design should be clearly justified and shown to be appropriate for the research question at hand. Study designs may include randomized trials, observational outcomes studies, or evidence synthesis studies. Qualitative research and mixed methods research are acceptable, as long as they are used to address a comparative question. If an observational design is proposed, considerations related to avoidance of selection bias and other threats to internal validity are of particular concern; if a randomized approach is chosen, applicants must discuss steps taken to ensure broad participation, efficient recruitment, and resulting applicability of study findings to broad patient populations; if an evidence synthesis study is proposed, rigorous systematic review methods should be used, following accepted standards in the field (e.g., AHRQ or IOM standards), and the choice of analytic methods for quantitative synthesis (e.g., traditional meta-analysis, network meta-analysis) should be justified. Consideration should be given to a discussion of potential heterogeneity or lack of consistency among included studies. (See PCORI draft Methodology Report).

- **Choice of outcomes:** Outcomes must be defined clearly, especially for complex conditions or for outcomes that may not have well-established clinical criteria. Applicants should provide information that supports the selection of outcomes as meeting the criteria of “clinically meaningful,” “patient-centered,” and “relevant to decision-makers” (see PCORI draft Methodology Report). Such information could be derived from published literature, surveys, or input collected at stakeholder meetings. Investigators should strive to include a broad range of outcomes, including traditional clinical measures and patient-reported measures, such as functional status, symptoms, quality of life, and satisfaction with care. Measures of health care use during or following treatments under study are also desirable. These include hospitalizations, specialty visits, and diagnostic and laboratory testing. Measures of lost productivity or time away from work (paid or unpaid) may be important patient-centered variables in some instances.

Applicants should address the validity and completeness of each proposed outcome in the available or proposed study dataset (see PCORI draft Methodology Report). Attention should be given to available evidence of validity in the specific populations under study.

Studies that propose to describe or compare costs of care, or to conduct empirical or simulated cost-effectiveness analyses, are not being solicited and will be returned as nonresponsive. One aspect of costs that may be important and is allowable is the measurement and analysis of out-of-pocket costs faced by patients. Out-of-pocket costs may influence treatment choices and subsequent adherence to therapy. Therefore, they may confound observational studies of treatment or mediate effectiveness differences in either observational or randomized studies. Measurement of any factors that may differentially affect
patients’ adherence to the alternatives should be discussed and measured (see PCORI draft Methodology Report). If measurement is not feasible, the implications for the validity and meaning of study inferences should be carefully discussed.

Other relevant outcomes may be specific to selected funding announcements. For example, measures of quality of care may be appropriate for studies of health systems interventions. Details may be found in the appropriate funding announcement.

2.2.3.3 Analytic Methods

- General: You may reference PCORI’s draft Methodology Report <www.pcori.org/methodology>. Because the final version of this report will not be complete before the July 31, 2012 application deadline, reference to the Report’s standards are not a required element, nor will they be used in the evaluation of, applications for this funding cycle.

- Avoidance of bias: Applications must address the strengths and limitations of selected study population, study designs, and analytic methods in assessing and controlling for research bias. (See PCORI draft Methodology Report) <www.pcori.org/methodology>

- Study population: Applicants should carefully describe the proposed study population in terms of its representativeness of broader populations. For observational studies, including registry studies, applicants should give special attention to reasons for variation in treatment assignment among patients, including the possibility of patient differences (selection bias) and the role of practice variation or differences in referral patterns as predictors of treatment choices. (See PCORI draft Methodology Report)

- Sample size: Studies should be able to demonstrate sufficient sample size to support rigorous comparisons of at least two comparator populations. Information on expected sample size within key subpopulations should also be provided, with a description of the precision expected for effectiveness estimates in those subpopulations (see PCORI draft Methodology Report). For evidence syntheses studies, an estimate of the number of studies likely to be included in the systematic review should be provided.

2.2.3.4 Part D. Inclusiveness of Different Populations

(See PCORI Review Criterion 6)

This refers to the inclusion of diverse study 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, it may be valuable to focus a study on a population that has been previously understudied and for whom novel effectiveness information is needed, such as “hard-to-reach” populations or patients with multiple conditions.

This section should describe how representative the study population is of the full population of interest (the population facing the health decision being studied). If the population of interest includes people who are difficult to identify, recruit, and/or retain in research studies (ie, “hard-to-reach” patients), then study
plans to address possible barriers, including language, education, social class, ethnicity, race, culture, geography, physical or cognitive impairments, and other differences should be addressed. A lack of trust (including prejudice and fear of potential legal or social consequences of engaging with researchers) may add to these barriers.

This section should also address plans to examine between-group and/or individual differences and the potential for enabling a more personalized approach to decision-making based on an individual’s unique biological, clinical, or sociodemographic characteristics. Applicants should provide sample size calculations to describe the power available to evaluate possible differences in effectiveness in different groups in the study, or the precision available for estimating effectiveness in a specific previously understudied population.

Please also refer to the Patient and Stakeholder Engagement Plan below in Step 3.

2.2.4 Replication and Reproducibility of Research and Data Sharing Plan (2 pages)

PCORI intends to support practical policies that promote transparency, replication, and reproducibility in research. These policies will be developed and will evolve over time in collaboration with PCORI’s Methodology Committee and in consultation with the research community. At this time, we wish to alert applicants that the following policies are expected to apply. We will update the research community via PCORI’s website as these policies are modified:

1. Replication of research findings: This requirement applies to all applicants, regardless of the size of the project. It refers to supporting efforts by other researchers to replicate study findings in other patient populations and datasets.

Applicants must describe a replication plan that accommodates the following:

- Provision of a complete, final study protocol, describing the study population; primary and secondary hypotheses to be tested; sources and methods of measuring exposures, outcomes, and all covariates used in analyses, including data definitions, coding instructions, discussion guides for qualitative research, and the analysis plan. The protocol will usually be expected to be delivered along with the first 12-month progress report, and always within three months of the end of the funding period. PCORI will reserve the right to share these materials with appropriate researchers, in consultation with the principal investigator of the study.

- Proposed clinical trials or observational outcomes studies must be registered at www.clinicaltrials.gov.

- Proposed evidence synthesis studies must be registered at http://www.crd.york.ac.uk/prospero/.

- Descriptions of study datasets, including code books, meta-data related to the datasets, and documented programming code used for creating the final study population, for creating variables, and for conducting all outcomes analyses. These must be provided within three months of the end of the final funding year.

2. Reproduction of research findings: This requirement for a data sharing plan applies only to studies that are requesting funding at a level greater than $500,000 in direct costs in any project year. It refers to
supporting the reproduction of research findings in the same dataset by another researcher(s) not affiliated with the applicant’s research team. The ability to reproduce important findings from the original data is critical to establishing trust in PCORI findings. PCORI will therefore require a data sharing plan (described below) for all larger studies as described above. However, subsequent data sharing will be requested by PCORI only after review of findings and a decision that the findings warrant the expense and time of data sharing.

The data sharing plan must:

- State that a complete, cleaned, de-identified copy of the final dataset used in conducting the final analyses will be made available within nine months of the end of the final year of funding.
- Propose a method by which investigators will make this dataset available if requested.
- Propose a budget that would cover costs of data sharing if requested.

NOTE: Depending on the nature, uses, and potential impact of the study findings, PCORI will consider whether incremental funding will be made available to assist investigators in complying with data sharing requests (http://pcori.devcloud.acquia-sites.com/). PCORI will consider requests for exemption from the replication and/or reproducibility requirements in cases where a data source (e.g., a hospital, healthcare system, or health plan) has legitimate proprietary concerns that cannot be addressed by investigators or where the nature of the data elements make it impossible to adequately de-identify patient-specific information. However, the waiver request will be reviewed by PCORI, and granting of the waiver is not guaranteed.

2.2.5 Dissemination and Implementation Assessment (2 pages)

PCORI is interested in funding studies with a high likelihood that results will be disseminated and incorporated into practice, if study findings warrant. To that end, it is important that key stakeholders are engaged early and throughout the research process, and that potential facilitators and barriers to dissemination and incorporation into practice are assessed and anticipated. The dissemination assessment should include:

- **Identification of key stakeholders:** Identify the stakeholders—including patients; nonprofessional caregivers; clinicians (e.g., physicians, nurses, pharmacists, counselors, and other providers of care and support services); patient-advocacy groups; community groups, researchers, health-related associations, policy makers, and institutions, including organizational providers, purchasers, payers, and industry for whom the results of the research will be relevant.

- **Description of engagement frequency:** Describe the points in the research process at which key stakeholders will be engaged. Ideally, key stakeholder representatives will be engaged from the early planning stages and throughout the study.

- **Description of engagement type:** Describe how you will engage stakeholders at each identified point during the study and at its conclusion, including sharing and discussion of study results when appropriate.
• **Governance plan:** Describe how you will develop a governance plan for the project that articulates specific roles and responsibilities for the research team and stakeholder groups and defines rules for decision making and conflict resolution.

• **Resource sharing:** Describe how you will allocate and share resources (including salary, consulting fees, supplies, travel, or equipment) for patients and other stakeholders.

• **Barriers assessment:** Assess the potential facilitators and barriers to dissemination and implementation of study results and their incorporation into practice, including how steps your study has taken to engaging stakeholders will promote and facilitate dissemination.

NOTE: Research budgets should not include funds for subsequent dissemination of findings. Decisions on the appropriateness of dissemination will depend on the findings. PCORI may subsequently entertain proposals to fund dissemination activities for projects with compelling findings.

**2.3 Research Plan: Section 3. References Cited**

Provide a list of references cited in the Research Plan. Each reference must include names of all authors (in the same sequence in which they appear in the publication); the article title; and journal or book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied on in preparing any section of the application.

Citations that are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference. *The references should be limited to relevant and current literature.* While there is not a page limitation for the references cited, it is important to be concise and to select only those literature references pertinent to the proposed research.

When referencing a website, the reference should be displayed in the standard URL format (ie, http://www.pcori.org), along with the date that the link was last accessed.

**2.4 Research Plan: Section 4. Protection of Human Subjects**

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, as found on the National Institutes of Health (NIH) website: www.grants.nih.gov/grants/funding/phs398/phs398.doc.

**2.5 Research Plan: Section 5. Consortium/Contractual Arrangements**

Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and any consortium/contractor organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the recipient.

When the authorized official for your applicant organization approves the application and it is submitted to PCORI, it signifies that the applicant and all proposed consortium participants understand and agree that the appropriate programmatic and administrative personnel of each organization involved in the PCORI
application are aware of the applicant organization’s consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

2.6 Research Plan: Section 6. Project Plan and Timeline
Provide a project plan with accompanying timeline for completion of the research project within the project duration being requested. There is no required format for this plan, but a timeline or Gantt chart is appropriate. Be sure to include all required components. Those required components include a list of major activities, milestones, and deliverables (including interim deliverables) and estimated dates for each. There is no need to include PCORI required dates, such as those for semiannual progress reports or financial reports. However, the project plan must include at least one deliverable or interim deliverable to be submitted to PCORI during each 12-month period of the project. This plan will be used to determine if progress is being appropriately made and will also be used to discuss the schedule of payments.

2.7 Research Plan: Section 7. Letters of Support
Provide all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators, such as principal investigators, investigators, stakeholder associations, and other significant contributors included in the contract application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. For consultants, letters should include rate/charge for consulting services.

2.8 Research Plan: Section 8. Technical Abstract (500 words)
After writing your research plan, the final step is to summarize the application in a structured abstract of 500 words or less. This technical abstract should be written so that it can be separated from the application and the project still fully understood. Review the information previously entered at the LOI phase (see Step 1, above). Please note that this summary can be used to determine programmatic fit. It must include:

- **The PI Name**
- **Background:** State the problem or question the research is designed to address.
- **Objectives:** Briefly describe the specific aims of the study, including specific research question(s) and the long-term objectives.
- **Methods:** Give a concise description of the study population, sample size, and analytic methods that will be employed.

2.9 Research Plan: Section 9. Brief Abstract (500 words)
PCORI also requires an abstract written in lay terms. This public abstract should be written so that it can be separated from the application and the project still fully understood. The abstract will be published on the PCORI website. It must include the same basic information as in the scientific abstract but in straightforward, simple language intended for nonscientific readers. This public abstract may not exceed 500 words. This abstract can be prepared in advance and either entered or pasted directly into the online system.
2.10 Research Plan: Section 10. Appendix
PCORI applications may include an appendix for additional materials the investigators think might be useful (eg, survey instruments, papers and publications from members of the research team); however, reviewers will not be required to include the appendices in the review and assessment of the project.

Step 3: The People and Places
To fully evaluate your proposal, PCORI will need to know the qualifications of the people who will be involved, the places where the research will be carried out, and the resources you can bring to the project (See PCORI Review Criterion 7). To do so, you may use the templates found on the PCORI online system or create your own similar formats.

The documents and information required in this step include:

<table>
<thead>
<tr>
<th>Required Information</th>
<th>Document</th>
<th>Submission Method</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of Personnel: Principal investigators, investigators, and other significant contributors</td>
<td>Entered into system</td>
<td>As needed</td>
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<tr>
<td>Professional Profiles/ Bio-sketches</td>
<td>Upload</td>
<td>4 pages each</td>
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<tr>
<td>Environment</td>
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<td>Patient and Stakeholder Engagement Plan</td>
<td>Upload</td>
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<tr>
<td>Project/Performance Site(s)</td>
<td>Upload</td>
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<td></td>
</tr>
<tr>
<td>Resources</td>
<td>Upload</td>
<td>As needed</td>
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</tr>
</tbody>
</table>

3.1 People
PCORI will need to know about the people who will be involved in the research. Our goal is to ensure that we fund projects with qualified researchers, as well as with partners representing patient and stakeholder perspectives.

3.1.1 Research Team Experience and Capabilities
Are the investigators appropriately trained and well-suited to carry out the planned studies? Is the work proposed appropriate to the experience level of the principal investigator? If the investigator does not have PCOR experience, are there appropriate collaborative arrangements with experts in PCOR? Does the study team have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project? Is there a high level of confidence that the PI and rest of the study team will be able to achieve the study aims as described?
Reference the submissions related to List of Personnel and Professional Profiles as required in Step 3: People and Places, as needed.

3.1.2 Requirements
Before getting started, there are three things for you to know and consider:

1. **Principal investigator**: PCORI requires that you designate one PI who will be our primary contact. That individual’s institution must be the primary institution for the award. For purposes other than acting as PCORI’s main contact, an application may include multiple PIs.

2. **Maximum awards per PI**: Investigators may serve as PI on only one application for any individual PCORI PFA. 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.

3. **Patient and stakeholder engagement**: The purpose of PCORI is to promote improved patient-centered outcomes. As a result, it is a strongly held value of PCORI that patient and stakeholder involvement is a critical factor for successful research in this field. You must include a plan for how the research team will engage and include relevant patients and other key stakeholders. Applications will be scored on how meaningfully patients and stakeholders are engaged. Stakeholders are appropriate partners, investigators, consultants, and key personnel. Examples of stakeholders include patients; nonprofessional caregivers; clinicians (e.g., physicians, nurses, pharmacists, counselors, and other providers of care and support services); patient-advocacy groups; community groups; researchers; health-related associations; policymakers; and institutions, including organizational providers, purchasers, payers, and industry for whom the results of the research will be relevant.

3.1.3 Required Documents
PCORI requires four documents related to the people on your project: (1) List of Personnel, (2) Professional Profiles, (3) Environment, and (4) Patient and Stakeholder Engagement Plan.

3.1.3.1 List of Personnel
PCORI requires a list of principal and co-investigators, as well as other significant contributors. This list must include the names, organizational affiliation, titles, and role for each person.

3.1.3.2 Professional Profiles
PCORI requires a professional profile for each person listed as a principal investigator, co-investigator, or other significant contributor (limit four pages each). If you have an existing profile or bio-sketch, you may use it, but, at a minimum, the professional profile must include the person’s name, title, and degrees, if any, along with the following information, where relevant:

- **Personal statement**: Briefly describe why your experience and qualifications make you particularly well-suited for your role in the proposed project. The limit is 250 words.

- **Education and training**: List all postsecondary education and training, including institution, degree conferred (if any), and year. Include internships, residencies, and fellowships and give beginning and end dates for each.
• **Employment and positions held:** List all professional positions held since completion of education.

• **Honors:** List any honors. Include present membership or leadership in relevant organizations or advisory groups.

• **Selected peer-reviewed publications:** We ask that you limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15 of those most relevant to the research being proposed.

• **Other selected publications:** This can include op-ed pieces, newsletters, blogs, and non-peer-reviewed reports. Please list no more than 10 of those most relevant to the research being proposed.

• **Public speaking or presentations:** This can include testimony, scientific talks, or presentations. Please limit to presentations given in the last two years.

• **Research support:** List both selected ongoing and completed research projects for the past three years. Begin with the projects that are most relevant to the research proposed in the PCORI application. Briefly indicate the person’s overall goals of the projects and responsibilities.

• **Other:** Please include any additional relevant information to help us assess the qualifications of the key personnel for the project. PCORI recognizes that not all sections of the Professional Profile may apply to a patient or stakeholder participant. If that is the case for you, include all sections that seem relevant and be certain to include the personal statement.

You may use an NIH bio-sketch as your professional profile to list the qualifications of the key personnel or create one using the PCORI template. To do so, you may use the templates found on the PCORI online system or create your own similar formats. If you create your own, you must use at least half-inch margins and 11-point or larger Arial or similar font. (See the Document Formatting Requirements section below.)

**3.1.3.3 Environment**

Does the scientific environment in which the work will be performed contribute to the probability of success? Do the experiments proposed take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

Reference the submissions related to Project and Performance Sites and Resources as required in Step 3: People and Places, as needed.

**3.1.3.4 Patient and Stakeholder Engagement Plan**

A key goal of patient engagement in research is to present information that best supports health decisions through generation of evidence relevant to patients. Patients should be meaningfully involved in the research plan. The specific features of the engagement plan will vary by team.

Research proposals must include a plan that clearly identifies the relevant patient population, as well as other key stakeholders who will be end-users of the research. Representatives of the patient population of interest, referred to here as patient partners, should be engaged in all phases of the research process. Patient partners may include individuals who have or have had the condition or who are at risk of the
condition under study; it may include patient surrogates or caregivers as well. It does not necessarily mean, but does not exclude, patient advocates or patient navigators. Engagement should encompass formulation of research questions; defining essential characteristics of study participants, comparators, and outcomes; monitoring of study conduct and progress; and dissemination of research results.

Applicants should rigorously formulate and describe methods of patient engagement in a research engagement plan. The engagement plan should describe how patient partners are identified, recruited, and retained; how patient partners are involved in developing the study design and monitoring the conduct of the study; and how patient partners are involved in dissemination of the research results.

PCOR principles of trust, transparency, co-learning, respect, and partnership should guide formulation of the research engagement plan. [See www.pcori.org/definitions][link to document providing definitions and research background for these concepts.]

The research engagement plan should describe how the research participants are representative of the spectrum of the population facing the health decision of interest. The engagement plan should reference the plan for selecting, recruiting, and retaining appropriate study participants, with reference to minimizing selection bias and with reference to the ways in which the engagement plan relates to generalizability of study results.

If the population of interest includes people who may be more difficult to identify, recruit, and/or retain than other study populations (sometimes referred to as “hard-to-reach”), then the plans to address population-unique issues should be included as part of the engagement plan. Here “hard-to-reach” is used as a general term for individuals or communities who are historically underrepresented in health care research and/or less likely to be involved in research because of differences or barriers that impede communication or collaboration with researchers. These barriers include language, education, social class, ethnicity, race, culture, geography, physical or cognitive impairments, and other differences. A lack of trust (including prejudice and fear of potential legal or social consequences of engaging with researchers) may add to these barriers.

In addition, if the population of interest includes people who are not “hard-to-reach” but are traditionally not well represented in health care research (eg, people with multiple chronic conditions), plans to include this group and a detailed description of their characteristics should also be included.

3.2 Places
PCORI must understand where the proposed research will be conducted and the characteristics of those locations that will benefit the project.

3.2.1 Required Documents
To document the locations and value of performance sites, PCORI requires two documents, as described below:
3.2.1.1 Project and Performance Sites
First, provide a list of the places where the work described in the Research Plan will be conducted. This list must include the organizational name, full physical address, city, county, state, ZIP code, and Congressional district. Be sure to list the primary research site first, then follow with the others as needed.

3.2.1.2 Resources
Second, provide a description of the facilities, including their capacities, capabilities, relative proximity, and extent of availability to the project. Describe how the research environment contributes to the probability of success (e.g., institutional support, physical resources, and patient engagement). Discuss ways in which the proposed study will benefit from unique features of the research environment or community involvement or will employ useful collaborative arrangements. Finally, describe institutional and community investment in the success of the research, such as the availability of organized peer groups; logistical support, such as administrative management and oversight, and best practices training; financial support, such as protected time for research with salary support; and access to and support of patient groups.

Step 4: The Budget
(See PCORI Review Criterion 8)

In this section, you will find PCORI’s budget-related rules and instructions for completing the budget information for your application.

4.1 Budget Policies
Acceptable uses of PCORI contract funds include salaries and fringe benefits for study investigators and other project staff, consultant fees, costs associated with collection and analysis of data (including costs associated with obtaining relevant datasets), investigator meetings (both in person and via teleconference), supplies, travel that is clearly project-related, and other direct research expenses. Specific information about allowable costs can be found in the PCORI Contract Policies. (www.pcori.org/policies)

- PCORI cap for salary will be $200,000 plus fringe benefits.
- Indirect costs are calculated as 40% of direct costs. Indirect costs for subcontracts may not exceed $25,000.
- PCORI is willing to consider projects with higher costs and/or longer durations than the limits set out within a PFA. However, potential applicants must seek and receive permission to do so from PCORI. In making decisions, PCORI will consider how strongly the proposal aligns with PCORI funding priorities and whether or not the project could be accomplished more efficiently or quickly. There is no guarantee that permission will be granted, and permission must be received prior to submission of an application. As a result, related discussions may require delays in submission. To submit a request to PCORI for consideration of a project with higher costs and/or of longer duration than what is specified in the funding announcement, please go to www.pcori.org/funding-opportunities/contact/.
4.2 Required Documents

Your application must include three documents related to your budget, as follows:

1. A budget summary for the full-proposed project period (entered in the PCORI online system).
2. Budget detail for the first year of the project (upload into PCORI online system).
3. A justification that supports the first year budget (see number 2, above) and a justification summary that supports the budget summary (see number 1, above).

You will find a template for your use in designing your budget, along with a template for the budget justification, on the PCORI online system.

4.2.1 Budget Summary

Provide the total amount requested for each year of the proposed project period for each of the following categories:

- Personnel (salary and fringe benefits)
- Consultant costs
- Equipment
- Supplies
- Travel
- Other expenses
- Consortium/Contractual direct costs
- Indirect costs

4.2.2 Budget Detail (First Year)

This document includes additional detail for each of the budget categories above for the project. At a minimum, this information must include:

- Personnel (salary and fringe benefits): Name, role on project, percentage of time to be spent on the project, institutional base salary, amount of salary requested, amount of fringe benefits requested, and total per person. Finally, the personnel costs must be totaled. In addition to providing personnel costs for scientific staff, you must also include costs for providing salary, consulting fees, or stipends to patient and stakeholder participants.
- Consultant costs: Provide the total costs for this category.
- Equipment: The item of equipment and the cost for each item. Total all equipment costs as well.
- Supplies: The type of category of supplies needed and the cost for each. Total all supply costs as well.
- Travel: A brief description of travel and the total costs requested.
- Other expenses: The total costs needed for other expenses not accounted for in other categories.
- **Consortium/Contractual**: List only the direct costs only associated with consortia or contractor costs.
- **Indirect costs**: The total amount of indirect costs for the applicant agency, the total for all consortia or contractors combined, and the total of both. See the Budget Policies above for the appropriate indirect cost calculation.

### 4.2.3 Budget Justifications

Provide a narrative that fully supports and explains the basis for the information in the Budget Detail (First Year). For example, provide the names, fees, and other costs associated with consultants; the destinations and number of people traveling; and the need for equipment and supplies. Also provide a breakdown of costs proposed for each consortia or contractor.

Additionally, the budget justification must specify any other sources of funding that are anticipated to support the proposed research project, including sources, amounts, and the time period for the other financial support.

Finally, provide a budget justification summary for the Budget Summary information (see section 4.2.1).

---

**Step 5: Submit the Application**

All required information must be submitted online via the PCORI online system. Failure to submit all required application documents online; failure to submit a budget, professional profiles, or any other component of the application by the deadline; or failure to adhere to the guidelines below may result in removal of the application from the review process (administrative triage). See Section 5.2, below, for details regarding creating and submitting an online application.

### 5.1 Administrative Requirements

#### 5.1.1 Document Format Requirements

For any uploaded document, you must use at least half-inch margins and an 11-point or larger Arial or similar font for the main body of the text. Figures and captions may have smaller type. Consecutively number the pages of each section and include the name of the contact PI in the page header. All attachments must be in PDF format. Also refer to the specific instructions for each document type, as described in the documentation above.

#### 5.1.2 Administrative Triage

Applications may be eliminated from the review process for administrative reasons (Administrative Triage). An application may be administratively triaged if it does not meet the criteria outlined in this document, if it is incomplete, or if it otherwise does not meet PCORI requirements.

#### 5.1.3 Budgets of $500,000 or More (Direct Costs)

If your application includes a budget of $500,000 or more (of Direct Costs) during any year of the project, you must request permission from PCORI before submitting your application. PCORI will administratively...
triage (see above) any applications that include a budget of $500,000 or more (of Direct Costs) during any year of the project period if the applicant did not seek prior permission from PCORI prior to submitting his/her application. You must make this request no later than July 1, 2012, to be able to submit your application on time. Permission requests should be made here: www.pcori.org/funding-opportunities/contact/.

5.1.4 Resubmissions
A PI or organization may resubmit an unfunded application under a specific PFA only once in 12 months from the time of the original submission.

5.2 Online Process

5.2.1 Requirements
Completing and submitting your application includes two parts. The first includes entering the basic information required by the online system, and the second involves the written forms and narratives that form the body of the application and that must be uploaded into the system, as indicated below.

5.2.2 Beginning Your Application
For login and password information, see the PCORI online system section, above. Note that you must complete an LOI prior to completion of an application; see Step 1, above. The left links allow you to navigate to all pages that you will need to complete, as described below:

1. **PI Information:** Review (and edit, if necessary) the information about the primary PI (information carried over from LOI entry, see Step 1).
2. **Project Information:** Review (and edit, if necessary) basic information about the project (information carried over from LOI entry, see Step 1).
3. **Subject and Focus Area:** Review (and edit, if necessary) the subject and focus area information (carried over from LOI entry, see Step 1).
4. **Personnel:** Review (and edit, if necessary) the key personnel information, including name, role on project, and institution (information carried over from LOI entry, see Step 1). Add additional key personnel using the “Add” button, if necessary.
5. **Budget:** Complete budget information for each year of the proposed project, including Direct and Indirect costs. Enter detailed information about the first year budget.
6. **Upload/Attach Required Auxiliary Documents:** See section 5.2.3, below.

5.2.3 Upload Attachments
Each of the following are required documents that must be uploaded into the PCORI online system. For each document that you create, place page numbers in the bottom margin; use consecutive, whole numbers. All attachments must be in a PDF format. (Letters of support do not need to be sequentially numbered.) Refer to the [Document Format Requirements](#), above, for additional formatting information.

Research Plan Documentation:
1. **Research Strategy:** Upload the research strategy document. See section 2.2, above, for additional information.

2. **References Cited:** Upload references cited for the application. See section 2.3, above, for additional information.

3. **Protection of Human Subjects:** Upload documents relating to the protection of human subjects. See section 2.4, above, for additional information.

4. **Consortium/Contractual Agreements:** Upload consortium/contractual agreements, if necessary. See section 2.5, above, for additional requirements.

5. **Project Plan/Timeline:** Upload project plan/timeline documentation. See section 2.6, above, for additional requirements.

6. **Letters of Support:** Upload letters of support. See section 2.7, above, for additional information.

7. **Appendix:** Upload appendix materials, as needed. See section 2.10, above, for additional information.

People and Places Documentation:

8. **Professional Profiles (Biographical Sketches):** Upload the completed PCORI template or your own completed template. See section 3.1.3.2, above, for additional content requirements.

9. **Environment:** Upload the completed environment information. See section 3.1.3.3, above, for additional content requirements.

10. **Patient and Stakeholders Engagement Plan:** Upload the patient and stakeholders engagement plan. See section 3.1.3.4, above, for additional information.

11. **Project/Performance Sites:** Upload project/performance site information. See section 3.2.1.1, above, for additional information.

12. **Resources:** Upload the resources documentation. See section 3.2.1.2, above, for additional information.

Budget Documentation:

13. **Budget Justification for the First Year:** Upload the completed budget justification. See section 4.2.3, above, for additional budget justification requirements.

### 5.2.4 Application Checklist

Use the checklist below to guide your application process and to ensure that all documents are completed. Note that you will not be able to submit an application in the PCORI online system without all required documentation.

<table>
<thead>
<tr>
<th>Document</th>
<th>Submission Method</th>
<th>Limit</th>
<th>Completed?</th>
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</thead>
<tbody>
<tr>
<td>Letter of Intent (see Step 1) (must be completed prior to creation and submission of full application)</td>
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<tr>
<td>Research Plan (see Step 2)</td>
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# Application Checklist

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<td>2.</td>
<td>Research Strategy</td>
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<td>3.</td>
<td>Replication and Reproducibility of Research and Data Sharing Plan</td>
<td>Upload</td>
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<td>4.</td>
<td>Dissemination and Implementation Assessment</td>
<td>Upload</td>
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<td>5.</td>
<td>References Cited</td>
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<td>6.</td>
<td>Protection of Human Subjects</td>
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<td>7.</td>
<td>Consortium/Contractual Arrangements</td>
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<td>8.</td>
<td>Project Plan and Timeline</td>
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<td>9.</td>
<td>Letters of Support</td>
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<td>10.</td>
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<tr>
<td>11.</td>
<td>Public Abstract</td>
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<tr>
<td>12.</td>
<td>Appendix</td>
<td>Upload</td>
<td>As needed</td>
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## People and Places (see Step 3)

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<tr>
<th></th>
<th>Personnel: Principal investigators, investigators, and other significant contributors</th>
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<td>6.</td>
<td>Resources</td>
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## Budget (see Step 4)

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<tr>
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<tbody>
<tr>
<td></td>
<td>Budget Detail for the First Year</td>
<td>Entered in system</td>
<td>As needed</td>
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</table>
5.2.5 Authorization
After all required information has been completed including the authorization section:

1. Enter (or edit) supporting role information: enter contact information and indicate role for signing officials and other individuals with supporting roles.
2. Select Permission Level from the drop-down menu.

Authorized signers will then be prompted by the system to accept the terms and conditions of PCORI and to electronically sign.

5.2.6 Application Submission
After all required materials have been uploaded to the system, the applicant must click the Submit button to submit the application to PCORI.

5.3 Contact Information
Please contact us with any questions at www.pcori.org/funding-opportunities/contact/.
## PCORI Review Criteria

<table>
<thead>
<tr>
<th>PCORI Criteria</th>
<th>Brief Description</th>
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<tbody>
<tr>
<td><strong>RESEARCH STRATEGY: Background and Significance</strong></td>
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<tr>
<td>1. Impact of the condition on the health of individuals and populations</td>
<td>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.</td>
</tr>
<tr>
<td>2. Innovation and potential for improvement through research</td>
<td>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?</td>
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<tr>
<td>3. Impact on health care performance</td>
<td>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?</td>
</tr>
<tr>
<td><strong>RESEARCH STRATEGY: Relevance to Patients</strong></td>
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<tr>
<td>4. Relevance to Patients</td>
<td>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?</td>
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<tr>
<td><strong>RESEARCH STRATEGY: Approach</strong></td>
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<tr>
<td>5. Rigorous research methods</td>
<td>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? Reference to the PCORI Methodology Report posted at <a href="http://www.pcori.org/what-we-do/methodology/">www.pcori.org/what-we-do/methodology/</a> is encouraged.</td>
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<tr>
<td><strong>RESEARCH STRATEGY: Inclusiveness of Different Populations</strong></td>
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<tr>
<td>6. Inclusiveness of different populations</td>
<td>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.</td>
</tr>
<tr>
<td>7. Research team and environment</td>
<td>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 (e.g., 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?</td>
</tr>
</tbody>
</table>

| 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 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.”

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.