These guidelines apply to the Cycle 3 2015 Funding Cycle for the following PCORI Funding Announcements: Assessment of Prevention, Diagnosis, and Treatment Options; Improving Healthcare Systems; Communication and Dissemination Research; and Addressing Disparities. Funding announcements, templates, and other resources are available at pcori.org/apply. The Cycle 3 2015 Funding Cycle closes February 16, 2016 at 5 p.m. (ET).
About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work. PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

PCORI was authorized by Congress in 2010 as a nonprofit, nongovernmental organization. PCORI’s purpose, as defined by our authorizing legislation, 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.”

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What Has Changed for the Cycle 3 2015 Funding Cycle:

- Applicants should use American Medical Association (AMA) citation style in references
- New Milestones/Deliverables Template created
- New section on Detailed Peer Review Budget for Peer-Review-Related Costs
About These Guidelines
This document provides key information to help researchers prepare and respond to the following PCORI Funding Announcements (PFAs):

- Assessment of Prevention, Diagnosis, and Treatment Options: [http://www.pcori.org/Cycle-3-2015-options/]
- Communication and Dissemination Research [http://www.pcori.org/Cycle-3-2015-communication/]

Researchers wishing to respond to the Improving Methods for Conducting Patient-Centered Outcomes Research PFA can find related information at [http://www.pcori.org/Cycle-3-2015-methods/].

These guidelines will answer many questions you might have, but other resources are also available, including the following:

- PCORI’s [Applicant FAQs][1] cover common questions about PCORI and the application process.
- Visit PCORI’s [Help Center][2] for additional applicant resources.
- **For Programmatic Inquiries:** Please contact the PCORI Helpdesk via email (sciencequestions@pcori.org), phone (202-627-1884), or online [http://www.pcori.org/PFA/inquiry]. PCORI will provide a response within three business days. However, we cannot guarantee that all questions will be addressed three business days prior to a Letter of Intent (LOI) or application deadline.
- **For Administrative, Financial, or Technical Inquiries:** Please contact the PCORI Helpdesk at pfa@pcori.org. PCORI will provide a response within two business days. Please note that during the week of the application deadline, response times may exceed two business days. Applicants may also call the PCORI Helpdesk (202-627-1885).

It is the applicant’s responsibility to submit the application on or before the deadline. Please refer to [PCORI’s Policy on Submission of Research Contract Applications][3].

Administrative Considerations
To ensure a thorough and competitive review process, PCORI strictly enforces the formatting and administrative compliance guidelines outlined in the PFAs, FAQs, and Application Guidelines.

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1. Available at http://www.pcori.org/content/faqs-applicants/.
3. Available at http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/.
Applicants who fail to submit the required documents or who exceed the stated page limits may be rejected from the merit review process.

All rejection decisions made by the Contracts Management and Administration department are final. Please email pfa@pcori.org with any formatting or administrative compliance questions to ensure that your LOI or application will not be deemed noncompliant once submitted to PCORI. See Appendix 3: Administrative Actions.

Unless otherwise stated within the application guidelines, all submissions on behalf of an applicant organization are the property of that organization. PCORI will not share or publicize the contents of an organization’s application.

**Funding Mechanism**

PCORI issues contracts, rather than grants, to fund and administer meritorious research. PCORI funds projects that demonstrate the highest probability of completing on time and within budget, and meeting all milestones and deliverables. Applicants should submit representative budgets and research plans that will realistically allow the project to conclude within the approved period of performance. As part of its active portfolio management, PCORI provides contractual and programmatic monitoring throughout the contract term period. To review PCORI’s contract terms and conditions, see PCORI Standard Contract for Funded Research Projects.

**Who Can Apply**

Applications may be submitted by any private-sector research organization, including any nonprofit or for-profit organization; any public-sector research organization, including any university or college hospital or healthcare system; a laboratory or manufacturer; or a unit of local, state, or federal government. The Internal Revenue Service must recognize all U.S. applicant organizations. Nondomestic components of organizations based in the United States and foreign organizations may apply, as long as there is demonstrable benefit to the U.S. healthcare system and U.S. efforts in the area of patient-centered research can clearly be shown. Organizations may submit multiple applications for funding. Individuals are not permitted to apply. If you have questions about eligibility, please contact pfa@pcori.org.

![Note: A Principal Investigator (PI) may submit multiple LOIs in a cycle, but they must ensure that the research topics/projects are not similar. If a PI submits an LOI to multiple PFAs, LOIs that show scientific overlap or that appear to be duplicate submissions will be disqualified. PCORI will contact the PI and give them an opportunity to choose which PFA they would like to apply to. A PI can only submit one distinct LOI per PFA. However, an individual listed as a PI on one LOI may submit an LOI to another PFA.](http://www.pcori.org/sites/default/files/PCORI-PFA-Standard-Contract-for-Funded-Research-Projects.pdf/).

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be listed and serve in another role (e.g., co-investigator, co-PI) on other LOIs within the same PFA during the same cycle.

How To Apply
To submit an LOI and application (if invited), including all required documents, please follow the instructions provided in these guidelines and in PCORI Online. All documents must be submitted through PCORI Online. Please refer to the specific PFA for more information regarding the review process of LOIs and applications.

To submit an application or to register your organization in PCORI Online, you need a Data Universal Numbering System (DUNS) number and an Employer Identification Number (EIN). You can apply for a DUNS number and an EIN, if applicable.

Step 1: Register
To apply for PCORI funding, an applicant (PI or PI designee) must register in PCORI Online. A name, an email address, a password, and a security question and answer are required to register. PCORI strongly encourages only the PI to create the LOI/application record, as whoever created the record will have permanent access to it in PCORI Online.

Step 2: Submit a Letter of Intent (LOI)
An LOI is required for new and resubmitted applications. Download the PFA-specific LOI Template from the Funding Center. LOIs that exceed the three-page limit stated within the PFA will not be reviewed. For formatting instructions, please reference step 4 and the instructions listed on the LOI Template.

To submit an LOI you must go into PCORI Online, complete the required fields, and upload the completed PFA-specific LOI into the system. For detailed instructions on how to navigate the system, please see the PCORI Online User Manual: Start a Letter of Intent.

5 Available at http://pcori.fluxx.io/.
6 Available at https://www.dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number/.
8 Available at http://www.pcori.org/sites/default/files/PCORI-Online-Start-LOI.pdf
**Step 3: Initiate Application Process**

Applicants will be notified by the date specified within the PFA as to whether or not they have been invited to submit an application.

The application consists of seven sections within PCORI Online that must all be completed prior to submission. Please log in to PCORI Online to view the full list of questions.

**Step 4: Format and Complete Required Templates**

Required templates are available in the [PCORI Funding Center](http://www.pcori.org/funding-opportunities/). Find the PFA to which you are applying and download the correct PFA-specific templates, as templates vary from PFA to PFA and cycle to cycle:

- Do not reorganize sections within the templates.
- Do not alter header questions of the templates within your submission.
- You may delete instructional text.

**All required documents must be formatted as follows:**

- **Header:** Include the PI’s full name on every page in the top left corner.
- **Margins:** Use at least half-inch margins. The header may fall within the top margin, but the body of the text should not begin closer than a half-inch from the edge of the page.
- **Font:** Use Calibri size 11. Figures and captions may have size 8 font.
- **Page Numbers:** Uploaded documents must be consecutively numbered.
- **Spacing:** Use single spacing.
- **References:** Use American Medical Association (AMA) citation style.

**Step 5: Upload Required Documents**

Follow the [Application Checklist](http://www.pcori.org/funding-opportunities/) included in these guidelines to enter required information. Upload required documents to PCORI Online in the correct order. Use Adobe Acrobat Professional to combine documents into a single PDF file for upload. To upload, select the name of the required document type from the dropdown list. For detailed instructions, refer to the Templates and Uploads section of the [PCORI Online User Manual: Submitting an Application](http://www.pcori.org/funding-opportunities/).

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9 Available at http://www.pcori.org/funding-opportunities/.
10 See adobe.com for more information on Adobe Acrobat Professional.
Step 6: Submit for Authorization

Once all required information has been completed and uploaded, click “Submit to AO” to forward the application to your Administrative Official (AO) to authorize and submit. The AO must approve and submit the final application for official submission to PCORI prior to the deadline. The PI should notify the AO when the application is ready for review, AO approval, and submission. The PI and the AO may not be the same individual. Both the AO and the PI will receive an email confirming that PCORI has received the application.

When To Apply

Deadlines for each funding cycle are noted in the PCORI Funding Center and the PFA. System or technical issues with PCORI Online affecting on-time submission of an application must be reported to PCORI before the specified deadline. Problems with computer systems at the applicant’s organization or failure to follow instructions in PCORI Online, PCORI application guidelines, or a specific PFA are not valid issues warranting consideration of a deadline extension. Please see PCORI’s Policy on Submission of Research Contract Applications\(^{11}\) for complete information.

What To Include

Note: Only applicants selected to submit an application should begin the application process. You will be notified by December 18, 2015 as to whether or not you have been invited to submit an application.

Applicants are encouraged to review this entire section. Print and complete the provided Application Checklist to ensure that the LOI and application are submitted correctly. Download all required templates from the PCORI Funding Center.\(^{12}\)

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\(^{11}\) Available at http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/.

\(^{12}\) Available at http://www.pcori.org/funding-opportunities/.
## Application Checklist

### Letter of Intent
- **Letter of Intent**
  - PI and Contact Information
  - PFA-specific LOI Template

### Application
- **PI and Contact Information**
  - Entered previously as part of the LOI; review and modify if needed

- **Project Information**
  - Technical Abstract
  - Public Abstract
  - Project Narratives

- **Key Personnel**

- **Milestones/Deliverables Template**

- **Resubmission Letter (if appropriate)**

- **Research Plan Template**
  - Research Strategy
  - Dissemination and Implementation Potential
  - Replication and Reproducibility of Research and Data Sharing
  - Protection of Human Subjects
  - Consortium Contractual Arrangements
  - References Cited
  - Appendix (optional)

- **People and Places Template**
  - Professional Profile/Biosketch
  - Patient/Stakeholder Partner Profile/Biosketch

### Length/Limit

<table>
<thead>
<tr>
<th>Letter of Intent</th>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter of Intent</td>
<td>Enter into PCORI Online</td>
<td>3 pages</td>
</tr>
<tr>
<td>PI and Contact Information</td>
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</tr>
<tr>
<td>PFA-specific LOI Template</td>
<td>3 pages</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Application</th>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
</thead>
<tbody>
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</tr>
<tr>
<td>Project Information</td>
<td>Enter into PCORI Online</td>
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</tr>
<tr>
<td></td>
<td>Enter into PCORI Online</td>
<td>3,000 characters/spaces</td>
</tr>
<tr>
<td></td>
<td>Enter into PCORI Online</td>
<td>Refer to PCORI Online</td>
</tr>
<tr>
<td>Key Personnel</td>
<td>Enter into PCORI Online</td>
<td>As needed</td>
</tr>
<tr>
<td>Milestones/Deliverables Template</td>
<td>Save file as “Milestones_PI LastName.pdf” and upload</td>
<td>3 pages</td>
</tr>
<tr>
<td>Resubmission Letter (if appropriate)</td>
<td>Save file as “Resubmission_PI LastName.pdf” and upload</td>
<td>3 pages</td>
</tr>
<tr>
<td>Research Plan Template</td>
<td>Save file as “ResearchPlan_PI LastName.pdf” and upload as a single file</td>
<td>As noted below</td>
</tr>
<tr>
<td></td>
<td>Research Strategy</td>
<td>20 pages</td>
</tr>
<tr>
<td></td>
<td>Dissemination and Implementation Potential</td>
<td>2 pages</td>
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<tr>
<td></td>
<td>Replication and Reproducibility of Research and Data Sharing</td>
<td>2 pages</td>
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<tr>
<td></td>
<td>Protection of Human Subjects</td>
<td>5 pages</td>
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<tr>
<td></td>
<td>Consortium Contractual Arrangements</td>
<td>5 pages</td>
</tr>
<tr>
<td></td>
<td>References Cited</td>
<td>10 pages</td>
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<tr>
<td></td>
<td>Appendix (optional)</td>
<td>10 pages</td>
</tr>
<tr>
<td>People and Places Template</td>
<td>Save as “PeoplePlaces_PI LastName.pdf” and upload</td>
<td>As noted below</td>
</tr>
<tr>
<td></td>
<td>Professional Profile/Biosketch</td>
<td>5 pages per individual</td>
</tr>
<tr>
<td></td>
<td>Patient/Stakeholder Partner Profile/Biosketch</td>
<td>5 pages per individual</td>
</tr>
</tbody>
</table>
- Project/Performance Site(s) and Resources 15 pages

<table>
<thead>
<tr>
<th>Budget Template</th>
<th>Combine and save as “Budget_PI LastName.pdf” and upload As needed</th>
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</thead>
<tbody>
<tr>
<td>- Detailed Budget for Each Project Year (prime and subcontractors)</td>
<td></td>
</tr>
<tr>
<td>- Budget Summary for Entire Project (prime and subcontractors)</td>
<td></td>
</tr>
<tr>
<td>- Budget Justification (prime and subcontractors)</td>
<td></td>
</tr>
<tr>
<td>- Federally Negotiated or Independently Audited Indirect Cost Rate Letter (prime contractor)</td>
<td></td>
</tr>
<tr>
<td>- Fringe Benefit Rate Policy Verification Document (prime contractor)</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Letters of Support</th>
<th>Save as “Letters_PI LastName.pdf” and upload as a single file As needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Letters of Support Table</td>
<td></td>
</tr>
<tr>
<td>- Letters of Support</td>
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</tr>
</tbody>
</table>
An LOI must be submitted before the completion of your application. Enter information in the required fields in PCORI Online.

Upon receipt of LOIs, PCORI program staff will review them for programmatic fit and potential overlap with existing projects in the portfolio. If program staff assess that the LOI is a better fit for another program, they may transfer the LOI to that program. If that program is interested in inviting the applicant to submit an application, PCORI will notify the applicant and obtain his/her approval to switch programs. An applicant whose LOI does not meet program areas of interest, or whose LOI overlaps with existing projects in the portfolio, will not be invited to submit an application. Applicants will receive an email notification accepting or declining their LOIs as specified in the PFA.

PI and Contact Information

PCORI refers to three specific roles with particular responsibilities. Please keep the following in mind as you complete this section.

Principal Investigator (PI)

A. Description

- Applicants must designate one PI as the primary contact.
- The PI is responsible for the scientific or technical aspects and peer-review-related activities of the project.
- Applications can include, in addition to the PI, multiple co-PIs. (Note that only the primary PI’s name will be published with the contract if the project is funded.)
- The PI’s institution must be the primary institution for the award, unless approval was granted before the application deadline.
- Investigators may serve as PI on only one application per cycle for any individual PFA.
- PIs can participate in other applications (from the same or another organization) in a different role, such as co-PI, co-investigator (co-I), or consultant.

B. Activities

- The PI assumes responsibility and accountability for research execution, compliance, and organization conduct.
- The PI manages day-to-day operations of the project.
- The PI acts as lead research representative of the organization.
- The PI serves as the PCORI lead point of contact for programmatic matters.

Administrative Official (AO)
A. Description
- The AO is responsible for matters related to the award and administration of the contract.
- The AO cannot be the PI.
- The AO’s signature certifies that the organization will be accountable for the appropriate use of funds awarded and for the performance of the PCORI-supported project.

B. Activities
- The AO manages contract activation, modifications, and additional required administrative matters.
- The AO certifies contract compliance of all applicable assurances and certifications referenced in the application.

Financial Official (FO)

A. Description
- The FO is responsible for all required expenditure reports.

B. Activities
- The FO completes and certifies the required yearly expenditure reports.
- The FO accounts for contract funds and submits invoices and payment details.

PFA-specific LOI Template

Download the PFA-specific LOI Template from the Funding Center. Provide a description that allows the scientific community to understand the project, including its aims and study design, without reviewing the full application. Any LOI that exceeds the three-page limit will not be reviewed. All references must be included as in-text citations using AMA citation style with full citations listed at the end of the LOI. *(Note: All LOI templates should follow the formatting guidelines listed in Step 4.)*

To submit an LOI, save the completed PFA-specific LOI as a PDF. Label your LOI file using the following nomenclature: “PI LastName_(last five digits of Request ID)_LOI.pdf.” A request ID number will be automatically generated once the LOI has been saved. Upon selecting the “Save and Review” button, the new request ID number will be visible at the top of the webpage in PCORI Online.

Application Requirements

The following sections are applicable only if you have been invited to submit an application. You are invited to submit an application based on the information provided in the LOI. Any changes to the following require PCORI’s approval:

- Principal Investigator
- Institution
- Study design
- Research question(s)
- Specific aims
Comparators

If you need to change any of this information or have any questions, email pfa@pcori.org.

PI and Contact Information

Review information transferred from your LOI and update as needed.

Project Information

Enter the following information directly into PCORI Online.

Technical Abstract

Provide a technical abstract within PCORI Online that summarizes your research strategy. The abstract should include the following sections:

- Background and Significance: State the problem or question the research is designed to address.
- Study Aims: Briefly describe the specific aims of the study, including specific research question(s) and long-term objectives.
- Study Description: Provide a detailed description of the study design. Please include, as applicable:
  - Overall study design
  - Main components of the intervention and comparator(s)
  - Study population (source, inclusion criteria, demographic information, clinical status, target sample size by arm)
  - Primary and secondary outcomes
  - Analytic methods

Project Narratives

PCORI may use these responses for programmatic assessment, to assign applications to the appropriate review panel, and to provide a high-level overview to merit review panel members. In addition to responding to other questions, you must fill in the following text boxes (refer to PCORI Online for character limits, including spaces, for each of the bullets listed below):

- Names of the study comparators
- Project goals
- Patient engagement plan
- Number of arms in the proposed trial, if applicable
- Length of follow-up after intervention, if applicable
- Primary and secondary outcomes
- Recruitment and retention plan for study participants and (if applicable) underserved populations
Log in to PCORI Online to view the full list of questions that must be completed prior to submission.

Public Abstract

Provide a description of your project, written in lay language, that the general public will understand. Please include the following:

- Description of the problem your project seeks to solve
- Outcomes you hope to achieve
- Brief background on why this project is important to patients
- Explanation of how patients and other stakeholder partners will help to make the project successful

This summary should be comprehensible to a variety of audiences and will be reviewed by scientists, patients, and stakeholders during the merit review process. Public abstracts from applications that are awarded a contract will be posted on PCORI’s website. The names of the individuals and organizations that comprise the research team, including patient and stakeholder partners, will also be posted on PCORI’s website, as described in the Key Personnel section below.

Key Personnel

PCORI identifies key personnel as any individual who is considered critical to the project’s scientific development and execution in a measurable way and whose absence from the project would negatively affect the likelihood of success.

Note the following:

- Applications can include one PI and multiple co-PIs.
- PIs can serve in other roles (co-PI, co-I, or consultant) on other applications.
- If applicable, applicants must explain the rationale for including a co-PI in the budget justification.
- Consultants and personnel from collaborating organizations may be included as key personnel if they meet the definition. See the Glossary for “Consultant” and “Subcontractor” definitions.
- Project Directors, or equivalent, are considered key personnel.
- Applicants are required to identify the patient and stakeholder partners, whether individuals or organizations, that will assist in conducting the project. In the event that your project is funded, these partners will be named on the PCORI website along with the PI and the recipient organization and may be recognized in other PCORI communications, such as press releases, or in response to requests for information. By providing the names of the partnering individuals and organizations, you represent that you have obtained any required permission or consent from the respective partners to disclose their names to PCORI and to permit PCORI to make their names publicly available. In the event that a patient or
stakeholder partner wishes to remain anonymous, please contact us at pfa@pcori.org for additional guidance on how to recognize such partners appropriately.

- If awarded, the addition or replacement of key personnel listed in the submitted application requires approval by PCORI during contract negotiation and post-contract execution, as detailed in the contract terms and conditions. To review PCORI’s contract terms and conditions, see PCORI’s Standard Contract for Funded Research Projects.  

Milestones

Complete all required sections in the Milestones/Deliverables Template and upload as a single PDF to PCORI Online. Milestones are concrete, specific events or accomplishments that are documented by deliverables. They include only activities that are supported by the PCORI contract. Examples of milestones include reaching specific patient accruals, survey development, commencement of the intervention, and establishment of project-specific databases. See Appendix 1: Example Milestones for a more complete list. Milestones should also include activities dedicated specifically to engagement, such as the recruitment of all patient and stakeholder research partners, results of annual surveys of patient and stakeholder partners, or meeting minutes of patient and stakeholder advisory councils.

Interim and final deliverables will be included in your research contract if your application is funded. Please note that PCORI reserves the right to request additional deliverables during the life of the project.

Examples of deliverables that may be required following contract execution include but are not limited to:

- Copies of Institutional Review Board (IRB) approval
- Abstracts accepted or presentations made
- Manuscripts accepted for publication
- Meeting minutes from patient and stakeholder advisory panels, committees, or work groups
- Copies of drafts of instruments, data dictionaries, educational materials, manuals, or other project deliverables
- Copies of newsletters highlighting the project from patient and stakeholder partner organizations
- Reports of endorsement of research findings by scientific and consumer groups
- Reports of plans to adopt research findings in practice
- Charts, tables, graphs, or other summaries of preliminary data
- Registration of the trial on ClinicalTrials.gov
- Data and Safety Monitoring Board (DSMB) meeting recommendations
- Other documents or materials, as appropriate

Note: Milestones entered into the template should be specific deliverables associated with a timeline and should include project objectives that will be accomplished at specific times during the proposed project.

Resubmission Policy and Letter

An applicant may resubmit an application that was not funded. A proposal is considered a resubmission after it has completed PCORI’s merit review process (i.e., the applicant has received a summary statement). A previous submission in the form of an LOI only (without a full application) is not considered a resubmission. If an application was deemed nonresponsive and did not progress through the full review process, the applicant is required to submit a new LOI. When resubmitting an application, applicants are required to include the three-page Resubmission Letter. All applications are evaluated using the same review criteria. Responsiveness to previous reviewers’ concerns is not sufficient; the application must be patient-centered, methodologically rigorous, and programmatically responsive.

If you submit the same application to a different program/PFA, it is considered a new submission. You may only resubmit to the same program/PFA, as different programs have different requirements. PCORI does not limit the number of times an applicant may resubmit.

Invitation To Resubmit

Program staff may invite applicants from previous cycles to resubmit. If invited, applicants will bypass the LOI review stage. Instead of completing and uploading an LOI template, invited applicants are required to upload their letter of invitation during the LOI process. Invited applicants are still required to complete the LOI and application fields in PCORI Online by the submission deadlines. Unless the applicant has explicit and documented approval from the program staff to alter the originally submitted study aims of the application, the invited resubmissions should remain the same as in the original application.

An invitation to resubmit is not a guarantee that the application will be selected for funding. Invited applicants must adhere to the updated guidance in the PFA and compete with other invited and new applicants.

Research Plan Template

Complete all required sections in the Research Plan Template and upload as a single PDF to PCORI Online. The research plan includes the following: Research Strategy, Dissemination and Implementation Potential, Replication and Reproducibility of Research and Data Sharing, Protection of Human Subjects, Consortium Contractual Agreements, References Cited, and an Appendix (optional).
This component (up to 20 pages) addresses the following sections: (A) Background, (B) Significance, (C) Study Design or Approach, (D) Patient Population, (E) Research Team and Environment, and (F) Engagement Plan.

While completing Study Design or Approach (Section C), applicants must cite PCORI’s Methodology Standards.

### Adherence to PCORI Methodology Standards

Applicants are required to adhere to the PCORI Methodology Standards and accepted best practices. PCORI Methodology Standards include 47 individual standards that fall into 11 categories. The first five categories are cross-cutting and relevant to most PCOR studies. Researchers should refer to all of these standards when planning and conducting their research projects. These five categories are:

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

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

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

These standards should be considered minimal. Additional best practices, including guidelines for the conduct of clinical trials developed by other organizations, should be addressed in the application.

All applicants should specifically discuss their capacity to measure such factors as differential adherence to chosen treatments (or participation in intervention programs) that could result in differences in the effectiveness of the alternative interventions being compared in clinical populations.

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Following PCORI’s Methodology Standards, cite each relevant standard and provide a brief statement indicating how your proposed research demonstrates adherence to the standard. Do not address standards that are not applicable to your study.

PCORI program staff will review relevant standards and plans for adherence with the research team during the contract negotiation phase for applications that are awarded funding.

While completing the Research Team and Environment (Section E) component, applicants should describe:

- How and why those research sites were selected
- How the sites tie back to the research project
- The resources, facilities, support, and collaborations available to ensure the project’s success
- Ways in which the project will benefit from the unique features of the research environment or community involvement
- How the sites will work together to ensure that milestones will be achieved
- 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
- Access to and support of patient groups

The Engagement Plan (Section F) follows PCORI’s Engagement Rubric\(^\text{15}\), which should be used as a guide. Before completing this section of the Research Strategy, applicants are encouraged to review the rubric, PCORI’s PCOR Engagement Principles (noted in the rubric), and PCORI’s Methodology Standards Associated with Patient-Centeredness\(^\text{16}\). Applicants must outline how patients and other stakeholders will participate as partners in various phases of the proposed research. To assist applicants, PCORI provides sample engagement plans\(^\text{17}\) from previously funded projects.

The rubric and sample engagement plans are not intended to be comprehensive or prescriptive; instead, they provide a variety of options to incorporate engagement, where relevant, into the research process. Applicants may choose to include some, but not all, activities and may include additional innovative approaches.

**Justification of Assumptions**

PCORI specifically seeks studies that are powered to detect meaningful effects. Applicants must justify the proposed sample sizes by explaining the assumptions used in all study power calculations.

\(^\text{15}\) Available at http://www.pcori.org/sites/default/files/Engagement-Rubric.pdf.
\(^\text{17}\) Available at http://www.pcori.org/sites/default/files/PCORI-Sample-Engagement-Plans.pdf.
For example, the application should clearly state all the necessary assumptions, such as the outcome(s) on which the power calculations are based, the estimated difference in the effect size between study arms, the standard deviation of the effect size measure, the type I and II error rates, and any other assumptions. All such estimates must be justified by referring to prior published research or preliminary data.

**Dissemination and Implementation Potential**

In this component (up to two pages), describe the potential for disseminating and implementing the results of your work in other settings.

PCORI is interested in robust research findings that can be rapidly disseminated and implemented in clinical and community practice, thus facilitating improvements in patients’ and other stakeholders’ healthcare decision making. Applicants should include a section that describes the potential for impact of disseminating project findings and facilitating their widespread use in practice. Applicants should describe possible barriers to dissemination and implementation of their work in other settings and any other limitations of the study that may have an impact on the usability of the findings (e.g., proprietary issues, applicability, scalability, appropriate settings of care). Please note: we are asking you to describe the potential for dissemination and implementation. PCORI does not expect you to budget for dissemination and implementation work at this juncture. For projects that produce important findings, PCORI will consider subsequent applications that support dissemination and implementation efforts through separate funding announcements and other mechanisms.

PCORI encourages applicants to think creatively about how to disseminate findings. Many patients and relevant stakeholders do not access information about their disease condition from scholarly journals or from attending scientific meetings. Refer to PCORI’s Methodology Standards and the Engagement Rubric for guidance on how to include patient and stakeholder partners in the dissemination process, as relevant. In addition, applicants should describe how study participants will be informed of the study results.

**Note:** Researchers are encouraged to submit documentation of any implementation agreement with the sponsoring organization confirming that successful interventions will be implemented by that organization on a large scale. This agreement will be viewed as a positive factor during Merit Review. Please include this with the letters of support PDF document, as the last item.

**Replication and Reproducibility of Research and Data Sharing**

In this component (up to two pages), describe the ability to replicate and reproduce potentially important findings from PCORI-funded studies in other data sets, clinical settings, and/or populations. This assessment is essential to building confidence in the accuracy of these findings. PCORI promotes sharing of study documentation (e.g., study protocol, programming code, and data definitions) so that other researchers may replicate the findings in other populations. Propose a
method for sharing data, if such activity is requested later. Applicants must describe the following requirements as they complete this template.

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

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 to PCORI with the 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 study’s PI.
- Proposed clinical trials or observational studies should be registered at ClinicalTrials.gov.
- Proposed evidence synthesis studies should be registered at http://www.crd.york.ac.uk/prospero/.

**Reproduction of research findings:** This requirement refers to reproducing research findings in the same data set 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. Therefore, PCORI will require a data-sharing plan (described below). Although the plan described below is required of all applicants, subsequent data sharing would be requested by PCORI only after review of findings and a decision that the findings warrant the expense and time of data sharing.

PCORI is committed to maximizing the utility and usability of data collected in our funded projects. We may request that awardees prepare documentation to accompany their final data sets—documentation that enables others in the research community to use the data for additional or secondary analysis and to make the data and documentation available upon request.

The data-sharing plan must:

- State how a complete, cleaned, de-identified copy of the final data set used in conducting the final analyses will be made available
- Propose a method by which investigators will make this data set available, if requested
- Propose a budget that would cover costs of data sharing, if requested

**Note:** Do not include this plan in the proposed budget of your application. 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.
Protection of Human Subjects

In this component (up to five pages), describe the protection of human subjects involved in your research. PCORI follows the Federal Policy for the Protection of Human Subjects (45 CFR part 46), including the Common Rule. For more detailed information, please see Section 5 “Human Subjects Research Policy” from the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, issued by the US Department of Health and Human Services (HHS). Please refer to the Required Education of Key Personnel on the Protection of Human Subject Participants requirement, below, as you complete this section.

Consortium Contractual Arrangements

In this component (up to five pages), describe the proposed research projects that will be performed by subcontracted organizations. Explain the strengths that these partners bring to the overall project to ensure successful submission of contract deliverables in accordance with the milestone schedule.

Please keep the following in mind as you complete this section:

- The prime applicant is required to flow down PCORI’s contract terms and conditions to all approved collaborators and subcontractors.
- Signed subcontract agreements are not required at the time of application submission to PCORI.
- The submission of an application to PCORI signifies that programmatic and administrative personnel from your organization and from all proposed subcontract organizations that will be involved in this project are aware of your organization’s subcontract agreement policy and that all involved organizations are prepared to establish the necessary interorganizational agreement(s) consistent with that policy.
- If applicable, subcontract personnel should be included under Key Personnel.
- Budget information for subcontracted organizations should be included in the Detailed Budget, Budget Summary for Entire Project, and Budget Justification.

References Cited

This component (up to 10 pages) is included in the Research Plan Template. Throughout the entire Research Plan, applicants should use in-text citations to reference published materials. In this section, list the full bibliographical citation of each reference. Each reference must include the 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 AMA style when 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 numbers along with the full reference. 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. Websites should be

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Appendix (Optional)

This component (up to 10 pages) is included in the Research Plan Template. Applicants may provide additional materials that support your study (e.g., survey instruments, interview guides). Note that reviewers are not required to review this section during merit review.

People and Places Template

Professional Profile/Biosketch and Patient/Stakeholder Partner Biosketch

These components are included in the People and Places Template. Complete a profile/biosketch section (up to five pages per individual) for each person listed as key personnel (including PI, co-PI, co-I, or other significant contributors), copying the tables provided in this section, as needed. Please note that you may submit a National Institutes of Health (NIH)-formatted biosketch in lieu of a PCORI-formatted biosketch. Patient or stakeholder partners serving as key personnel may choose to fill out a Patient/Stakeholder Partner Biosketch in lieu of the Professional Profile/Biosketch. At a minimum, each profile must include the person’s name, title, and degrees; each profile or biosketch may be no more than five pages. PCORI is especially interested to learn how each individual’s previous experience, past performance, and training in the field of patient-centered outcomes research (PCOR) has prepared him or her to conduct this research. The backgrounds, relevant experiences, and roles of patient and stakeholder partners should also be described.

Applicants should assemble a research team that is best poised to complete the work. Applicants should demonstrate that the study team’s experience, leadership approach, governance, and organizational structure are appropriate for the project and will serve to achieve the project goals.

Project Performance Site(s) and Resources

This component (up to 15 pages) is included in the People and Places Template. Demonstrate in detail that the proposed facilities have the appropriate resources required to conduct the project to plan, within budget, and on time.

Applicants should provide a description of the facilities that will be used during the project, including capacity, capability, characteristics, proximity, and availability to the project.

Budget Template

Complete all required sections, including the Peer Review Budget section, and upload the Budget Template and Budget Justification to PCORI Online as a single PDF. Do not upload separate budget files for subcontractors; include all subcontractor budget files within the prime applicant’s PDF budget upload.
Detailed Research Project Budget for Each Year of the Research Project Period

Complete a Detailed Budget for each year of the project for the prime applicant and any subcontractor(s) proposed in your application. For example, if your study lasts two years, the prime applicant must complete a Detailed Budget for Year Two as well as for Year One. The subcontractor should follow the same process and complete a Detailed Budget for each year of the proposed study.

All personnel information should be entered in the Personnel tab corresponding to that year in the budget template. You may add additional rows for personnel as needed. Following the example of a two-year study, you may delete the unused Year Three–Five Detailed Budget tabs. However, you may not add additional years. Maximum project periods are stated in each PFA. Note the following:

A. Personnel Costs

- Personnel Costs: Include the base salary for each scientific/technical staff member, employee patient or stakeholder partner, or other personnel on your project that is or are not accounted for in Section B: Consultant Costs. Provide a clear distinction between individuals who are considered Key Personnel and Other Personnel.
- PCORI will reimburse personnel costs that are consistent with and do not exceed what the applicant would normally pay under its own policy. PCORI may request salary verification during the contract activation process. Such compensation may include salaries and fringe benefits. See Appendix 2: Allowable and Unallowable Costs for more information.
- Salaries include wages earned by an employee, and fringe benefits may include insurance and retirement plans. If the application is recommended for funding, the applicant will be required to provide documentation to support the fringe benefits.
- Level of Effort: Personnel contributing to a PCORI-funded research project are expected to monitor their total percent effort across all their active funding, so it does not exceed 100 percent. Before the application is submitted to PCORI, the AO must certify that all key personnel will not exceed 100 percent effort, if funded. Effort must be reported by the percentage of time over the course of the project year. If salary support is not being requested, use $0 for the base salary.
- All personnel 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 each person in the Budget Justification and Detailed Budget. Describe in the Budget Justification detail the specific functions of the personnel in each project role. Provide an explanation of how the role supports the project aims and note any overlap in job functions.
- Salary Cap: The PCORI base salary cap for personnel is $200,000 annualized per individual, per year, exclusive of fringe benefits. An individual who earns less than $200,000 should use his or her actual base salary to calculate personnel costs. An individual with a full-time employee base salary of 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 institution’s own policy. In the budget upload, following the Budget Justification, applicants must provide a verification of the fringe benefit rate policy for the prime organization.

Personnel costs must account for the level of effort required to initiate and complete the mandated Peer Review Process. See the Detailed Peer Review Budget for Peer-Review-Related Costs section for additional instructions.

B. Consultant Costs

• Consultant costs apply to those individuals who are not employees of the applicant organization or under a subcontract agreement as members of the contracted staff.
• Payments to nonemployee patient and stakeholder representatives should be included as consultant costs in the budget.
• Provide the total cost of consultant(s), as well as names, expected number of hours, and hourly rate.
• Include the daily consultant fee, travel expenses, nature of the consulting effort, and reasons that consultants are required for the proposed project. Note any overlap in duties with personnel. Consultant costs must be reasonable and justified within the Budget Justification.
• Include letters of support from all consultants, verifying the work to be performed and how the negotiated rate was established. See the Letters of Support section for more detailed information.

C. Supply Costs

• Supplies must be directly allocable and allowable to the proposed project and not part of general or administrative use. Supplies are 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.
• Indicate general categories such as mailings, printing, lab, and equipment with less than $5,000 per-unit cost. Provide detailed explanations for all costs that exceed $1,000. You will be asked to provide further detail for each of these costs in the Budget Justification.
• For all supply costs, provide computations for how applicants arrived at the specific number.

Note: PCORI considers computers, tablets, docking stations, mobile data and protection plans, and software to be general office supplies that are not allowable as direct cost charges. If these items are proposed as essential in the performance of the research project, the following must be in the Budget Justification:

  o Detailed explanation of reason that the purchase of these items is required to complete the proposed research project
Statement verifying that the requested items are not currently available for use by the PI
Statement assuring that the items will be purchased in accordance with applicable cost principles

- **Items purchased under PCORI-funded projects are not to be used as incentives to recruit or retain graduate students or any other project personnel.**

### D. Travel Costs

- Travel may include any domestic or international travel by project personnel or consultants directly related to, and necessary for, the project and within the limits explained below. PCORI uses the Federal Travel Regulations guidelines for per diem and other reimbursements.
- Travel costs should be itemized per trip and be described as either scientific travel or programmatic travel, as outlined below:
  - Scientific travel includes travel to present at conferences, symposiums, and similar events. Scientific travel is capped at $10,000 over the life of the project. This cap is inclusive of the prime and all subcontractor scientific travel costs.
  - Programmatic travel includes travel needed for the conduct of the project (e.g., focus groups, project team meetings, data collection). PCORI closely reviews all travel costs for reasonableness.
  - Airline or rail costs cannot exceed the customary standard commercial fare (coach or equivalent) or the lowest commercial discount fare. PCORI will not compensate upgrades.
- 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 Budget Justification, applicants must provide additional detail to explain the basis for the costs listed and describe how the travel is directly related to the proposed research project and is necessary for achieving programmatic objectives.

### E. Other Expenses

- Indicate and include general categories such as printing, publication, illustration costs, and nonconsulting service contracts, when applicable.
- Use this section to include direct costs that cannot be accounted for in other budget categories. For example, these costs may include warranties, computer services, data warehousing, or participant incentives.
- In the space provided, include a detailed explanation for items that exceed $1,000. Applicants must provide further detail for each of these costs in the Budget Justification.

### F. Equipment Costs
• Equipment costs include tangible items that have a per-unit cost of $5,000 or more and a useful life greater than one year.
• Up to three quotes for each item of proposed equipment must be included with the Budget Justification.
• Costs must be reasonable and necessary for the project.

Note: Title to equipment vests with the recipient organization. PCORI, at its discretion, may require applicants to share or transfer equipment to other PCORI-funded projects within the recipient organization. Equipment disposition must be approved by PCORI.

G. Subcontractor Costs

• This category includes all consortium and contractual costs. The prime awardee must issue a subcontract agreement to a collaborator if the criteria listed below are met:
  o The subcontractor PI’s effort on the project is calculated as part of his or her “professional time” for his or her employer organization.
  o The subcontractor will be using significant resources (e.g., office space, supplies, computer, and personnel) at his or her own organization when working on the PCORI-funded project.
• State in the Budget Justification why each subcontractor was selected. Provide detail on their specific role and the aim/deliverable they will be supporting on this project.
• Subcontractors must adhere to all PCORI budget guidelines, including allowable and unallowable costs.

H. Indirect Costs

• PCORI limits the total indirect costs to 40 percent of personnel, consultant costs, travel, supplies, other expenses, and to $25,000 of all combined subcontractor costs.
• Applicants who do not have a federally negotiated indirect cost rate may assess up to 10 percent indirect costs, to be noted in the Budget Justification.
• Foreign applicants are eligible for no more than 10 percent indirect costs.

A copy of the prime applicant’s federally negotiated or independently audited indirect cost rate letter must be submitted with the application. Include these copies in a single file with the Budget Justification.

In the event that an indirect cost rate agreement is more restrictive than that of PCORI’s accepted indirect cost application, PCORI will allow the applicant to use the less restrictive rule when calculating indirect costs on submitted budget categories.

Detailed Peer Review Budget for Peer-Review-Related Costs

The detailed Peer Review Budget shall include costs related to the Peer Review Process. Please complete a Detailed Budget for the Peer Review Process (see Peer Review Budget tab in the Detailed Budget Template). Please note that the Total Budget will include the Peer Review Budget and the
Research Project Budget when determining compliance with the **Maximum Project Budget in the PFA.**

- Personnel costs related to Peer Review Process are limited as follows:
  - PI's level of effort for the completion of Peer Review Process is limited to a maximum of 20 percent level of effort for 90 days
  - Support staff's level of effort for the completion of Peer Review Process is limited to a maximum of 100 percent for 1 FTE for 90 days
- PCORI may accept variations to the Peer Review Budget limitation. For example, the Peer Review Budget may be extended to 180 days at 10 percent PI's level of effort and 50 percent support staff's level of effort. Alternatively, the Peer Review Budget may budget for two peer review support staff at 50 percent level of effort. The maximum funding for the Peer Review Budget may not exceed the total budget calculation based on the aforementioned limitations.
- The Salary Cap applied to the Research Project Budget applies to the Peer Review Budget.
- Include a Budget Justification for the Peer Review Budget.
- Ensure that the Peer Review Budget is included in the Budget Summary.
- PCORI expects applicants to identify the peer review support staff role within the budget at the time of submission. The PI has full discretion in identifying peer review support personnel.
- Personnel costs associated with the peer review process are to be budgeted within the prime institution’s budget.

**Budget Summary for Entire Project**

Complete a Budget Summary for the entire project for the prime applicant and each subcontracted organization. See Appendix 2 to review acceptable and unacceptable uses of PCORI funding.

**Budget Justification**

Complete a Budget Justification for the prime applicant and each subcontracted organization for the entire Research Project Budget and Peer Review Budget for all research and peer-review-related costs. Provide sufficient detail to explain the basis for costs and the reason that the costs are necessary to the project.

Provide detail to explain the basis for travel costs and describe how the travel is directly related to the proposed research and necessary for achieving programmatic objectives.

Describe in detail the specific role and tasks each member of the research team will be performing and their impact on the project plan. PCORI will evaluate each member contribution as listed in the Budget Justification to validate meaningful contribution. Provide a clear distinction between individuals who should be considered Key Personnel and those who should be considered Other Personnel.
Specify any other sources of funding, currently available or anticipated, to support the proposed research project. Include funding amounts and the period during which the funding will be available. Use continuation pages as needed.

Letters of Support

Save all letters of support as a single PDF file and upload to PCORI Online, using the Letters of Support Table as the first page of the file. Follow the guidance below and in the table template to enable easy reference for merit reviewers and PCORI staff. Reviewers are asked to consider the letters of support as outlined in the template and in this guidance. Failure to assemble the letters properly may result in key information being missed by the reviewers. If this occurs, PCORI will not send the application for re-review because it will be deemed an error in application assembly, not an error in review.

All letters of support should be addressed to the PI and demonstrate the commitment of key personnel and supporting organizations (e.g., co-PIs, co-Is, consultants, patient and stakeholder partners, stakeholder organizations) to your proposed project. Letters of support are not required for personnel who are not contributing in a substantive, measurable way to the scientific development or execution of the project. Letters of support should clearly reflect the involvement and material contribution to be provided by the signatory parties, and are meant to confirm the commitment of collaboration.

PCORI may contact any individuals/organizations included in the letters of support with questions or to confirm support as described in the letters.

Letters of support should be organized in the following manner:

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organizational official, confirming the institutional support of the proposed project, space to conduct the research, equipment, and other resources available for the project, including staff. Also strongly encouraged is a letter from the leadership of your department or organization affirming support to disseminate research findings that are appropriate and warranted for implementation.

- **Letters of Collaboration:** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. Letters of support from patient and stakeholder partners should describe clearly the origin of the study topic and the role of the partners in defining the question, outcomes, comparators, goals and outcomes, etc. We also strongly encourage letters from patient or stakeholder partners or partnering organizations affirming support to disseminate and implement research findings that are germane and warranted for implementation. Please include a letter of support for each consultant verifying the work to be performed and their negotiated rate.

- **Letters Confirming Access to Patient Populations, Data Sets, or Additional Resources:** If the proposed research plan involves access to patient populations, data sets, or additional
resources, include a letter of support, signed by the person with approval authority, confirming such access. If access cannot be confirmed at the time of contract negotiation, PCORI reserves the right to withhold funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.

- List all letters in the table and include the page number on which the letter can be found in the single PDF file. PCORI will not accept letters of support submitted more than 24 hours after the deadline.

**Additional Requirements**

Awardees are required to comply with the following requirements.

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

PCORI requires all applicants to adhere to the NIH policy on education in the protection of human subject participants in the conduct of research. This applies to all personnel listed as Key Personnel in the application. The policy and FAQs are available from the NIH website.¹⁹

**PCORI Public Access Policy**

PCORI requires all awardees to adhere strictly to PCORI’s publication policies, which will be shared with awardees within the research contract.

**Registering Research Projects**

PIs are required to use the following naming convention: “PCORI-PCORI application number” (i.e., PCORI-XXXX-XXXXX). Clinical trials must be registered before enrollment of the first patient. All trials that meet the definition on the NIH database²⁰ (see “Data Element Definitions”) are required to register.

Funded clinical trials or observational outcomes studies must be registered at ClinicalTrials.gov.

Funded evidence-synthesis studies must be registered at PROSPERO.²¹ Funded patient registries must be registered at https://patientregistry.ahrq.gov/.

**Standards for Privacy of Individually Identifiable Health Information**

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

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²⁰ Available at https://prsinfo.clinicaltrials.gov/.
²¹ Available at http://www.crd.york.ac.uk/prospero/.
of individually identifiable health information and is administered and enforced by the HHS Office for Civil Rights.

Decisions about the applicability and implementation of the Privacy Rule reside with the researcher and his or her institution. The Office for Civil Rights 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 is available at NIH.

**Award Funding Conditions**

At any time during the contract, PCORI reserves the right to discontinue funding for awardees who fail to meet the mutually-agreed-upon milestones. Applicants’ proposed milestones will be finalized in contract negotiations and prior to execution. For more information, please see PCORI’s [Standard Contract Template](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html).

**Co-Funding**

PCORI partners with various other research organizations to leverage additional funds for some of its programs. If you currently have a funded project and would like to seek PCORI funding to add a new aim to the study that advances PCORI funding objectives, you may submit an application. We recommend that you speak with a Program Officer in advance.

**Note:** PCORI will not fund a project already funded through another funding entity. By submitting the application to PCORI, the AO is certifying that there is no overlap in funding at the time of submission. Prior to receiving a PCORI contract, awardees must disclose all current and pending support.

**Dissemination and Data Sharing**

PCORI is committed to the publication and dissemination of all information and materials developed using PCORI funding, in accordance with its authorizing legislation. All recipients of PCORI contracts must agree to these principles and take steps to facilitate availability of data.

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22 Available at [http://www.hhs.gov/ocr/](http://www.hhs.gov/ocr/).
Appendix 1: Example Milestones

Milestones are significant events, deliverables, tasks, and/or outcomes that occur over the course of each project signifying progress of the study. The completion of each milestone is intended to mark progress toward the project goals and to ensure that the project is on schedule and likely to be completed within the contract period. Below is a list of milestone examples you may reference as you complete this section of your application:

- IRB approval
- Documentation of adherence to PCORI’s Methodology Standards
- Recommendations from DSMB meetings every six months
- Determination of the appropriate study database and registration (e.g. ClinicalTrials.gov, RoPR, or other)
- Start of recruitment (indicate target total)
- Completion of 25 percent of recruitment (indicate the number)
- Completion of 50 percent of recruitment (indicate the number)
- Completion of 75 percent of recruitment (indicate the number)
- Completion of recruitment (indicate the number)
- Start of follow-up data collection (if multiple follow-up time points are included in the study protocol, create a separate milestone for each data collection time point)
- Completion of 25 percent of follow-up data collection (if multiple follow-up time points are included in the study protocol, create a separate milestone for each data collection time point)
- Completion of 50 percent of follow-up data collection (if multiple follow-up time points are included in the study protocol, create a separate milestone for each data collection time point)
- Completion of 75 percent of follow-up data collection (if multiple follow-up time points are included in the study protocol, create a separate milestone for each data collection time point)
- Completion of follow-up data collection (if multiple follow-up time points are included in the study protocol, create a separate milestone for each data collection time point)
- Intervention materials complete
- Final study protocol
- Primary completion date (if applicable; the primary completion date is the date that the final subject [or participant] was examined or received an intervention for the purposes of final collection of data for the primary outcome; the primary completion date is defined in Section 801 of the Food and Drug Administration Amendments Act of 2007)
- Notification of posting final protocol on ClinicalTrials.gov
- Conduct baseline assessments or measurements
- Start follow-up assessments or measurements
- Complete follow-up assessments or measurements
- Submit results to ClinicalTrials.gov, as applicable
- Manuscript submission or notification of publication
- Data sets, analytic data sets, and codebook
- Copies of published manuscripts
- Engagement updates, every six months, noting specific engagement activities that patients and stakeholders participated in during the reporting time period; examples of engagement activities, include describing how patients and stakeholders were involved in the development of intervention materials and describing patient and stakeholder involvement and contribution in the early stages of the research project, such as the enrollment of research participants, baseline assessments, and the process evaluation component

At the discretion of the Program Officer, milestones listed above may be deemed irrelevant (e.g., recruitment milestones may not be relevant for observational studies), or additional reporting, such as monthly recruitment numbers, may be required.
Appendix 2: Allowable and Unallowable Costs

Acceptable uses of PCORI research contract funds are those that directly support the proposed research project, including collection and analysis of data and obtaining relevant data sets. Because PCORI primarily funds comparative effectiveness research (CER), the research projects generally involve the comparison of clinical interventions or strategies that are considered to be accepted standard of care and are not experimental or investigational. As a result, in developing proposed Detailed Budgets, it is important for funding applicants to think carefully about which costs derive from, and directly support, the research project, as opposed to those costs that would otherwise be incurred in the course of providing the clinical care and health-related costs around which the research project is organized.

Allowable costs (i.e., those costs that can be included in a proposed Detailed Budget in applying for a PCORI Funding Award and charged to the award) may include the following costs that derive from and directly support the research project:

- Salaries and fringe benefits for study investigators and other research project staff (including engaged patient and stakeholder research study partners) related to their percentage of effort on conducting the research project (such costs should not include personnel who deliver patient care as a component of their participation in the research project)
- Consultant fees
- Travel for mandatory investigator meetings
- Travel that is otherwise necessary for conducting the research project
- Supplies
- Equipment
- Subcontracts
- Expenses related to conducting engagement activities with patients and other stakeholders
- Other direct research expenses
- Indirect costs

Costs related to the conduct of the research project must be specifically requested by a funding applicant through itemization on the Detailed Budget and will be considered by PCORI in the course of making an award. The following principles and requirements generally apply to PCORI’s evaluation of the proposed budget and determination of allowable costs and should guide applicants in preparing their Detailed Budgets:

- In general, costs for study interventions that constitute the procedures, treatments, interventions, or other standard clinical care (“patient care”) that are being proposed for comparison in the research project (“patient care costs”) will not be covered by PCORI. Patient care costs should be covered by the host healthcare delivery system, third-party payer, manufacturer of the product, developer of an intervention, or other interested party.
- The willingness of one or more stakeholder groups to cover patient care costs that will be incurred during the research project, even when one of the comparators is not currently directly covered by insurance, will be taken as a strong endorsement of the research project.
by the stakeholder group. Such commitments also provide an indication that the stakeholder groups will use the research study’s findings. (Such support for the study by a stakeholder group should be discussed in the application.)

- Except for specific permission in exceptional circumstances, PCORI will not cover patient care costs.
- PCORI may consider coverage of the co-payment or coinsurance costs of participating study subjects when necessary to preserve blinding in a study or to ensure access to the study for vulnerable populations.
- PCORI will generally cover costs for ancillary tasks necessary in the implementation or monitoring of patient care as part of conducting the research project. Examples include costs for obtaining informed consent to participate in the research project, collecting data pursuant to the research protocol, or study subject data collection and monitoring that would not normally be performed in the course of patients receiving the patient care being evaluated in the research project.

All proposed costs will be reviewed by PCORI. Costs must be deemed allowable, allocable, and directly necessary to the successful execution of the proposed research project. A notification of pending award is subject to budgetary review and successful contract negotiation. The actual award amount may vary.

PCORI considers computers, tablets, docking stations, mobile data and protection plans, laboratory and office furnishings, and software to be general office supplies that are not allowable as direct cost charges.
Appendix 3: Administrative Actions

Applicants who fail to submit required documents or adhere to administrative requirements may be rejected from the merit review process. The chart below explains the reasons for rejection, modification, and appended requests.

<table>
<thead>
<tr>
<th>Automatic Rejection</th>
<th>Modification by PCORI</th>
<th>Appended upon PCORI’s Request*</th>
</tr>
</thead>
<tbody>
<tr>
<td>An application or LOI will be automatically rejected if it:</td>
<td>PCORI will modify an application by removing all pages that exceed stated limits for the following components:</td>
<td>Unless automatically rejected or modified, PCORI may request that the applicant submit missing documents or correct noncompliant ones.</td>
</tr>
<tr>
<td>• Exceeds the specified page limit</td>
<td>• Resubmission Letter</td>
<td></td>
</tr>
<tr>
<td>• Exceeds the specified period of performance outlined in the PFA</td>
<td>• Research Strategy</td>
<td></td>
</tr>
<tr>
<td>• Exceeds the maximum budget specified in the PFA</td>
<td>• Dissemination and Implementation Potential</td>
<td></td>
</tr>
<tr>
<td>• Has adjusted margins or font size</td>
<td>• Reproducibility and Transparency of Research</td>
<td></td>
</tr>
<tr>
<td>• Does not include or has an incomplete Research Strategy</td>
<td>• Protection of Human Subjects</td>
<td></td>
</tr>
</tbody>
</table>

* PCORI will not accept documents submitted more than one business day after initial request.