



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Patient-Centered Outcomes Research Institute

Application Guidelines

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PCORI Application Guidelines

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 healthcare 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.

As stated in the statute, PCORI awards contracts using funding announcements (PFAs) released at standard times throughout the year (July, November, and March). In addition, PCORI will release 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 application (including your research plan), and information on the use of the PCORI online system. For questions regarding any of the information contained in this document or for help with your LOI, application, or with the PCORI online system, please review our [Frequently Asked Questions](#) or contact us at pfa@pcori.org. Questions will be responded to within 2 business days.

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. Nondomestic components of organizations based in the United States and foreign organizations may apply, as long as there is demonstrable benefit to the US healthcare system and US efforts in the area of patient-centered research can be clearly shown. Individuals may not apply. Organizations may submit multiple applications for funding.

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.

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Roles and Responsibilities

Principal Investigator (PI)

The Principal Investigator (PI) is the individual responsible for the scientific or technical aspects and day-to-day management of the project. The PI is responsible and accountable to the recipient organization for the proper conduct of the project, including the submission of all required reports. PCORI requires that the applicant designate *one* Principal Investigator who will be the primary contact. This individual should be listed as the “investigator” in LOI and application materials. This individual’s institution must also be the primary institution for the award. For purposes other than acting as PCORI’s main contact, an application may include multiple PIs. However, any additional PIs should be listed in the application as “co-investigators.”

Administrative Official (AO)

The Administrative Official (AO) is designated by the recipient organization and is responsible for the proper administration of the project, including, but not limited to, overseeing submission of the contract activation, renewals, milestones, and additional materials required. The Administrative Official is the Signing Official and designated representative of the recipient organization in matters related to the award and administration of its contract(s). In signing a PCORI contract, this individual certifies that the recipient organization will comply with all applicable assurances and certifications referenced in the application. This individual’s signature further certifies that the applicant organization will be accountable both for the appropriate use of funds awarded and for the performance of the PCORI-supported project or activities resulting from the application. Note that the PI should not be the Signing Official.

Financial Official (FO)

The Financial Official (FO) is designated by the Recipient and is responsible for the proper accounting of contract funds and submission of invoices and payment details. In this role, the individual is required to complete and certify the required yearly expenditure reports.

Registering for PCORI’s Online System

To apply for a PCORI research project, you must first register using our online system. PCORI Online will be open 30 days prior to the submission deadline. The submission deadlines schedule can be found [here](#). You can register and apply [here](#) for all PCORI Funding Announcements (PFAs). You will be required to enter the following information upon registration:

- Name
- E-mail
- Password

- Security question and answer

Note that the e-mail address you use to register will serve as your login or username.

Administrative Considerations

In general, PCORI PFAs fund projects for three years, with budgets of less than \$500,000 (of Direct Costs) during any year of the project period. However, PCORI is willing to consider projects that exceed either the three-year project limit or the \$500,000 (of Direct Costs) budget cap, provided special permission is granted from PCORI, as described below. Other administrative considerations are also described below.

Budgets of \$500,000 or More (Direct Costs) or Contracts Exceeding Three Years

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. In addition, if the proposed project length exceeds three years, you must request permission before submitting your application. PCORI will administratively triage (see below) any application that includes a budget of \$500,000 or more (of Direct Costs) during any year of the project period or any application with a project period exceeding three years if the applicant did not seek permission from PCORI prior to submitting his/her application. You must make these requests at the time of LOI submission to be considered by PCORI for permission to submit during the cycle in question.

Permission requests must be made in the online LOI Application simultaneously when completing the LOI. You must also attach the following completed Excel template that includes your budget detail: <http://www.pcori.org/assets/PFA-Budget-Template.xls>. Include a clear explanation of why your budget exceeds the limit. You may be contacted for additional information.

PCORI will convene promptly to discuss all submitted requests. The decision-making process may require additional time or information, which may postpone the submission until a subsequent application cycle. Note that although both subcontractor direct and indirect costs are considered to be direct costs to the prime, subcontractor indirect costs are not included when determining if the budget exceeds the \$500,000 limit.

Document Format Requirements

PCORI provides required templates for the following: (a) Research Plan (sections 2-8), (b) People and Places, and (c) Budget. These templates should be completed following the formatting instructions in the templates themselves and in this document, and then uploaded in PCORI Online. Other documents must be created by the applicant and uploaded in PCORI Online. For any uploaded document (aside from letters of support), the following formatting must be used:

- *Header*: Each page should include the name of the PI in the page header's left corner.
- *Margins*: Half-inch margins or greater. The header may fall within these margins, but the body text should not begin closer than one half-inch from the edge of the page.

- *Font:* Please use size 11 Arial or Times New Roman font for the main body of the text. Figures and captions may have smaller type.
- *Page Numbering:* Consecutively number each document.
- *Spacing:* Use single spacing.
- **Document Format: All attachments must be in PDF format.**

Also refer to the specific instructions and page number limitations for each document type, as described in the documentation below and in the PCORI templates, when applicable.

LOI/Application Withdrawal

You may withdraw your LOI on [PCORI Online](#) prior to submission of your full application. Applications may be also be withdrawn on [PCORI Online](#); however, applications cannot be withdrawn online after the application deadline. To withdraw your application after the application deadline, contact us at pfa@pcori.org.

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.

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 administrative or formatting criteria outlined in this document, in the PCORI Templates, or on PCORI Online; if it is incomplete; or if it otherwise does not meet PCORI requirements.

Programmatic Triage

Applications may also be eliminated from the review process for programmatic reasons (Programmatic Triage). An application may be programmatically triaged if it is not responsive to the guidelines as described in the PCORI PFA, if it describes research that is non-comparative, or if it otherwise does not meet PCORI programmatic requirements.

In addition, as per [established legislation](#), PCORI is not allowed to fund research projects that include cost effective analysis.

Application Review

Each proposal is evaluated using the [eight PCORI Review Criteria](#) found at the end of this document. The PCORI merit review process is made up of patient, stakeholder, and scientific reviewers.

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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:



- **Step 1: 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.
- **Step 2: Design the research plan:** As part of your application, you must state the specific aims of the project, the research question(s) to be studied, and how you will answer that question. In addition, applicants must:
 - Explain how the research plan aligns with PCORI review criteria.
 - Describe plans for dissemination and implementation.
 - Describe plans for supporting replication and reproducibility of research and data sharing.

Applicants are encouraged to refer to the contents of the PCORI draft [Methodology Report](#) in developing their research plan. Because the draft report will not have been finalized with the benefit of public comment before the application deadline, adherence to the Report's standards will not be a required element of applications for this funding cycle. (Adherence to the finalized Methodology standards will be required in future funding cycles.)

- **Step 3: 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 as part of the research team in the research project.
- **Step 4: Develop the budget:** Determine, list, and justify the costs associated with the project.
- **Step 5: Submit the application:** Compile and submit your application using [PCORI Online](#).



Step 1: Letter of Intent (LOI)

To be eligible to apply for PCORI funding, you must first submit a letter of intent (LOI). Submission of this letter through PCORI Online is **required** before submitting a full application. Letters of Intent will not be scored. Consequently, no additional approval from PCORI is required prior to submitting a full application, unless your application is

for more than \$500,000 of direct costs in any given year or if your project exceeds three years (see [Administrative Considerations](#), above). **If you do not submit a letter of intent by the deadline indicated in the funding announcement, you will not be able to submit a full application.**

If you decide to not submit your application, you must withdraw your LOI no later than five business days prior to the application submission deadline. 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 PCORI Online, you will be allowed to proceed to complete an LOI. After you log in, click on the PCORI Online “Apply for Funding” button. This 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 links on the left side of the page 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 PCORI Online, you will be asked to enter the following information (all fields are required):

- Principal Investigator (PI) Information
- Project Information
- Key Personnel
- Additional Information (about the project)

A. PI Information. This section allows applicants to update the information entered at registration. **Only** if your organization is not currently in our system you must enter:

- 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 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. Are Direct Costs requested greater than \$500,000 during any year of the project? (Select yes or no.) If yes, a permission request must be completed and uploaded (see [Administrative Considerations](#)).
- iii. Is the Project Length greater than three years? (Select yes or no.) If yes, a permission request must be completed and uploaded (see [Administrative Considerations](#)).
- iv. Technical Abstract (3,000 character limit, including spaces). Summarize the project using the following required sections:
 - a. **Background:** State the problem or question the research is designed to address.
 - b. **Objectives:** Briefly describe the specific aims of the study, including specific research question(s) and the long-term objectives.
 - c. **Methods:** Give a concise description of the study population, sample size, and analytic methods that will be employed.
 - d. **Patient Outcomes (Projected):** Specify the study outcomes and state briefly why these are important to patients.

The Technical Abstract may be prepared in advance and either entered or pasted directly into PCORI Online. A template is provided for this purpose [here](#).

- C. Key Personnel. You will be required to complete the following information for key personnel on the project:
 - i. Name
 - ii. Title
 - iii. Organization
 - iv. Role (on project)
 - v. Contact information (address, phone number, and e-mail)
- D. Additional Information. You will be required to complete the following questions:
 - i. What diseases or conditions does your proposal address? (Choose all that apply.)
 - ii. Does your proposal focus on a vulnerable and/or underserved population? (Choose all that apply.)
 - iii. What specific research area of the PCORI priorities does your application address? (See PCORI's [National Priorities for Research](#) for a list of priorities.) (Select from list provided in the system.)
 - iv. What study design does your research utilize? (Select from list provided in the system.)

- v. Does your application include any of these specific analytic methods? (Select from list provided in the system.)
- vi. Are you interested in becoming a PCORI reviewer? (Select your answer in the system.)
- vii. How many years of research experience do you have after attaining your terminal degree? (Enter your answer in the system.)
- viii. How many years of research experience do you have related to this field of research? (Enter your answer in the system.)
- ix. Approximately how many grants/contracts have you had funded? (Enter your answer in the system.)
- x. Total dollar amount for largest grant/contract: (Enter your answer in the system.)
- xi. Have you received grants from: (Check all that apply.)

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.

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Step 2: The Research Plan

The Research Plan consists of the following **11 required sections and an optional appendix**, as described in the Sections table below. 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 is organized by and will be scored against the eight [PCORI Review Criteria](#) found at the end of this document. Six of these criteria apply to material contained in the Research Plan (the remaining two concern the [People and Places](#) and the [Budget](#); more information found in Steps 3 and 4). The PCORI Research Plan template, which includes sections 2-8, below, is required and can be found [here](#). Applicants are required to follow template instructions and formatting.

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.

| Sections | | |
|---|-------------------------|-------------------------------------|
| Document | Submission Method | Limit |
| 1. Research Plan: Specific Aims | Entered in PCORI Online | 3,000 characters (including spaces) |
| 2. Research Plan: Research Strategy | Upload | 15 pages |

| Sections | | | |
|---|-------------------|---|-------------------------------------|
| Document | Submission Method | Limit | |
| 3. Research Plan: Replication and Reproducibility of Research and Data Sharing Plan | | 2 pages | |
| 4. Research Plan: Dissemination and Implementation Assessment | | 2 pages | |
| 5. Research Plan: References Cited | | Not to exceed 10 pages | |
| 6. Research Plan: Protection of Human Subjects | | Not to exceed 5 pages | |
| 7. Research Plan: Consortium/Contractual Arrangements | | Not to exceed 5 pages | |
| 8. Research Plan: Project Plan and Timeline | | Not to exceed 5 pages | |
| 9. Research Plan: Appendix (Optional) | | As needed | |
| 10. Research Plan: Letters of Support | | As needed. May be combined into one PDF for upload. | |
| 11. Research Plan: Technical Abstract | | Entered in PCORI Online at LOI stage. Edit if applicable. | 3,000 characters (including spaces) |
| 12. Research Plan: Public Abstract | | Entered in PCORI Online. | 3,000 characters (including spaces) |
| <p><i>Note:</i> Your application will be Administratively Triaged if it does not meet the content <i>and</i> formatting requirements described in this document, in the PCORI Templates, and in PCORI Online.</p> | | | |

2.1 Research Plan: Specific Aims (3,000 characters, including spaces)

In this section, concisely state the goals of the proposed research. Describe the study design, the research questions (hypotheses), the comparisons to be evaluated and the outcomes that will be studied, and describe the anticipated impact of study results on clinical or patient decision making and on patient outcomes.

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2.2 Research Plan: Research Strategy (15 pages)

Organize the Research Strategy in the order shown below and use the instructions provided below and in the PCORI Research Plan [template](#). Number your citations and insert them using superscript; provide the full reference in a numbered list in the References Cited section ([Section 5 of the Research Plan](#)).

Components of the Research Strategy are aligned with the first six PCORI review criteria (found at the end of this document); 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 the [PCORI Review Criteria](#).

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. 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 of great interest, as are studies of rare, understudied conditions.

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. Preliminary studies or other published research that suggests a potentially important difference in outcomes should be mentioned. Research that addresses a recognized gap in knowledge may also be more likely to be noticed and, if appropriate, implemented. Thus, 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. 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 would help make the case that the proposed topic is a priority and could improve patient outcomes. Applicants 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 could 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. Furthermore, 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.

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](#) in developing their research plan. Because the draft report will not have been finalized with the benefit of public comment before the application deadline, adherence to the Report's standards will not be a required element of applications for this funding cycle. (Adherence to the finalized Methodology standards will be required in future funding cycles.)

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 options being compared must be explicitly justified (see PCORI draft [Methodology Report](#)). Interventions, comparator treatment(s), 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 intervention(s) or 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 interventions or 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 (eg, [AHRQ](#) or [IOM](#) standards), and the choice of analytic methods for quantitative synthesis (eg, 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. However, measurement of any factors that may differentially affect patients’ adherence to the alternatives should be discussed and measured (see PCORI draft [Methodology Report](#)). This includes direct measures of adherence and indirect measures including co-payment levels or other assessments of out-of-pocket costs. Such factors may influence treatment choices and subsequent adherence to therapy and, therefore, may confound observational studies of treatment or mediate effectiveness differences in either observational or randomized studies. 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:** Applicants are encouraged to refer to the contents of the PCORI draft [Methodology Report](#) in developing their research plan. Because the draft report will not have been finalized with the benefit of public comment before application deadline, adherence to the Report's standards will not be a required element of applications for this funding cycle. (Adherence to the finalized Methodology standards will be required in future funding cycles.)
- **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](#).)
- **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.

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2.2.4 Part D. Inclusion 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](#).

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2.3 Research Plan: 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 Web site 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. PCORI will consider requests for exemption from the replication and/or reproducibility requirements in cases where a data source (eg, 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.

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2.4 Research Plan: 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:

- **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 or honoraria, supplies, travel, or equipment) for patients and other stakeholders.

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.

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2.5 Research Plan: References Cited (not to exceed 10 pages)

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.* It is important to be concise and to select only those literature references pertinent to the proposed research so that the 10-page limit is not exceeded.

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

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2.6 Research Plan: Protection of Human Subjects (not to exceed 5 pages)

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) Web site:

www.grants.nih.gov/grants/funding/phs398/phs398.doc.

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2.7 Research Plan: Consortium/Contractual Arrangements (not to exceed 5 pages)

Use this section to further describe the research projects of the subcontracts and explain the strengths that the partners bring to the overall project.

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.

The following must be provided for all subcontracts:

1. Subcontract personnel should be treated as key personnel and should be included in the key personnel section of the application.
2. Budget information, including the first year detailed budget and the budget justification. (Note: you must utilize the PCORI Budget Template located [here](#)).

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2.8 Research Plan: Section 8. Project Plan and Timeline (not to exceed 5 pages)

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.

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2.9 Research Plan: Appendix

PCORI applications may include an appendix for additional materials the investigators think may 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.

2.10 Research Plan: 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. Note that Letters of Support must be combined into one PDF and uploaded in PCORI Online.

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2.11 Research Plan: Technical Abstract (3,000 characters)

After writing your research plan, the final step is to summarize the application in a structured abstract of 3,000 characters (including spaces) 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:

- **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.
- **Projected Patient Outcomes:** Specify the study outcomes and state briefly why these are important to patients.

The Technical Abstract may be prepared in advance and either entered or pasted directly into PCORI Online. A template is provided for this purpose [here](#).

2.12 Research Plan: Public Abstract (3,000 characters)

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 Web site. 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 3,000 characters (including spaces). This abstract can be prepared in advance and either entered or pasted directly into the online system.

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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](#)). Applicants are required to use the PCORI People and Places Template, found [here](#).

Below are the required sections to document the project's People and Places. Where applicable, maximum page limits are listed in the table for each section; a description of expected content for each section follows.

| Required Information | | |
|---|---------------------|------------------------|
| Document | Submission Method | Limit |
| List of Personnel: Principal investigators, investigators, and other significant contributors | Entered into system | As needed |
| Professional Profiles/Bio-sketches | Upload | 4 pages each |
| Patient and Stakeholder Engagement Plan | | 4 pages |
| Project/Performance Site(s) and Resources | | Not to exceed 15 pages |
| <i>Note: Your application will be Administratively Triaged if it does not meet the content and formatting requirements described in this document, in the PCORI Templates, and in PCORI Online.</i> | | |

3.1 People

PCORI must 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 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.

- 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 other 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 other stakeholders are engaged. Stakeholders are appropriate partners, investigators, consultants, and key personnel. Other examples of stakeholders include patients; nonprofessional caregivers; clinicians (eg, 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. One consideration in assessing the extent of engagement is the proposed plan for compensating these collaborators for their efforts. Compensation should reflect an expectation of meaningful participation.

3.1.3 Required Documents

PCORI requires three documents related to the people on your project: (1) List of Personnel, (2) Professional Profiles, and (3) Patient and Stakeholder Engagement Plan. Applicants are required to use the PCORI People and Places Template, found [here](#).

3.1.3.1 List of Personnel

PCORI requires a list of principal and co-investigators, as well as other significant contributors (entered into PCORI Online). This list must include the names, organizational affiliation and DUNS number (for scientific personnel only), titles, and role for each person.

3.1.3.2 Professional Profiles (4 pages each)

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 PCORI Online or you may 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 above.)

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3.1.3.3 Patient and Stakeholder Engagement Plan (4 pages)

A key goal of patient and stakeholder engagement in research is to present information that best supports health decisions through generation of evidence relevant to patients and other relevant stakeholders. As a result, PCORI requires that patients and stakeholders must be meaningfully involved in the research project. 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 and stakeholder engagement in a research engagement plan. The engagement plan should describe how patients and other relevant stakeholders are identified, recruited, retained, and compensated; how patients and stakeholders are

involved in developing the study design and monitoring the conduct of the study; and how patients and stakeholders 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.

The following elements should be addressed within this section:

- **Identification of key stakeholders:** Identify the stakeholders—including patients; nonprofessional caregivers; clinicians (eg, 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.
- **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.

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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 one document, as described below:

3.2.1.1 Project and Performance Sites and Resources (not to exceed 15 pages)

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, and then follow with the others as needed.

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 (eg, 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.

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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. Applicants are required to use the PCORI Budget Template, found [here](#).

4.1 General 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. Additional guidelines are described below.

4.2 Required Documents

Below are the required sections to document the project’s Budget. Where applicable, maximum page limits are listed in the table for each section; a description of expected content for each section follows.

| Required Information | | |
|---|-------------------|------------------------|
| Document | Submission Method | Limit |
| Budget Summary for Entire Proposed Project Period | Entered in system | As required |
| Budget Detail for the First Year | Upload | 1 page |
| Budget Justification Details for the First Year and Budget Justification Summary for the Entire Proposed Project Period | Upload | Not to exceed 10 pages |
| <i>Note: Your application will be Administratively Triaged if it does not meet the content and formatting requirements described in this document, in the PCORI Templates, and in PCORI Online.</i> | | |

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

1. A budget summary for the full-proposed project period (entered in PCORI Online). There is a template available [here](#) that can be used to calculate the Indirect Costs for completing this section.
2. Budget detail for the first year of the project (uploaded into PCORI Online). The Excel template available [here](#) has tabs for the Prime as well as for subcontracts.
3. A justification that supports the first year budget detail (see number 2, above) and a justification summary that supports the budget summary (see number 1, above) (uploaded into PCORI Online). There is a template available [here](#) to assist you.

All templates are provided [here](#) to assist you with developing your budget and budget justification.

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)
- Patient Care Costs
- Consultant costs
- Equipment
- Supplies
- Travel
- Other expenses
- Consortium/Contractual Direct costs
- Consortium/Contractual Indirect Costs
- Prime Indirect costs

4.2.2 Budget Detail (First Year)

Please include the budget detail for the first year. Listed below are guidelines to assist you with completing your budget:

A. Unallowable Costs

Unallowable costs should not be included either as direct costs or through an indirect cost pool. The following are examples of costs not considered allowable under PCORI contracts. Note that the following list is not all-inclusive. PCORI reserves the right to review each cost associated with a contract. Unallowable cost examples include:

- Advertising costs, other than those associated with personnel recruitment or procurement of goods or services
- Airfare costs in excess of the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare

- Alcoholic beverages
- Alumni activities and similar services
- Students stipends and fees
- Audits and related services
- Bad debts, including losses (whether actual or estimated) arising from uncollectable accounts and other claims, related collection costs, and related legal costs
- Contributions, donations, or gifts including cash, property, and services
- Entertainment, including amusement, diversion, and social activities (eg, tickets to shows or sports events, meals, lodging, rentals, transportation, and gratuities)
- Fundraising, including financial campaigns, endowment drives, solicitation of gifts and bequests, and similar expenses incurred solely to raise capital or obtain contributions
- Goods or services for personal use
- Housing (eg, depreciation, maintenance, utilities, furnishings, rent), housing allowances, and personal living expenses
- Idle facilities
- Insurance costs (eg, medical malpractice)
- Interest on borrowed capital, temporary use of endowment funds, or the use of the institution's own funds
- Legal fees or other costs incurred in connection with any criminal, civil, or administrative proceeding (including filing of a false certification) commenced by the Federal Government or a State, local, or foreign government
- Lobbying of any kind
- Losses on other grants or contracts
- Membership in any civic or community organization or private club
- Pre-agreement costs other than those specifically approved by PCORI
- Rent associated with facilities needed to run the project

- Selling and marketing any products or services of the recipient organization

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B. Personnel Costs

General:

- Salaries include wages earned by an employee and may include fringe benefits, including insurance and retirement plans.
- All personnel from the applicant organization dedicating effort to the project should be listed on the personnel budget with their base salary and effort, even if they are not requesting salary support.
- Include the name, role on project, percentage of time to be spent on the project, institutional base salary, salary and fringe benefits requested, and total per person. In addition to providing personnel costs for scientific/technical staff, you should also include costs for providing salary, consulting fees, or stipends to patient and stakeholder members of the research team.
- The PCORI salary cap for personnel is \$200,000. Note the following:
 - Fringe benefits are not included in the cap.
 - The salary cap is **by individual**, not in total.
 - An individual who earns more than this cap per year must use \$200,000 as the base salary rate in determining the amount of salary and time to charge to the project.
 - An individual who earns less than \$200,000 should use his/her Institutional Base Salary (IBS) to calculate personnel costs. (Review the [Budget FAQs](#) if you have additional salary-related questions.)

Effort:

- Personnel contributing to a PCORI-funded research project are expected to monitor their total percent effort across all funding (PCORI or others), which may not exceed 100%. Effort must be reported in calendar months.

Fringe Benefits:

- The fringe benefits rate is based on your institution's policy. As referenced above, there is no cap on the fringe benefits rate.

Senior/Key Personnel:

- The Senior/Key Personnel section should include any senior or key personnel from the applicant organization who are dedicating effort to this project. "Other Significant Contributors" should also be included.

Other Personnel:

- Other personnel can be listed by project role. The salaries of clerical and Administrative staff should be treated as indirect costs and not included as direct costs.

Tuition and Associated Fees:

- May not be included as a budgeted cost.

C. Travel Costs

Travel may include any domestic and/or international travel by an employee or other personnel directly related to and necessary for the project. For all travel, include the destination, number of people traveling, and dates or duration of the stay, and describe how the travel is directly related to the proposed research (and is necessary for achieving programmatic objectives) in the budget justification (see [section 4.2.3](#), below). Further, travel costs should be described as either scientific travel or programmatic travel, as outlined below:

- Scientific Travel—including travel to present at conferences, symposiums, etc:
 - Scientific PCORI travel for an in-person progress report update must be included in your budget if applicable to the project.
 - If there is no PCORI travel required for your project, scientific travel is capped to one trip per year or up to \$2,000 a year, whichever is less.
- Programmatic Travel—including travel needed for the conduct of the project (ie, focus groups, consultants, and others):
 - Programmatic travel will be reviewed on a case-by-case basis.

PCORI reserves the right to review each travel expense on a case-by-case basis depending on the project needs. In addition, airline costs cannot exceed those in excess of the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare.

D. Supply Costs

Supplies are general-purpose consumable items that are used on a regular basis or other tangible items that do not meet the definition of equipment. Include the category of supplies needed and the cost for each. In the budget justification, indicate general categories such as glassware, chemicals, animal costs, including an amount for each category. Categories that include costs less than \$1,000 do not have to be itemized.

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E. Equipment Costs

- Equipment costs include tangible items with a cost of \$5,000 or more or that is capitalized

according to the recipient's own policies.

- Equipment costs must be approved in advance by PCORI and must be reasonable and necessary for the project and not otherwise easily available or accessible at lower costs.
- In general, PCORI will allow equipment, when applicable, on the first year of the contract.

F. Consultant Costs

Provide total cost of consultant(s). Consultant costs must be reasonable.

G. Inpatient/Outpatient Costs

PCORI will cover project-related inpatient/outpatient costs that insurance does not cover. In the Budget Justification (see [section 4.2.3](#), below), justify the costs associated with inpatient/outpatient care. Provide cost information for inpatient and outpatient separately.

H. Contractual Costs

Contractual costs include all subcontract, contract, and fee-for-service costs. A Consortium/Contractual Arrangement (also called **Subcontract**) is required for an individual's participation if the time the PI is devoting is in lieu of time they would:

- Normally spend for the activities associated with their organization appointment.
- Their effort on the Prime's project (eg, 12 calendar months effort) is calculated as part of their 100% "professional time" for their institution.
- The subcontractor will be using significant resources (eg, office space, supplies, computer, personnel) at his/her own organization when working on the Prime's grant.
- The Prime is required to pay the subcontractor Indirect Costs associated with his/her participation.

If the criteria listed above are not met, it is likely a Consulting Agreement. A **consultant** is an individual who is hired to give professional advice or services for a fee. (See section F, above.)

Direct Costs:

- Consortium/Contractual personnel should be treated as key personnel and included in this section of the application.
- Consortium/Contractual costs should include the total cost of the sub-award, and the entire sub-award is part of the direct costs of the consortium for the purposes of calculating the primary applicant's direct costs.

Indirect Costs:

- Consortium indirect costs are NOT included as part of the primary institution's direct cost base when determining whether prior approval is needed to submit an application (ie, whether direct costs exceed \$500,000 for any year.)
- Facilities & Administrative (F&A) costs for the initial \$25,000 of all consortiums (not individually).

- If the consortiums are allowed, up to 40%, similar to the Prime.
- If the consortium is a foreign institution or international organization, F&A for the consortium is limited up to 40%.

I. Other Direct Costs

This category includes other direct costs that cannot be accounted for in other budget categories. These costs may include travel costs or participation incentives for study subjects, publication costs, service contracts, or coverage of copayments/coinsurance.

J. Total Direct Costs

This includes the total of the Personnel costs and the Other Direct Costs.

K. Indirect Costs

Indirect costs are calculated at **up to 40%** of the Personnel and Other Direct Costs including consultant, supplies, travel, and other expenses costs.

- **Equipment is excluded** from the indirect cost calculation.
- **Subcontractor direct costs greater than \$25,000 are also excluded** from the Indirect Cost calculation. The Prime may only assess Indirect Costs on Consortium/Contractual direct costs less than \$25,000. (For example, if the subcontract is for \$100,000 in direct costs, the Prime may only assess indirect costs on \$25,000: $40\% \times \$25,000 = \$10,000$.) The remaining \$75,000 is not eligible for Indirect Costs. The \$25,000 limit applies for the entire project period, not just year one, and to the total costs for **all** subcontracts. That is, the total allowable indirect costs for all Consortium/Contractor subcontracts are calculated based on a maximum of \$25,000, regardless of the number or size of individual subcontracts. [Note: this is different from the way Modified Total Direct Cost (MTDC) is calculated.]
 - The subcontractor is entitled to the Indirect Cost rate of up to 40% on his/her direct costs. Both the direct and indirect costs for the consortium/subcontract site appear on the Prime Institution's budget line item for Consortium/Contractual Arrangements and are considered to be direct costs to the Prime.
 - Although both a subcontractor's direct and indirect costs are considered to be direct costs to the Prime, subcontractor indirect costs are not included when determining if the budget exceeds the \$500,000 limit.
- For-profit institutions are entitled to receive up to 40% of indirect costs.
- Foreign Institutions are entitled to receive up to 10% of indirect costs.

Justification: Each consortium should include a budget justification following the detailed budget. The justification should be separate from the primary grantee's justification and address only those items that pertain to the consortium.

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L. Future years

Please provide a reasonable estimation of what you intend to spend with enough detail for reviewers to have a good understanding of the overall costs of the project. Escalation of costs for future years is acceptable as long as total costs do not exceed \$500,000 for each year. Any large variations from one year to the next should be described in your Budget Justification (see [section 4.2.3](#), below). ***Please note that Criterion number 8 includes the assessment of the budget and how it supports programmatic efforts of your proposal.*** The budget must reasonably reflect the activities that will be performed. You should ensure that you have provided the most accurate estimates as possible.

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. See the [Administrative Considerations](#) section, above, for additional information.

4.2.3 Budget Justifications (not to exceed 10 pages)

Provide a narrative that fully supports and explains the basis for the information in the Budget Detail (First Year) described above. 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. Additional information and guidance is supplied in the [Budget Detail \(First Year\) section](#) above. 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](#), above).

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Step 5: Submit the Application

All required information must be submitted online via PCORI Online. 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 outlined in this document, on the PCORI Templates, or on PCORI Online may result in removal of the application from the

review process ([Administrative Triage](#)). See Section 5.1, below, for details regarding creating and submitting an online application.

5.1 Submission Using the PCORI Online Process

5.1.1 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.

5.1.2 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 5.1.3, below.

5.1.3 Upload Attachments

Each of the following are required documents that must be uploaded into PCORI Online. 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](#) section, above, for additional formatting information. Templates for all documents can be found in PCORI Online and [here](#).

A. Research Plan Documentation (upload the completed Research Plan template found [here](#), that includes the following):

1. **Research Strategy:** See [section 2.2](#), above, for additional information.
2. **Replication and Reproducibility of Research and Data Sharing Plan:** See [section 2.3](#), above, for additional information.

3. **Dissemination and Implementation Assessment:** See [section 2.4](#), above, for additional information.
4. **References Cited:** See [section 2.5](#), above, for additional information.
5. **Protection of Human Subjects:** See [section 2.6](#), above, for additional information.
6. **Consortium/Contractual Agreements:** See [section 2.7](#), above, for additional requirements.
7. **Project Plan/Timeline:** See [section 2.8](#), above, for additional requirements.
8. **Appendix:** Upload appendix materials, as needed. See [section 2.9](#), above, for additional information.
9. **Letters of Support:** Upload letters of support. See [section 2.10](#), above, for additional information.

B. People and Places Documentation (upload the completed People and Places template found [here](#), that includes the following):

10. **Professional Profiles (Biographical Sketches):** See [section 3.1.3.2](#), above, for additional information.
11. **Patient and Stakeholders Engagement Plan:** See [section 3.1.3.3](#), above, for additional information.
12. **Project/Performance Sites and Resources:** See [section 3.2.1.1](#), above, for additional information.

C. Budget Documentation (upload the completed Budget template found [here](#), that includes the following):

13. **Budget Detail for the First Year.** See [section 4.2.2](#), above, for additional information.
14. **Budget Justification for the First Year and Budget Justification Summary for the Entire Proposed Project Period:** See [section 4.2.3](#), above, for additional budget justification requirements. This should include a budget justification for any subcontracts.

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5.1.4 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 PCORI Online without *all* required documentation.

| Application Checklist | | | |
|--|---------------------|-------|------------|
| Document | Submission Method | Limit | Completed? |
| Letter of Intent (see Step 1) <i>(must be completed prior to creation and submission of full application)</i> | Entered into system | N/A | |
| Research Plan (see Step 2) | | | |

| Application Checklist | | | |
|--|---------------------|-------------------------------------|------------|
| Document | Submission Method | Limit | Completed? |
| 1. Specific Aims | Entered into System | 3,000 characters | |
| 2. Research Strategy | Upload | 15 pages | |
| 3. Replication and Reproducibility of Research and Data Sharing Plan | | 2 pages | |
| 4. Dissemination and Implementation Assessment | | 2 pages | |
| 5. References Cited | | Not to exceed 10 pages | |
| 6. Protection of Human Subjects | | Not to exceed 5 pages | |
| 7. Consortium/Contractual Arrangements | | Not to exceed 5 pages | |
| 8. Project Plan and Timeline | | Not to exceed 5 pages | |
| 9. Appendix (optional) | | As needed | |
| 10. Letters of Support | | Upload | As needed |
| 11. Technical Abstract | Entered in system | 3,000 characters (including spaces) | |
| 12. Public Abstract | Entered in system | 3,000 characters (including spaces) | |
| People and Places (see Step 3) | | | |
| 1. Personnel: Principal investigators, investigators, and other significant contributors | Entered into System | As needed | |
| 2. Professional Profiles/Bio-sketches | Upload | 4 pages each | |
| 3. Patient and Stakeholder Engagement Plan | | 4 pages | |
| 4. Project/Performance Site(s) and Resources | | Not to exceed 15 pages | |

| Application Checklist | | | |
|---|-------------------|------------------------|------------|
| Document | Submission Method | Limit | Completed? |
| Budget (see Step 4) | | | |
| Budget Summary for Entire Proposed Project Period | Entered in system | As required | |
| Budget Detail for the First Year | Upload | 1 page | |
| Budget Justification Details for the First Year and Budget Justification Summary for the Entire Proposed Project Period | | Not to exceed 10 pages | |

5.1.5 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. Please note that your signing official must approve your application before you can submit your application in the system.

5.1.6 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.

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5.2 Contact Information

Please contact us with any questions at pfa@pcori.org.

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 through research | 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. Relevance to patients | 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? |

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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.