



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

## **PCORI Funding Announcements: Application Guidelines**

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These guidelines apply to the following PCORI Funding Announcement (PFA):

- Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma

Content	Revision History
Letter of Intent and Application	July 29, 2013
Review Process	July 29, 2013

### About PCORI

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

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

**Our History:** PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a non-profit, nongovernmental organization. PCORI’s purpose, as defined by the law, is to help patients, clinicians, purchasers, and policy makers make better informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.”

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

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## 1.0 INTRODUCTION

This document provides guidelines for submitting Letters of Intent (LOI) and full applications in response to the PCORI Funding Announcement (PFA) for Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma. It also provides guidance for meeting additional administrative requirements for this announcement. PCORI encourages all prospective applicants to contact us through [pfa@pcori.org](mailto:pfa@pcori.org) for any questions regarding this announcement.

## 2.0 PURPOSE

This document describes the Patient-Centered Outcomes Research Institute (PCORI) application process, major concepts, checklists, and key terminology to help applicants to initiate, design, and submit an application for the following PFA:

- Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma

For any questions regarding the information contained in this document, please review our [Frequently Asked Questions](#) or contact us at [pfa@pcori.org](mailto:pfa@pcori.org).

### 2.1 Overview of PCORI Funding Announcements

PCORI accepts applications that respond to three types of PFAs:

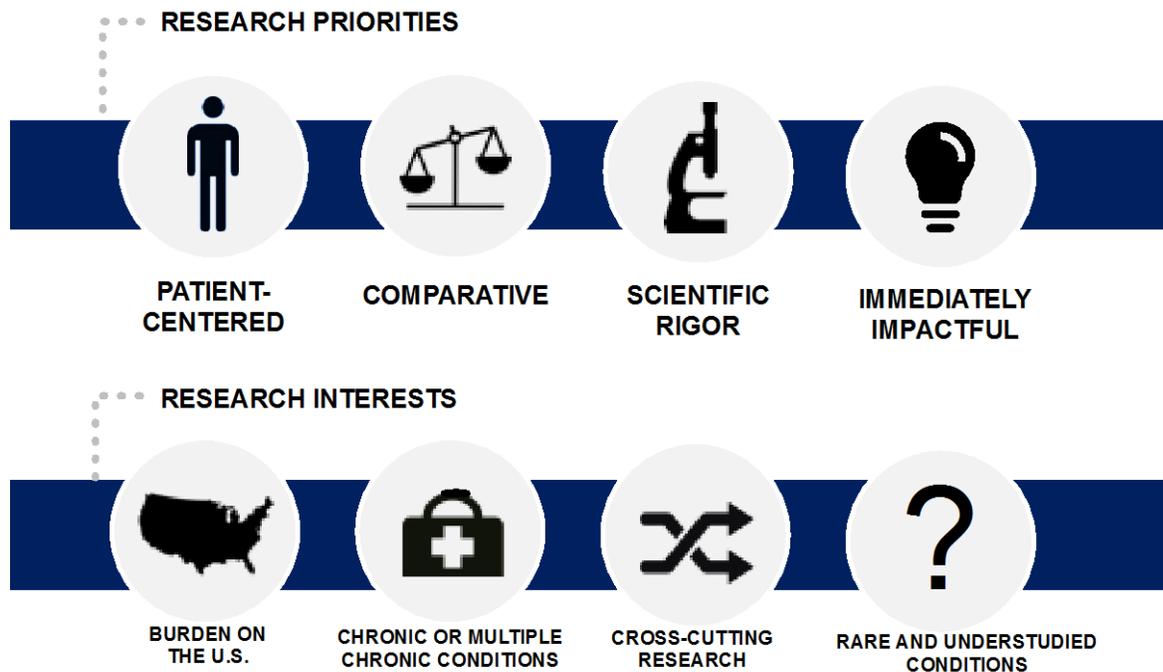
**Broad PFAs**—One path to funding involves broad funding announcements that are issued by PCORI's five scientific programs and align with PCORI's National Priorities for Research and Research Agenda. These broad PFAs solicit applications to address a wide range of comparative effectiveness research topics.

**Targeted PFAs**—A second path to funding evolved from PCORI's commitment to generate and prioritize research topics over the long term by starting with questions solicited directly from patients and stakeholders through our website, workshops, and roundtables, and similar efforts undertaken by others. These PFAs have specific application guidelines, such as this one on Treatment Options for African Americans and Hispanic/Latinos with Uncontrolled Asthma.

**Engagement Awards**—PCORI is currently developing engagement awards as a third path to funding. These small awards will help to foster new, local partnerships between the patients, stakeholders, and researchers that will serve as platforms to develop patient-centered projects.

## 2.2 PCORI'S Research Agenda and Priorities

The Patient-Centered Outcomes Research Institute (PCORI) is an independent non-profit, non-governmental organization created to help people make informed healthcare decisions and improve healthcare delivery. PCORI commissions research that is guided by patients, caregivers, and the broader healthcare community, and produces high-integrity, evidence-based information. Below are key components of PCORI's research priorities and interests:



## 3.0 GENERAL INFORMATION

This section outlines the standard and specific requirements for the PFA for Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma.

### 3.1 Standard Requirements Eligibility

Below is a high-level overview of PCORI contracts available through the PFA for Treatment Options for

PFA Application Guidelines: Treatment Options for Asthma



## African Americans and Hispanics/Latinos with Uncontrolled Asthma.

- Funding for three years
- Budgets up to \$4,000,000 in total costs:
  - Year 1: up to \$500,000 total costs
  - Year 2: up to \$1.75 million total costs
  - Year 3: up to \$1.75 million total costs
- Patient-centered research
- For comparative effectiveness research applications with budgets exceeding the amounts per year listed above or with durations of longer than three years, a separate request is required. A template for this can be found in the applicant resources section online.
- 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.

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 or manufacturer
- unit of state or local government

All US applicant organizations must be recognized by the Internal Revenue Service. Non-domestic 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. Organizations may submit multiple applications for funding. Individuals are not permitted to apply.

### Document Format Requirements

PCORI provides required templates for the following sections: Research Plan, People and Places, Budget, and Budget Justification. Templates are available in the Applicant Resources section within the [Funding Center](#) when reviewing your PFA of interest. Templates should be completed according to the formatting instructions provided in the templates and in this document, and then uploaded to the PCORI Online System. Other documents must be created by the applicant and uploaded to the PCORI Online System. For any uploaded document (aside from letters of support), the following formatting must be used:

- *Header:* Each page should include the full name of the principal investigator (PI) in the page header's left corner.
- *Margins:* Use half-inch margins or greater. The header may fall within the top margin, 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.

### Larger Budgets and Longer Projects

If your application includes a budget greater than \$500,000 (of total costs) in year 1 and/or greater than \$1.75 million (of total costs) in year 2 and/or 3, 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 exceeding these budget limits 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, including your budget detail. Include a clear explanation of why your budget or project duration 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 submission of an application. Note that total costs include direct and indirect costs when determining if you should submit a request for a budget beyond the scope of this announcement.

### Biographical Sketch Template

Please note that you have the option to use the National Institutes of Health (NIH) biographical sketch template instead of the PCORI Online System template, as needed.

### Methodology Standards

Adherence to PCORI's [methodology standards](#) is required.

## 3.2 Additional Requirements

Awardees are required to comply with the following federal regulations:

## Human Subject Protection

Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained

(<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>).

## Required Education of Key Personnel on the Protection of Human Subject Participants

PCORI requires all applicants to adhere to NIH policy on education in the protection of human subject participants in the conduct of research. This applies to all personnel listed in the application as key personnel. The policy is available at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

## PCORI Public Access Policy

These contracts require all awardees to adhere strictly to publication policies that will be elaborated by PCORI during contract's activation.

## Standards for Privacy of Individually Identifiable Health Information

The Department of Health and Human Services (HHS) issued a final modification to the *Standards for Privacy of Individually Identifiable Health Information*, the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the HHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (<http://www.hhs.gov/ocr/>) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

## Contract Terms and Conditions of Award

The administrative and funding instrument used for this program will be contracts, not grants, in which PCORI programmatic involvement with the awardees is anticipated during the performance of the activities. PCORI is solely a funding organization.

## Award Funding Conditions

*PCORI also reserves the right to discontinue funding for awardees who fail to meet the mutually agreed upon milestones at any time during the contract. Proposed milestones should be presented in*

the application, but final milestones will be negotiated in the post-award period prior to the beginning/activation of the funding period.

Proposals will be reviewed and evaluated in their totality; however, project funds will be disbursed in two stages, with disbursement of funds in Stage 2 (years 2 and 3) contingent on successful performance in Stage 1 (year 1).

### **Co-Funding**

PCORI partners with various other research organizations to leverage additional funds. PCORI contracts under these announcements are open to co-funding from other organizations. Therefore, applicants to PCORI programs are urged to explore all potential funding sources, including other private organizations, government initiatives, and consortia.

### **Dissemination and Data Sharing**

PCORI is committed to the publication and dissemination of all information and materials developed using PCORI funding. All recipients of PCORI contracts must agree to these principles and must take steps in order to facilitate availability of data and samples.

## **4.0 ABOUT THE PCORI ONLINE SYSTEM**

### **4.1 Registration**

To apply for a PCORI research project, you must first register using the PCORI Online System. The PCORI Online System will be open at least 30 days prior to the submission deadline. You can register and apply through the [PCORI Funding Center](#) for all 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.

### **4.2 Instructions**

PCORI Online System instructions can be found in the [PCORI Funding Center](#).

## 5.0 LETTER OF INTENT AND APPLICATION

### 5.1 Letter of Intent

To complete the Letter of Intent (LOI), you will need:

#### For the PFA Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma

Information Needed	What Is It?
PI Information	<ul style="list-style-type: none"><li>i. Name of organization</li><li>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.)</li><li>iii. Data Universal Numbering System (DUNS) (This 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 <a href="http://www.dnb.com">www.dnb.com</a> under the D&amp;B D-U-N-S Number tab.)</li><li>iv. City</li><li>v. State</li><li>vi. Country</li><li>vii. Type of organization</li><li>viii. For the purposes of this project, which of the following stakeholder groups reflect your primary affiliation? (Select from dropdown menu.)</li><li>ix. How have you interacted with PCORI in the past? (Select from dropdown menu.)</li></ul>
Project Information	<ul style="list-style-type: none"><li>i. Project title (limit 100 characters)</li><li>ii. Are total costs requested greater than \$500,000 in year 1 or greater than \$1.75 million in year 2 and/or 3? (Select yes or no.) If yes, a permission request must be completed and uploaded (see <a href="#">Standard Requirements</a>).</li><li>iii. Is the project length greater than three years? (Select yes or no.) If yes, a permission request must be completed and uploaded (see <a href="#">Standard Requirements</a>).</li><li>iv. The estimated total cost for the duration of the project.</li><li>v. Technical Abstract (3,000-character limit, including spaces). The Technical Abstract may be prepared in advance and either entered directly or pasted into the PCORI Online System. Summarize the project using the following required sections:<ul style="list-style-type: none"><li>a. <b>Background:</b> State the problem or question the research is designed to address.</li><li>b. <b>Objectives:</b> Briefly describe the specific aims of the study, including specific research question(s) and the long-term objectives.</li><li>c. <b>Methods:</b> Give a concise description of the study population, sample size, and analytic methods that will be employed.</li><li>d. <b>Patient Outcomes (Projected):</b> Specify the study outcomes and state briefly why these are important to patients.</li><li>e. <b>Partnerships to Facilitate Study:</b> Briefly describe established partnerships with community organizations, patient groups, etc., that would facilitate your project. Provide a list of partners. If you do not have partnerships in place, indicate so.</li></ul></li></ul>

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Key Personnel

- i. Name
- ii. Title
- iii. Organization
- iv. Role on project
- v. Contact information (address, phone number, and e-mail)
- vi. Will the patient or stakeholder partners engaged in the study receive financial compensation for their role in this project? (If yes, a text box will appear to provide additional information.)

Additional Information (You will be required to answer these 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.)
  - xii. Provide three to six words that reflect the focus of your project. (There are six blank text fields. The first three are required, the second three are optional.)
  - xiii. On which, if any, of the following vulnerable or underserved populations does your proposal focus? (Check all that apply.)
  - xiv. Which study design(s) does your proposed research utilize? (Check all that apply.)
  - xv. Which specific analytic method(s) does your application use? (Check all that apply.)
  - xvi. Please explain how the proposed research is comparative. Name the comparators and state why the comparison is important to decision makers.
-

## 5.2 Application

To complete your application, you will need to complete the following sections:

### For the PFA for Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma

Document	Submission Method	Length/Limit
<b>Letter of Intent</b> <i>(must be completed prior to creation and submission of full application)</i>	Entered into PCORI Online System	N/A
<b>Research Plan</b>		
Specific Aims	Entered into PCORI Online System	3,000 characters (including spaces)
<p><b>Research Strategy</b>—<i>see PFA for instructions for sections 1–8 and below for sections 9–15</i></p> <ol style="list-style-type: none"> <li>The application demonstrates that <b>the condition imposes a significant burden on the health of individuals and/or populations</b></li> <li>The application explains how the results of the proposed <b>study</b> would likely improve healthcare and patient outcomes</li> <li>The application demonstrates strong <b>technical merit</b></li> <li>The application demonstrates <b>patient-centeredness</b></li> <li>The application demonstrates a commitment to <b>patient and stakeholder engagement</b></li> </ol>	Upload	15 pages
6. Dissemination and Implementation Potential		2 pages
7. Reproducibility and Transparency of Research		2 pages
8. Protection of Human Subjects		5 pages
9. References Cited		10 pages
10. Consortium/Contractual Arrangements		5 pages
11. Appendix (optional)		As needed
12. Project Plan and Timeline (Milestones)	Entered into PCORI Online System	As needed

<b>13. Letters of Support</b>	Upload	As needed
<b>14. Technical Abstract</b>	Entered into PCORI Online System	3,000 characters (including spaces)
<b>15. Public Abstract</b>	Entered into PCORI Online System	3,000 characters (including spaces)
<b>16. Narratives</b>	Entered into PCORI Online System	1,000 characters (including spaces) each
<b>17. People and Places</b>		
<b>1. Key Personnel: PIs, investigators, and other significant contributors</b>	Entered into PCORI Online System	As needed
<b>2. Professional Profiles/Bio-sketches</b>	Upload	4 pages each
<b>3. Project/Performance Site(s) and Resources</b>	Upload	15 pages
<b>Budget—<a href="#">see budget section for instructions</a></b>		
<b>1. Budget Summary for Entire Proposed Project Period</b>	Entered into PCORI Online System	As required
<b>2. Budget Detail for the First Year</b>	Upload	1 page
<b>3. Budget Justification Details for the First Year and Budget Justification Summary for the Entire Proposed Project Period</b>	Upload	10 pages
<b>4. Consortium/Contractual Budget Detail for the First Year</b>		1 page
<b>5. Consortium/Contractual Budget Justification Details for the First Year and Budget Justification Summary for the Entire Proposed Project Period</b>	Upload	10 pages

Applicants are required to adhere to template instructions and PCORI formatting (see [Standard Requirements](#)). The research plan must be submitted through the [PCORI Online System](#). Each section has defined size limits. See [Appendix 5](#): PCORI Application Checklist, as well as instructions within each template.

The application will be scored against PCORI Review Criteria 1–5, listed in [Appendix 1](#).

## Specific Aims

Please provide the overall goals of the proposed research. Describe the study design and the research questions (hypotheses), including:

- The comparisons to be evaluated,
- The outcomes that will be studied,
- The anticipated impact of study results on clinical or patient decision making and on patient outcomes.

## 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.* 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 website, the reference should be displayed in the standard URL format (i.e., <http://www.pcori.org>) with the date the link was last accessed.

## Consortium/Contractual Arrangements

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 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, budget summary, and the budget justification. Please utilize the PCORI Budget template.

## Project Plan and Timeline

Provide project plan with accompanying timeline for completion of the research project within the project duration being requested. This plan will be used to determine if progress is being appropriately made and will also be used to discuss the schedule of payments.

Complete the Milestone Schedule on PCORI Online, which includes fields for milestone names, descriptions, and anticipated dates. Milestones that measure concrete, specific outcomes (i.e., deliverables) should include only activities that are supported by the PCORI application in question. Specific indicators or metrics of these milestones may include: recruitment of patients or research subjects, survey development, inception of a proposed intervention, and establishment of databases. Exclude any PCORI reporting requirements, such as semiannual progress or financial reports, from your Milestone Schedule. These required deliverables will be included in your final agreement if your application is awarded the contract.

In addition to specific activities and products, we are interested in learning how your work is having an impact. Should you be selected for a PCORI contract, following contract execution, these deliverables may be required:

- Abstracts from presentations made to professional groups or associations
- Copies of papers accepted for publication
- Copies of drafts of instruments, data dictionaries, educational materials, manuals, or other project deliverables
- Charts, tables, graphs, or other summaries of preliminary data
- Other documents or materials as appropriate.

## Appendix (Optional)

PCORI applications may include an appendix for additional materials the investigators think may be useful (e.g., 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.

## Letters of Support

Provide letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators, such as PIs, 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 to the [PCORI Online System](#).

## Technical Abstract

Summarize the project using the following required sections:

- Background—state the problem or question the research is designed to address.
- Objectives—describe briefly 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.
- Patient Outcomes—specify the study outcomes and state briefly why these are important to patients.
- Partnerships to Facilitate Study—describe established partnerships with groups, such as community organizations and patient groups, that would facilitate your project. Provide a list of partners. If you do not have partnerships in place, indicate so.

### Public Abstract

PCORI also requires an abstract written in lay terms. This public abstract should provide a thorough description that allows readers to understand the project without reviewing the full application. 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 the general public. This public abstract may not exceed 3,000 characters (including spaces).

### Narratives

Submit a brief summary of your comparators in your research project. Please note that only comparative effectiveness research is responsive to this PFA. The summary may not exceed 1,000 characters (including spaces).

Also submit a summary of your patient and stakeholder engagement potential. This may be distributed for public use. This summary may not exceed 1,000 characters (including spaces).

### People and Places

The People and Places section consists of **three required sections**: (1) List of Key Personnel, (2) Professional Profiles, and (3) Project and Performance Sites and Resources. The People and Places section will describe the qualifications of individuals who will be involved in the research, and the resources that will be used to conduct the research. Applicants are required to adhere to PCORI formatting.

### Research Team Experience and Capabilities

Applicants will need to outline the experience and capabilities of the research team members. Demonstrate that the researchers, investigators, and other team members are appropriately trained and well suited to carry out the planned studies by listing years of experience and past performance with patient-centered outcomes research (PCOR). If the investigator does not have PCOR experience, please outline appropriate collaborative arrangements with PCOR experts. Demonstrate the study team's experience as it relates to the leadership approach, governance, and

organizational structure appropriate for the project. Outline how the team's complementary experience will serve to achieve the study aims as described.

Before getting started, there are three things for applicants to consider:

1. **Principal Investigator:** PCORI requires that applicants 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 per cycle for any individual 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.

### List of Key Personnel

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

### Professional Profile/Bio-sketch

Outline the experience and capabilities of the research team members. Demonstrate that the researchers, investigators, and other team members are appropriately trained and well suited to carry out the planned studies by listing years of experience and past performance with PCOR. If the investigator does not have PCOR experience, please outline appropriate collaborative arrangements with PCOR experts. Demonstrate the study team's experience as it relates to the leadership approach, governance, and organizational structure appropriate for the project. Outline how the team's complementary experience will serve to achieve the study aims as described.

PCORI requires a professional profile for each person listed as a principal investigator, co-investigator, or other significant contributor (limit four pages each). If applicants have an existing profile or bio-sketch, applicants may use it, but, at a minimum, the professional profile must include the person's name, title, and degrees, if any, along with the information outlined in [Appendix 2](#), where relevant. Note: PCORI recognizes that not all sections of the Professional Profile may apply to patient or stakeholder members of the research team.

### Project Performance Site(s) and Resources

PCORI requires 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 (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.

## 6.0 BUDGET

In this section, applicants will find PCORI's budget-related rules and instructions for completing the budget information for an application.

### 6.1 General Budget Policies

Acceptable uses of PCORI contract funds are those that directly support the proposed research project, including collection and analysis of data and obtaining relevant data sets. Overall, costs include salaries and fringe benefits for study investigators and other project staff, consultant fees, travel for investigator meetings (both in person and via teleconference), travel that is clearly project-related, supplies, equipment in the first year, contractual and consortium agreements, and other direct research expenses, and indirect costs. Additional guidelines are described below.

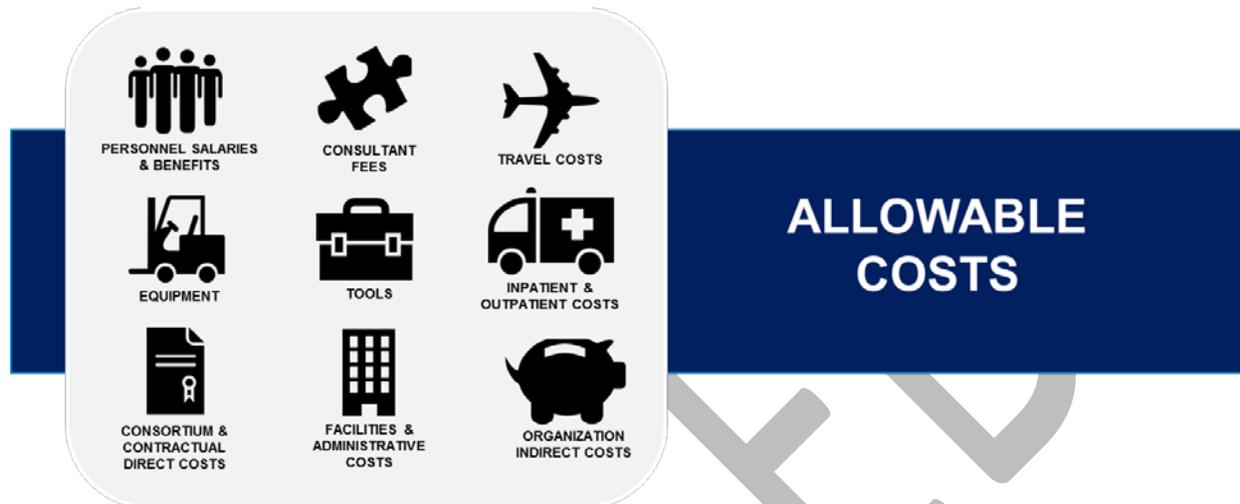
### 6.2 Required Documents

Applications must include three sections related to your budget, as follows:

1. **Online Budget:** A budget summary for the full proposed project period. The budget template available online can be used to calculate the indirect costs for completing this section.
2. **Budget Upload:** Budget detail for project for the applicant organization and for each consortium/contractual agreement. The Excel template available in the [PCORI Funding Center](#) has tabs for the prime as well as for consortium/contractual agreements. Also to be included in this upload is a budget summary for the entire project period for each consortium/contract.
3. **Budget Justification:** A justification that supports the cost proposed in the budget detail and summary (for the applicant organization and for each consortium/contractual agreement) (see number 2, above) and a justification summary that supports the budget summary for all years (see number 1, above).

## Budget Summary—Allowable and Unallowable Costs

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



All templates are provided in the [Funding Center](#) to assist applicants with developing the budget and budget justification.

### ***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:



## Budget Detail

### ***Section 1—Online Budget Summary***

In this section, please follow the instructions in the PCORI Online System to complete your budget template.

### ***Section 2—Budget Upload***

In this section, there are three required parts that applicants will need to complete. The three parts follow the same budget template, but have different instructions associated with each of them. The three parts are:

1. Organization Budget Detail (applicant organization)—Detail and list the overall organization costs for the project's first year. Applicants are required to complete this only once for their organization.
2. Consortium Budget Detail (one for each consortium/contract agreement)—Detail and list the overall consortium/contract costs for the project's first year. Applicants are required to complete one for each consortium/contract agreement.
3. Budget for the Entire Project Period (one for each consortium/contract agreement)—Detail and list the overall organization costs for the entire project period. Applicants are required to complete one for each consortium/contract agreement.

## Organization Budget Detail (for Both Organization and Consortium)

### **A. Personnel Costs—General Policies**

- Allowable Costs: Salaries include wages earned by an employee, and eligible costs also include fringe benefits, including insurance and retirement plans. Note: Key personnel include those who, if they left, would significantly impact the project.
- Level of 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 by percentage time over the course of the project year. All personnel from the applicant organization dedicating effort to the project should be listed on the personnel budget with their level of effort, even if they are not requesting salary support. Please list the base salary for such persons in the justification, using \$0 for base salary on the Detailed Budget for the First Year.
- Salary Cap: The PCORI salary cap for personnel is \$200,000 per individual, per year, exclusive of fringe benefits. An individual who earns less than \$200,000 should use his/her base salary to calculate personnel costs. An individual with a base salary more than \$200,000 must use \$200,000 as the base salary rate in determining the amount of salary and time to charge to the project.
- Fringe Benefits: These costs are calculated based on the applying institution's policy. As referenced above, there is no cap on the fringe benefits rate.
- Tuition and Associated Fees: These costs may not be included as a budgeted cost.

### **Form Instructions for Detailed Budget**

- Include the name, role on project, percentage of time to be spent on the project, base salary, salary and fringe benefits requested, and total per person. In addition to providing personnel costs for scientific/technical staff, applicants should also include costs for providing salary or stipends to patient and stakeholder members of the research team, if not accounted for under consulting costs.
- For all personnel costs, provide computations for how applicants arrived at the specific number.

### **B. Consultant Costs—General Policies**

- Consultant costs are those for individuals who have dedicated time to the project not as an employee of the applicant organization or under a consortium/contractual agreement as a member of the contractor staff.
- Consultant costs must be expressed in an hourly rate.
- Consultant costs must be reasonable and justified within the budget justification.

### **Form Instructions for Detailed Budget**

- Provide total cost of consultant(s) as well as names, expected number of hours, and hourly rate.
- For all consultant costs, provide computations for how applicants arrived at the specific number.

### **C. Supply Costs—General Policies**

- 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.
- Tangible items with per-unit costs of \$5,000 or more are considered equipment and cannot be accounted for under this category.

### **Form Instructions for Detailed Budget for the First Year**

- Indicate general categories such as glassware, chemicals, animal costs, including an amount for each category.
- Categories that include costs of more than \$1,000 must be described in a further level of detail on the budget form and itemized within the justification.
- For all supply costs, provide computations for how applicants arrived at the specific number.

### **D. Travel Costs—General Policies**

- Travel may include any domestic and/or international travel by an employee or other personnel directly related to and necessary for the project and within the limits explained below.
- Travel costs should be described as either scientific travel or programmatic travel, as outlined below:
  - Scientific Travel—including travel to present at conferences, symposiums, and so forth. Scientific travel is capped at 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 (i.e., focus groups, consultants, and others). Programmatic travel will be reviewed on a case-by-case basis.
  - Airline costs cannot exceed those in excess of the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare.
  - PCORI reserves the right to review each travel expense on a case-by-case basis depending on the project needs.

### **Form Instructions for Detailed Budget**

- For each category of travel (scientific and programmatic), include number of trips and a brief description of the trips to include the number of people traveling, and dates or duration of the stay.
- In the justification, provide added detail to explain the basis for the costs listed and describe how the travel is directly related to the proposed research (and is necessary for achieving programmatic objectives) in the budget justification.
- For all supply costs, provide computations for how applicants arrived at the specific number.

### **E. Other Direct Costs—General Policies**

- This category includes 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.

### **Form Instructions for Detailed Budget**

- List the total for all other costs in the appropriate rows. Indicate general categories such as printing costs, publication costs, and service contracts, including an amount for each category.
- Categories that include costs of more than \$1,000 must be described in a further level of detail on the budget form and itemized within the justification.

### **F. Inpatient and Outpatient Costs—General Policies**

- PCORI will cover project-related inpatient/outpatient costs that insurance does not cover.

### **Form Instructions for Detailed Budget**

- List the total for inpatient costs and outpatient costs in the appropriate row.
- In the Budget Justification below, justify the costs associated with inpatient/outpatient care. Provide cost information for inpatient and outpatient care separately.

### **G. Equipment Costs—General Policies:**

- Equipment costs include tangible items with a cost of \$5,000 or more.
- Equipment costs must be approved 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, and only in the first year of the contract.

### **Form Instructions for Detailed Budget**

- List each item of equipment and its cost.

### **H. Consortium and Contractual Costs—General Policies**

- This category includes all consortium, contractual, and fee-for-service costs. A Consortium/Contractual Arrangement is required for an individual's participation if:
  - The time a person is devoting is on behalf of his/her employer and becomes part of his/her duties.

- His/her effort on the project is calculated as part of his/her “professional time” for his/her employer organization.
- The contractor will be using significant resources (e.g., office space, supplies, computer, personnel) at his/her own organization when working on the PCORI-funded project.
- 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 B, above.)

**Policies for Direct Costs:**

- Consortium/Contractual personnel should be treated as key personnel and included in that 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.

**Policies for Facilities and Administrative (F&A) Costs:**

- Consortium F&A is not included as part of the applicant organization’s direct cost base when determining whether prior approval is needed to submit an application (i.e., whether direct costs exceed \$500,000 for any year.)
- F&A costs are calculated at up to 40% (for US organizations) of the total of personnel, consultant, supplies, travel, and other expenses plus an amount equal to the total of consortium/contractual direct costs or \$25,000, whichever is less. If total consortium and contractual costs are less than \$25,000 in the first year, then the remainder may be used in future years’ indirect cost calculations. This \$25,000 allocation is across the full project period; it is not an annual allocation. Please note that equipment costs and subcontractor indirect costs (F&A) are not included in this calculation. Foreign institutions are limited to a 10% rate using the same general calculation as above. For more information about this calculation, see the section on the applicant agency’s indirect costs below.

**Form Instructions for Detailed Budget for the First Year**

- Enter the total amounts for the direct and indirect costs in the appropriate row.

**I. Indirect Costs—General Policies**

- Indirect costs are calculated at up to 40% (for US organizations) of the total of personnel, consultant, supplies, travel, and other expenses (not inclusive of inpatient and outpatient costs) plus an amount equal to the total of consortium/contractual direct costs or \$25,000, whichever is less. If total consortium and contractual costs are less than \$25,000 in the first year, then the remainder may be used in future years’ indirect cost calculations. This \$25,000 allocation is across the full project period; it is not an annual allocation. Please note that equipment costs, consortium/contractual indirect costs (F&A), inpatient costs, and outpatient costs are not included in this calculation. Foreign institutions are limited to a 10% rate using the same calculation as above.

Example: If the total applicant organization's costs for personnel, consultants, supplies, travel, and other expenses is \$300,000, and applicants have two contractual agreements, each at \$30,000 in direct costs, and outpatient costs of \$20,000, then the total indirect cost base is \$325,000, not \$380,000, because the calculation requires inclusion of the lesser of \$25,000 or the total related costs, which are \$80,000 in this example.

If the institution has an indirect cost less than 40%, applicants are required to use the lesser rate.

#### Form Instructions for Detailed Budget

- Enter the indirect costs rate. The resulting total for indirect costs will be calculated in the Excel template for Detailed Budget for the First Year.

#### Totals

- Ensure that the subtotal for each category above and total costs are included. The budget template will calculate these after amounts are entered.

#### Consortium/Contractor Budget Summary for the Entire Project Period

Include within the Budget Detail document a full budget for each proposed project period for each consortium and contractor agreement. In doing so, please refer to the budget policies above.

#### Section 3—Budget Justifications

- **Applicant Organization Justification.** Using the template or a similar format, provide the detail needed to understand both the basis for costs and the reason why the costs are necessary to the project for each budget category, providing adequate detail to understand any major cost variances from the first year or new types of expenses. 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 summary justification to support each budget category for the full project period, providing adequate detail to understand any major cost variances from the first year or new types of expenses.
- **Consortium/Contractor Agreement Justification(s).** Provide a detailed justification for each consortium/contractual agreement by budget category. This justification also requires specification of any other sources of funding direct to the consortium/contractor in support of its portion of the project (see below). Finally, provide a summary justification to support each budget category for the full project period, providing adequate detail to understand any major cost variances from the first year or new types of expenses.
- **Specifying Other Funding Sources.** 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.
- **Justification for the Full Project Period.** Finally, provide a summary justification to support the Budget Summary for the full project period, providing adequate detail to understand any major cost variances from the first year or new types of expenses.

## 7.0 SUBMIT THE APPLICATION

All required information must be submitted online via the [PCORI Online System](#). Failure to submit all required application documents online may result in removal of the application from the review process.

### 7.1 Submission Using the PCORI Online System

#### Requirements

Completing and submitting applications comprises two parts. The first involves 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.

#### Beginning the Application in the PCORI Online System

For login and password information, see the PCORI Online System section, above. Note that applicants must complete an LOI *prior* to completion of an application. The links on the left side of the page allow you to navigate to all pages that applicants 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).
2. **Project Information:** Review (and edit, if necessary) basic information about the project (information carried over from LOI entry).
3. **Key Personnel:** Review (and edit, if necessary) the key personnel information, including name, role on project, and institution (information carried over from LOI entry). Add additional key personnel using the “Add” button, if necessary.
4. **Budget:** Complete budget information for each year of the proposed project, including direct and indirect costs. Enter detailed information about the first-year budget.
5. **Milestone Schedule:** enter project milestones, descriptions, and anticipated completion dates.
6. **Upload/Attach Required Auxiliary Documents:** See section below.
7. **Review and Submit:** See section below.

#### Upload Attachments

Please refer to the application checklist for a comprehensive list of the required documents that must be uploaded into the PCORI Online System. For each document that applicants create, place page numbers in the bottom margin; use consecutive, whole numbers. (Letters of support do not need to be sequentially numbered.) All attachments must be in PDF format. Refer to [Document Format Requirements](#) for additional formatting information. Templates for all documents can be found in the [PCORI Funding Center](#).

### **Application Submission**

After all required materials have been uploaded to the system, the applicant must click the “Submit” button to submit the application for their Administrative Official (AO) to authorize.

### **Authorization**

Upon completion of your application, you must submit the application to your administrative official (AO) for approval. Only your administrative official may approve the final application. Please ensure that your AO approves and submits your application to PCORI prior to the submission deadline.

CLOSED

## APPENDIX 1: APPLICATION REVIEW CRITERIA AND PROCESS

### Review Criteria

PCORI’s review criteria are consistent with patient-centeredness and are specifically designed to include a diverse set of perspectives in decision making.

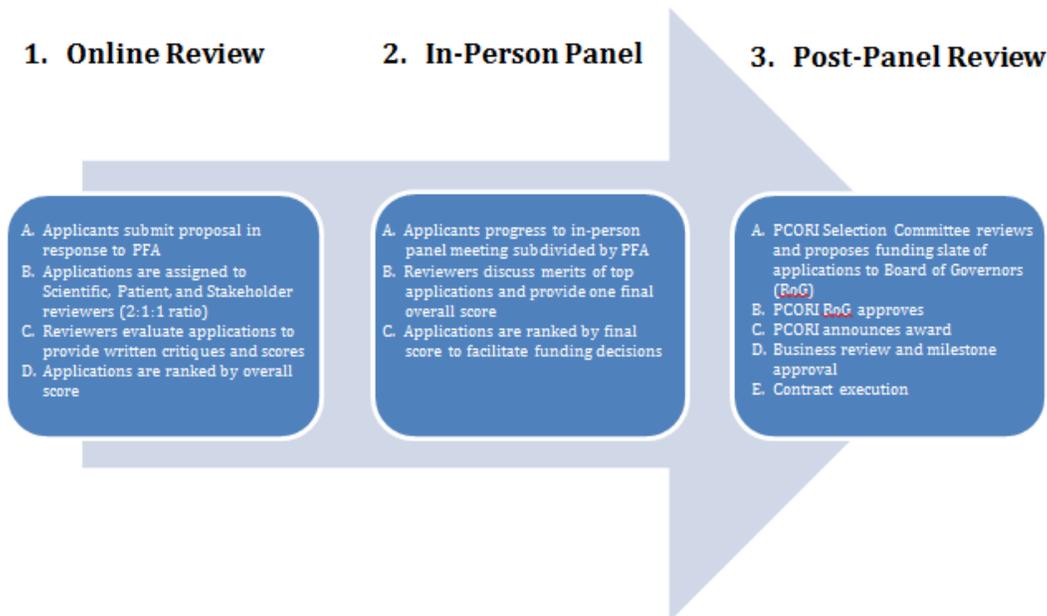
### For the PFA, Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma

PCORI Criteria	Brief Description
<p><b>1. Impact of the condition on the health of individuals and populations</b></p>	<ul style="list-style-type: none"> <li>▪ 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?</li> <li>▪ Does it impose a significant burden on a smaller number of people who have rare diseases?</li> <li>▪ A particular emphasis is on patients with chronic conditions, including those patients with multiple chronic conditions.</li> </ul>
<p><b>2. Potential for the study to improve health care and outcomes</b></p>	<p>Refers to the potential for the proposed research to lead to meaningful improvement in the quality and efficiency of care and to improvements in outcomes that are important to patients.</p> <ul style="list-style-type: none"> <li>▪ Does the research question address a critical gap in current knowledge as noted in systematic reviews, guideline development efforts, or previous research prioritizations?</li> <li>▪ Has it been identified as important by patient, caregiver, or clinician groups?</li> <li>▪ Do wide variations in practice patterns suggest current clinical uncertainty?</li> <li>▪ Is the research novel or innovative in its methods or approach, in the population being studied, or in the intervention being evaluated, in ways that make it likely to improve care?</li> <li>▪ Do preliminary studies indicate potential for a sizeable benefit of the intervention relative to current practice?</li> <li>▪ How likely is it that positive findings could be disseminated quickly and effect changes in current practice?</li> </ul>

<p><b>3. Technical merit</b></p>	<p>Refers to inclusion of the following:</p> <ul style="list-style-type: none"> <li>▪ Clear research plan with rigorous methods and key milestones clearly articulated.</li> <li>▪ Research team has appropriate expertise and project organizational structure is appropriate for the study.</li> <li>▪ Research environment is sufficient to support conduct of the work; appropriate resources are available.</li> <li>▪ Includes diverse population with respect to age, gender, race, ethnicity, and clinical status as appropriate for the study.</li> <li>▪ Focuses on defined population for whom effectiveness information is particularly needed.</li> </ul>
<p><b>4. Patient-centeredness</b></p>	<ul style="list-style-type: none"> <li>▪ Is the proposed research focused on questions that affect outcomes of specific interest to patients and their caregivers?</li> <li>▪ Does the research address one or more of the key questions mentioned in PCORI’s definition of patient-centered outcomes research?</li> <li>▪ How credible are the application’s claims that engaged patients and stakeholders will exert meaningful influence on the design and conduct of the research, to ensure patient-centeredness of the questions and outcomes addressed?</li> </ul>
<p><b>5. Patient and stakeholder engagement</b></p>	<ul style="list-style-type: none"> <li>▪ Does the proposal describe how patients and stakeholders were or will be identified and engaged in the research?</li> <li>▪ What are the roles of patients and key stakeholders in formulating the study’s hypotheses and design and in the study’s conduct and dissemination of results?</li> <li>▪ What roles do patients and stakeholders have in any planned dissemination or implementation plans?</li> </ul> <p><b>Applications need to demonstrate patient and stakeholder engagement</b> through the integration of patients and stakeholders in the development of the research plan and in key elements of the proposed project including:</p> <ul style="list-style-type: none"> <li>▪ Participation in formulation of research questions.</li> <li>▪ Defining essential characteristics of the study, participants, comparators, and outcomes.</li> <li>▪ Monitoring study conduct and progress.</li> <li>▪ Dissemination of research results.</li> </ul> <p>If the project has not included patient and stakeholder engagement (for example, in the area of analytic methods), has the application justified their non-inclusion?</p> <p>If engagement is not applicable, explain why it is not.</p>

## Review Process

PCORI conducts rigorous merit review of the applications it receives. In order to support high-quality patient-centered scientific research, PCORI’s merit review process is distinguished by the full participation of scientists, patients and their caregivers, and stakeholders. The review sequence includes initial online review, in-person merit review meetings, and post-panel assessments, as outlined in the graphic below.



For the online review, four reviewers are assigned to evaluate each application—two scientists, one stakeholder, and one patient/caregiver reviewer. Reviewers evaluate each application based on PCORI’s Merit Review Criteria (as described in the PFA). Reviewers then submit electronically to PCORI their initial scores and their detailed written critiques.

The top-scored applications advance to the PFA-specific, in-person, merit review meetings. There, the reviewers discuss the applications’ strengths and weaknesses, each panelist assigns a score to each application, and each panel assigns a final overall score to each application.

After the in-person merit review meetings, the top-scored applications are reviewed by a Selection Committee composed of members of PCORI’s staff and its Board of Governors. The Selection Committee proposes a slate of applications for possible funding based on merit review scores, programmatic balance, and PCORI’s strategic priorities. The Board of Governors then considers the slate and selects applications for funding. Finally, awards are announced and research contracts are executed.

### **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 the PCORI Online System, or if it is incomplete or does not meet other PCORI requirements. Applicants should refer to PCORI application checklists to ensure that all application requirements are met.

#### **Applications are considered nonresponsive if research is proposed that:**

- Conducts a formal cost-effectiveness analysis in the form of dollar-cost per quality-adjusted life-year (including non-adjusted life-years) to compare two or more alternatives
- Directly compares the costs of care between two or more alternative approaches as the criterion for choosing the preferred alternative

### **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 PFA, if it describes research that is non-comparative, or if it otherwise does not meet PCORI programmatic requirements. Applicants should refer to PCORI application checklists to ensure that all application requirements are met.

## APPENDIX 2: PROFESSIONAL PROFILE INFORMATION

### Professional Profiles

Below is additional guidance regarding information to be included in the professional profiles.

Professional Profile Item	Description	Limits
Personal Statement	Describe how experiences and qualifications make the team member well suited for the role in the proposed project.	250 words
Education and Training	List all post-secondary education and training, including institution, degree conferred (if any), and year. Include internships, residencies, and fellowships and give beginning and ending dates for each.	None
Employment and Position Held	List all professional positions held since completion of education.	None
Honors	List any honors. Include present membership or leadership in relevant organizations or advisory groups.	None
Selected Peer-Review Publications	List publications or manuscripts that are relevant to the research being proposed.	No more than 15 pages
Other Selected Publications	List op-ed pieces, newsletters, blogs, and non-peer-reviewed reports.	No more than 10 pages
Public Speaking or Presentations	Provide testimonies, scientific talks, or presentations.	Presentations in the last two years
Research Support	List both selected ongoing and completed research. Briefly indicate the person's overall goals for the projects and responsibilities.	Research supported in the past three years
Other	Include any additional relevant information to help us assess the qualifications of the key personnel for the project.	None

## APPENDIX 3: GLOSSARY

### Key Role Descriptions:

PCORI refers to three specific roles with particular responsibilities. Below is detailed information and terminology applicants should use in their applications:

Role	Description	Key Activities	PCORI Application Instructions
<b>Principal Investigator (PI)</b>	<ul style="list-style-type: none"> <li>Day-to-day management of the research and project</li> <li>Responsible for scientific or technical aspects</li> <li>Lead research representative of the organization/institution</li> </ul>	<ul style="list-style-type: none"> <li>Serve as PCORI lead point of contact</li> <li>Assume responsibility and accountability for research execution, organization conduct, and compliance</li> </ul>	<ul style="list-style-type: none"> <li>Applications can include multiple PIs</li> <li>PIs can serve in other applications as other roles (co-investigator or consultant)</li> <li>Individuals cannot serve as PIs for multiple PCORI Funding Awards in the same cycle</li> </ul>
<b>Administrative Official (AO)</b>	<ul style="list-style-type: none"> <li>Management of the contract activation, renewals, milestones, and additional materials required</li> <li>Responsible for matters related to the award and administration of the contract</li> </ul>	<ul style="list-style-type: none"> <li>Oversee submission of the contract activation, renewals, milestones, and additional materials required</li> <li>Certify contract compliance of all applicable assurances and certifications referenced in the application</li> </ul>	<ul style="list-style-type: none"> <li>The AO must not also be the PI</li> <li>The AO's signature certifies that the organization/institution will be accountable for both the appropriate use of funds awarded and for the performance of the PCORI-supported project or activities resulting from the application</li> </ul>
<b>Financial Official (FO)</b>	<ul style="list-style-type: none"> <li>Responsible for required annual expenditure reports</li> </ul>	<ul style="list-style-type: none"> <li>Complete and certify the required yearly expenditure reports</li> <li>Execute accounting of contract funds and submission of invoices and payment details</li> </ul>	N/A

## Key Terms:

**Allowable Costs**—A cost that is approved within the budget and is not otherwise unallowable under the PCORI Funded Research Policies. A direct cost is allocable to the project if the goods or services involved are chargeable or assignable to the project in accordance with relative benefits received or other equitable relationship. As a result, a cost is allocable to the funded project if (1) it is incurred solely to advance the work under the project, or (2) it benefits both the funded project and other work of the recipient organization, in proportions that can be approximated through use of reasonable methods.

**Brief Abstract**—A summary of the research plan written for a non-scientific audience. This abstract is made publicly available if the project is funded.

**Bio-sketch**—A profile of the experience and accomplishments of the key personnel in an application. Such a bio-sketch also satisfies the requirements of the PCORI Professional Profile.

**Burden**—A term that refers to the frequency of the condition, the expected mortality and morbidity, and/or the burden of suffering associated with symptoms, complications, or other consequences of the condition. Additionally, it may include the costs to the US population of healthcare services used, the individual patients' out-of-pocket expenses, as well as intangible costs to the patient, such as time away from paid or unpaid occupations.

**Clinical Practice Guidelines**—Systematically developed statements or recommendations to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. They present indications for performing a test, procedure, or intervention, or the proper management for specific clinical problems. Guidelines may be developed by government agencies, institutions, organizations such as professional societies or governing boards, or by convening expert panels.

**Closeout**—The process by which PCORI determines that all applicable administrative actions and all required work of the contract have been completed and officially closes the contract.

**Comparative Effectiveness Research (CER)**—The direct comparison of existing healthcare interventions to determine which interventions work best for which patients and which interventions pose the greatest benefits and harms. The core question of comparative effectiveness research is which treatment works best, for whom, and under what circumstances.

**Conflict of Interest**—As defined by PCORI's authorizing legislation, a conflict of interest is any "association, including a financial or personal association, that has the potential to bias or have the appearance of biasing an individual's decisions in matters related to the Institute or the conduct of activities" [Patient Protection and Affordable Care Act, Pub L No. 111-148, 124 Stat 727, §6301(a)(3)]. Conflicts of interest will be considered and managed throughout every step of the review and selection process, including, but not limited to, the technical and programmatic reviews, the selection and assignment of scientific and stakeholder reviewers, Board of Governors deliberations, and post-award negotiations and monitoring.

**Consultant**—An individual hired to provide professional advice or services for a fee.

**Contract**—The legally binding document that PCORI uses to make awards for research projects.

**Data Universal Numbering System (DUNS)**—A unique identifier assigned to a single business entity. You may apply for a DUNS number online at: <http://www.dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number>.

**Employer Identification Number (EIN)**—The Federal Tax Identification Number used to identify a business entity. You may apply for an EIN in various ways, including online. See:

<http://www.irs.gov/businesses/small/article/0,,id=102767,00.html>.

**Financial Official (FO)**—The individual designated by the recipient organization who is responsible for the proper accounting of contract funds and the submission of payment details. The FO is responsible for completing and certifying the required yearly expenditure reports.

**Fringe Benefits**—A form of pay for the performance of services. Fringe benefits commonly include health insurance, group term life coverage, and non-wage compensation.

**Indirect Costs**—Costs not directly accountable to the project. Indirect costs include taxes, administration, personnel, and security costs.

**Institutional Review Board (IRB)**—A group that follows federal regulations, state laws, and institutional policy to review, monitor, and approve research in order to protect the ethical rights and privacy of the subjects involved.

**Letter of Intent (LOI)**—A notification to PCORI that an organization intends to apply. Submission of an LOI is a prerequisite to submitting an application.

**Merit Review**—A review of applications by qualified reviewers who read, score, and provide feedback on the applications.

**Methodology Committee**—Per PCORI's authorizing legislation, the 17-member group working to develop and advance scientific methods in patient-centered outcomes research. The Methodology Committee is a subfunding committee that supports the PCORI Board of Governors.

**Patients**—Individuals who have or have had 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.

### **Patient-Centered Outcomes Research**

**(PCOR)**—Research that helps people and their caregivers communicate and make informed healthcare decisions, while allowing their voices to be heard in assessing the value of healthcare options. This research answers patient-centered questions. A full definition can be found at: <http://www.pcori.org/what-we-do/pcor/>.

**PCORI Online System**—PCORI's online application and management system, designed to facilitate the applicant's submission of materials, and the activation of a contract through completion and closeout.

**Principal Investigator (PI)**—Lead scientist(s) for a research project. The primary Principal Investigator on a contract or application for funding who serves as PCORI's primary point of contact for that contract or application.

**Professional Profile**—A profile of the experience and accomplishments of a person who will play a significant role on a PCORI-funded research project. See also bio-sketch.

**Programmatic Review**—A review of the scientific portion(s) of the application to ensure that it meets PCORI's programmatic requirements.

**Randomized Controlled Trial (RCT)**—An experiment in which participants are randomly allocated to receive one of two (or more) diagnostic, preventive, therapeutic, or palliative interventions and are then followed to determine the effects of the intervention

**Reasonable Costs**—A cost may be considered reasonable if the nature of the goods or services acquired or applied is appropriate and justifiable. The amount involved reflects the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made.

**Renewed Support**—Approval of an additional funding period for the same project within the approved project period. The original agreement

will remain in place and additional funds obligated near the end of each funding period. Any funds remaining on the contract prior to the new obligation will remain available for the recipient's use.

**Research Team**—A group of people organized to function cooperatively to design and conduct research. For PCORI, teams should include patients and other stakeholders as key contributors to the research process.

**Scientific Review Officer (SRO)**—A scientist who presides over a scientific merit review panel and is responsible for coordinating and reporting the discussion of each application assigned to it. The SRO serves as an intermediary between the applicant and reviewers, and prepares summary statements for all applications reviewed.

**Senior/Key Personnel**—Individuals who contribute to the scientific development or execution of the project in a substantive and measurable way. The contribution is independent of financial compensation.

**Stakeholder**—Stakeholders include 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 organizational providers, purchasers, payers, and industries for whom the results of the research will be relevant.

**Technical Abstract**—A summary of the research plan written for scientists and researchers.

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## APPENDIX 4: SCORING

This scoring section applies to all PFAs.

### LOI

LOIs will not be scored.

### Applications

One patient, one stakeholder, and two scientists review each application.

### Critique

Each reviewer scores the application against each of the review criteria and provides a list of three strengths, three weaknesses, and an overall score for each criterion. Then the reviewer assigns the application an overall score based on its responsiveness to the PFA as a whole and provides comments about overall strengths and weaknesses.

### Scoring

The scoring range consists of a nine-point scale. All reviewers will use this scale when assigning a final overall score.

### PCORI Scoring Scale

Range	Score	Descriptor	Characteristics
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weakness
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses

## APPENDIX 5: APPLICATION CHECKLISTS

### PCORI Funding Announcements: Application Checklist

Please use this checklist when completing an application for one of the following broad funding announcements to ensure that all materials are submitted:

- Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma

Once all portions of an application are submitted in the PCORI Online System, you will receive a confirmation of submission via email. *Note: Deadlines are at 5:00 PM ET. If deadlines fall on a weekend or a federal holiday, the deadline will be the following Monday or the next day after the federal holiday.*

If you have any questions, please contact us at [pfa@pcori.org](mailto:pfa@pcori.org).

Letter of Intent	How to Submit	Length/Limit
<input type="checkbox"/> <b>Letter of Intent</b> <i>(must be completed prior to creation and submission of full application)</i>	Enter into PCORI Online System	N/A
Research Plan	How to Submit	Length/Limit
<input type="checkbox"/> <b>Specific Aims</b>	Enter into PCORI Online System	3,000 characters (including spaces)
<input type="checkbox"/> <b>Research Strategy</b> <ol style="list-style-type: none"> <li>The application demonstrates that the condition imposes a significant burden on the health of individuals and/or populations</li> <li>The application explains how the results of the proposed study would likely improve healthcare and patient outcomes</li> <li>The application demonstrates strong technical merit</li> <li>The application demonstrates patient-centeredness</li> <li>The application demonstrates a commitment to patient and stakeholder engagement</li> </ol>	Upload	15 pages
<input type="checkbox"/> <b>Dissemination and Implementation Potential</b>		2 pages

<input type="checkbox"/>	<b>Reproducibility and Transparency of Research</b>		2 pages
<input type="checkbox"/>	<b>Protection of Human Subjects</b>		5 pages
<input type="checkbox"/>	<b>References Cited</b>		10 pages
<input type="checkbox"/>	<b>Consortium/Contractual Arrangements</b>		5 pages
<input type="checkbox"/>	<b>Appendix (optional)</b>		As needed
<input type="checkbox"/>	<b>Project Plan and Timeline (Milestones)</b>	Enter into PCORI Online System	As needed
<input type="checkbox"/>	<b>Letters of Support</b>	Upload	As needed
<input type="checkbox"/>	<b>Technical Abstract</b>	Enter into PCORI Online System	3,000 characters (including spaces)
<input type="checkbox"/>	<b>Public Abstract</b>	Enter into PCORI Online System	3,000 characters (including spaces)
<input type="checkbox"/>	<b>Narratives</b>	Enter into PCORI Online System	1,000 characters (including spaces) each

<b>People and Places</b>		<b>How to Submit</b>	<b>Length/Limit</b>
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<input type="checkbox"/>	<b>Personnel: Principal investigators, investigators, and other significant contributors</b>	Enter into PCORI Online System	As needed
<input type="checkbox"/>	<b>Professional Profiles/Bio-sketches</b>	Upload	4 pages each
<input type="checkbox"/>	<b>Project/Performance Site(s) and Resources</b>		15 pages

<b>Budget—<i>See Budget (Section 6.0) for Instructions</i></b>		<b>How to Submit</b>	<b>Length/Limit</b>
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<input type="checkbox"/>	<b>Budget Summary for Entire Proposed Project Period</b>	Enter into PCORI Online System	As required
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- |                          |   |        |          |
|--------------------------|---|--------|----------|
| <input type="checkbox"/> | <b>Budget Detail for the First Year</b>   | Upload | 1 page   |
| <input type="checkbox"/> | <b>Budget Justification Details for the First Year and Budget Justification Summary for the Entire Proposed Project Period</b>                        |        | 10 pages |
| <input type="checkbox"/> | <b>Consortium/Contractual Budget Detail for the First Year</b>  | Upload | 1 page   |
| <input type="checkbox"/> | <b>Consortium/Contractual Budget Justification Details for the First Year and Budget Justification Summary for the Entire Proposed Project Period</b> | Upload | 10 pages |

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## APPENDIX 6: RESOURCES AND CONTACT INFORMATION

- All active opportunities can be found in PCORI's [Funding Center](#).
- To find application templates and any additional instruction for a specific opportunity, select the opportunity of interest in the Funding Center and review the applicant resources section of the page.
- PCORI's [Applicant FAQs](#) cover common questions that an applicant may have about PCORI and the application process. These are updated on a regular basis to reflect questions received through our helpdesk and applicant town halls.
- Applicant training materials and information about PCORI's applicant town hall sessions will be posted on PCORI's [Training Materials](#) page. Once available, applicants will receive an email about these opportunities.
- If you have questions, please contact us at [pfa@pcori.org](mailto:pfa@pcori.org).

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