Cycle 3 2019 Funding Cycle

PCORI Application Guidelines
Improving Methods for Conducting Patient-Centered Outcomes Research (PCOR)

Published September 3, 2019

These guidelines apply to the Cycle 3 2019 Funding Cycle for Improving Methods for Conducting Patient-Centered Outcomes Research (PCOR). Funding announcements, templates, and other resources are available at pcori.org/apply. The Cycle 3 2019 Funding Cycle closes January 14, 2020, at 5 pm (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 and other stakeholders.

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, caregivers, clinicians, policy makers, and other healthcare system stakeholders 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 2019 Funding Cycle:

- See the PFA for programmatic details and requirements.
I. About These Guidelines

This document provides key information to help researchers prepare for and respond to the Patient-Centered Outcomes Research Institute (PCORI) Funding Announcement (PFA) entitled “Improving Methods for Conducting Patient-Centered Outcomes Research (PCOR),” available at https://www.pcori.org/funding-opportunities/announcement/improving-methods-cycle-3-2019.

These guidelines should answer many questions applicants may have, but the following resources are also available:

- See PCORI’s Applicant FAQs¹ and Methods-Specific FAQs² for common questions about PCORI and the application process.
- Visit PCORI’s Help Center³ 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 respond within two business days. However, we cannot guarantee that all questions will be addressed within two business days before 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 respond 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 at 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 Funding Application Submission.⁴

Administrative Considerations

To ensure a thorough and competitive review process, PCORI strictly enforces the formatting and administrative compliance guidelines outlined in the PFA, FAQs, and Application Guidelines. 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 department are final. Please email pfa@pcori.org with any formatting or administrative compliance questions to ensure that your LOI or application will be compliant once submitted to PCORI. See Appendix 3: Administrative Actions.

Unless otherwise stated in the Application Guidelines, all materials submitted 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.

¹ Available at http://www.pcori.org/content/faqs-applicants/.
³ Available at https://help.pcori.org/hc/en-us/.
⁴ Available at http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/.
Funding Mechanism

PCORI utilizes a contract mechanism, not a grant mechanism, for its awards. PCORI funds projects that demonstrate the highest probability of being completed on time and within budget, and meeting all milestones and deliverables. *Applicants must submit representative budgets and Research Plans that allow the project to conclude within the approved contract term.*

As part of its active portfolio management, PCORI provides contractual and programmatic monitoring throughout the contract term period. Applicant institutions and the Administrative Officials are advised to carefully review PCORI’s standard Contract templates provided on the [Awardee Resources](http://www.pcori.org) page on the PCORI website. Note that international awardees will be issued a contract in U.S. dollars. Fluctuations in currency exchange rates will have no bearing on the contract value, nor will adjustments be made to accommodate losses or gains associated with such currency fluctuations.

II. Who Can Apply

**Applications.** Submissions must align with the four current program priorities: (1) Methods Related to Ethical and Human Subjects Protections (HSP) Issues in patient-centered outcomes research (PCOR)/comparative effectiveness research (CER); (2) Methods to Improve Study Design; (3) Methods to Support Data Research Networks; and (4) Methods to Improve the Use of Natural Language Processing (NLP). Please see the [Cycle 3 2019 Improving Methods for Conducting PCOR PFA](http://www.pcori.org/sites/default/files/PCORI-PFA-Standard-Contract-for-Funded-Research-Projects.pdf) for additional information.

**Organizations.** 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; any laboratory or manufacturer; or any unit of local, state, or federal government. The Internal Revenue Service must recognize all U.S. applicant organizations. Organizations may submit multiple funding applications. Individuals are not permitted to apply. If you have questions about eligibility, contact [pfa@pcori.org](mailto:pfa@pcori.org).

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 be shown clearly. However, PCORI’s general preference is that prime awards be made to a U.S.-based organization.

A prime award contract to a non-U.S.-based organization should be carefully justified and preferably include a key U.S.-based organization and co-Principal Investigator as a subcontractor. In assessing whether a research award can be made to a non-U.S. organization as a prime contractor or subcontractor, and/or whether the research can be conducted outside the United States, PCORI will carefully review and consider the following factors:

- The research funded by PCORI must result in findings that are relevant and useful to U.S. patients and healthcare decision makers.

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• The proposed project must demonstrate that essential scientific needs will be met by conducting the study outside the United States or having the study conducted by non-U.S. research organizations.
• The proposed study must demonstrate meaningful effort and involvement of U.S. organizations and investigators with pertinent expertise and experience to contribute to the project. The engagement plan for the proposed study should also adequately and sufficiently include U.S. patients and stakeholders and have clear relevance to the U.S. healthcare system.

**Note:** A Principal Investigator (PI) can submit only one LOI per PFA. However, an individual listed as a PI on one LOI may be listed as and serve in another role (e.g., co-PI, co-investigator, or consultant) on other LOIs within the same PFA during the same cycle. A PI may submit multiple LOIs to different program PFAs in a cycle, but the PI must ensure that the research topics and projects are not similar. If a PI submits an LOI to multiple program PFAs, LOIs that exhibit scientific overlap or that appear to be duplicate submissions will be disqualified. PCORI will contact the PI and provide him or her with an opportunity to choose which PFA he or she would like to apply to. This applies to single- and dual-PI submissions.

**III. How To Apply**

To submit an LOI and full application (if invited), including all required documents, please follow the instructions provided in these guidelines and in [PCORI Online](https://pcori.force.com/engagement). All documents must be submitted through PCORI Online. 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](https://www.test.grants.gov/applicants/organization-registration/step-1-obtain-duns-number.html) and [an EIN](https://www.irs.gov/businesses/small-businesses-self-employed/apply-for-an-employer-identification-number-ein-online) if applicable.

**Step 1: Register**

To apply for PCORI funding, an applicant (PI or PI designee) must register in [PCORI Online](https://pcori.force.com/engagement). To register, you must provide a name, an email address, a password, and a security question and answer. Once signed in, you will be directed to the home screen. Click on the Research Awards tile to apply for funding. PCORI strongly recommends that only the PI create the LOI/application record, because whoever creates the record will have permanent access to it in PCORI Online.

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6 Available at https://pcori.force.com/engagement.
7 Available at https://www.test.grants.gov/applicants/organization-registration/step-1-obtain-duns-number.html
8 Available at https://www.irs.gov/businesses/small-businesses-self-employed/apply-for-an-employer-identification-number-ein-online
Step 2: Submit a Letter of Intent

An LOI is required for new and resubmitted applications. Download the PFA-specific LOI Template from the PCORI Funding Opportunities webpage. PCORI will not review LOIs that exceed the two-page limit. For formatting instructions, please reference Step 4.

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 reference the PCORI Online: Pre-Award User Guide for Research Awards.9

Step 3: Begin Application Process

PCORI will notify applicants by the date specified in the PFA as to whether or not they have been invited to submit an application.

The application consists of multiple sections in PCORI Online, all of which must be completed before 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 on the PCORI Funding Opportunities10 web page. Find the PFA to which you are applying, and download the correct PFA-specific templates, because they vary among PFAs and cycles. Keep the following in mind:

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

You must format all required documents as follows:

- **Header:** Include the PI’s full name in the top-left corner of every page.
- **Font:** Use size 11 Calibri font. Figures, tables, and captions may be size 8 font.
- **Spacing:** Use single spacing.
- **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 one half-inch from the edge of the page.
- **Page Numbers:** Number each consecutively for each PDF upload. Begin each section of an uploaded document with page 1.
- **Page Limit:** This varies based on the document.
- **File Name Format:** This varies based on the document.
- **References:** PCORI suggests including all references as in-text citations using American Medical Association (AMA) citation style, but other citation styles are acceptable.

9 Available at http://www.pcori.org/sites/default/files/PCORI-Online-Pre-Award-User-Guide.pdf.
10 Available at http://www.pcori.org/funding-opportunities/.
Step 5: Upload Required Documents

Follow the Application Checklist included in these guidelines to enter required information. Upload required documents to PCORI Online in the correct order. When instructed, use Adobe Acrobat Professional\(^{14}\) to combine documents into a single PDF file for upload. Within the Templates & Uploads tab, click “Choose file” to select a file from your computer, and click “Upload.” For detailed instructions, refer to the Templates & Uploads section of the PCORI Online: Pre-Award User Guide for Research Awards.

Step 6: Submit for Authorization

Once you have completed and uploaded all required information, select “Review & Submit,” and then select “Submit” 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 before the deadline. PCORI Online will email the AO, but 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.

IV. When To Apply

Deadlines for each funding cycle are noted in the PCORI Funding Opportunities web page and in the PFA. System or technical issues with PCORI Online that affect the 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, in the PCORI Application Guidelines, or PFAs are not valid issues warranting consideration of a deadline extension. Please see PCORI’s Policy on Submission of Research Contract Applications\(^{12}\) for complete information.

V. What To Include

Note: Only applicants selected to submit an application should begin the application process. You will be notified October 29, 2019, regarding whether PCORI has invited you 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. All required templates can be downloaded from the PCORI Funding Opportunities\(^{13}\) web page.

\(^{11}\) See adobe.com for more information on Adobe Acrobat Professional.

\(^{12}\) Available at http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/.

\(^{13}\) Available at http://www.pcori.org/funding-opportunities/.
## Application Checklist

<table>
<thead>
<tr>
<th>Letter of Intent</th>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Letter of Intent (LOI)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Contact Information</td>
<td>Enter into PCORI Online</td>
<td>N/A</td>
</tr>
<tr>
<td>• Pre-Screen Questionnaire</td>
<td>Enter into PCORI Online</td>
<td>N/A</td>
</tr>
<tr>
<td>• Resubmission</td>
<td>Enter into PCORI Online</td>
<td>N/A</td>
</tr>
<tr>
<td>• Principal Investigator (PI) Information</td>
<td>Enter into PCORI Online</td>
<td>N/A</td>
</tr>
<tr>
<td>• Project Information</td>
<td>Enter into PCORI Online</td>
<td>N/A</td>
</tr>
<tr>
<td>• Project Personnel</td>
<td>Enter into PCORI Online</td>
<td>N/A</td>
</tr>
</tbody>
</table>

| Templates & Uploads: LOI Template | | |
| Save file as “PI LastName_(five digit LOI number)_LOI.pdf” and upload | | 2 pages |

<table>
<thead>
<tr>
<th>Application</th>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Project Information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Technical Abstract</td>
<td>Enter into PCORI Online</td>
<td>700 words</td>
</tr>
<tr>
<td>• Public Abstract</td>
<td>Enter into PCORI Online</td>
<td>700 words</td>
</tr>
</tbody>
</table>

| Budget | | |
| Enter into PCORI Online | | As needed |
| • Detailed Budget for Each Project Year (prime) | | |
| • Budget Summary for Entire Project (prime and subcontractors) | | |

| Milestones Template | | |
| Save file as “Milestones_PI LastName.xls” and upload | | As needed |

| People and Places Template | | |
| Save file as “PeoplePlaces_PI LastName.pdf” and upload | | As noted below |
| • Leadership Plan Template (required if proposing dual-PI application) | | 5 pages |
| • Professional Profile/Biosketch | | 5 pages per individual |
| • Patient/Stakeholder Partner Profile/Biosketch | | 5 pages per individual |
| • Project/Performance Site(s) and Resources | | 15 pages |

<p>| Research Plan | | |
| Save file as “ResearchPlan_PI LastName.pdf” and upload as a single file | | As noted below |</p>
<table>
<thead>
<tr>
<th>Section</th>
<th>Pages</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Strategy</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Research Team and Environment</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Dissemination and Implementation Potential</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Protection of Human Subjects</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Consortium Contractual Arrangements</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>References Cited</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Appendix (optional)</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

- **Methodology Standards Checklist**
  - Save file as “MethodologyStandardsChecklist_PI LastName.xls” and upload
  - As needed

- **Subcontractor Detailed Budget (for each project year) Template**
  - Save file as “SubcontractorDetailedBudget_PI LastName.pdf” and upload as a single file
  - As needed

- **Budget Justification (prime and subcontractors)**
  - Save file as “BudgetJustification_PI LastName.pdf” and upload
    - Budget Justification (prime and subcontractor) Template
      - As needed
    - Federally Negotiated or Independently Audited Indirect Cost Rate Letter (prime contractor)
      - As needed
    - Fringe Benefit Rate Policy Verification Document (prime contractor)
      - As needed

- **Letters of Support**
  - Save file as “Letters_PI LastName.pdf” and upload as a single file
    - Letters of Support Table
      - As needed
    - Letters of Support
      - As needed

- **Resubmission Letter (if appropriate)**
  - Save file as “Resubmission_PI LastName.pdf” and upload
    - 1 page
Letter of Intent

You must submit an LOI before you complete your application. Enter the information in the required fields in PCORI Online.

Upon receipt of the LOIs, PCORI program staff will screen them for programmatic fit and potential overlap with existing projects in the portfolio. If program staff determine 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 or her approval to switch programs. PCORI will not invite an applicant to submit an application if the applicant’s LOI does not meet program areas of interest, or if it substantially overlaps with existing projects in the portfolio. Applicants will receive an email notification accepting or declining their LOI, as specified in the PFA.

Resubmission Policy

An applicant may resubmit an application that was not funded but that did complete PCORI’s merit review process (i.e., the applicant received a summary statement). PCORI does not limit the number of times an applicant may resubmit.

If a full application was deemed nonresponsive and did not progress through the full merit review process, it is considered a new submission and requires submission of an LOI. Submitting the same application to a different program’s PFA is also considered a new submission. Each program’s PFA has different requirements; therefore, applicants should carefully review the program-specific PFA to which they are applying.

Submitting an LOI is also a requirement of resubmissions unless the applicant has received an Invitation to Resubmit, outlined below.

Invitation To Resubmit

Program staff may invite applicants from previous cycles to resubmit their revised applications. If invited, applicants will bypass the LOI review stage. Instead of completing and uploading an LOI Template, invited applicants are required to upload their Invitation to Resubmit letter and complete the PCORI Online LOI questions by the LOI submission deadline. Unless the applicant has explicit and documented approval from the program staff to alter the originally submitted study aims of the application, the invited resubmission application’s aims should remain the same as in the original application.

An Invitation to Resubmit is not a guarantee that PCORI will select the application for funding. Invited applicants must adhere to the updated guidance in the PFA and compete with other invited and new applicants.
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
- If electing to submit an application with two PIs, you must designate one as the Contact PI. The Contact PI is responsible for submitting the application and will serve as PCORI’s primary point of contact for all communication. **No more than two PIs can be named on an application.**
- The PI is responsible for the project’s engagement, scientific or technical aspects, and peer-review-related activities.
- The Contact PI’s institution must be the primary institution for the award.
- PIs can participate in other applications (from the same or another organization) in the same or a different role, such as co-PI, dual-PI, co-investigator, or consultant. Refer to the *Who Can Apply* section for specific instructions.

B. Activities
- The PI (or PIs) assume responsibility and accountability for research execution, compliance, and organizational conduct.
- If applicable, the Contact PI is responsible for submitting the application, submitting all progress reports, and serving as PCORI’s programmatic and administrative contact. PCORI will send all communication to the Contact PI, and it is his or her responsibility to share PCORI communications with PI #2.
- The PI (or PIs) manages day-to-day project operations.
- The PI (or PIs) acts as the organization’s lead research representative.

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 appropriately using the funds awarded and for performing 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 financial reporting.

B. Activities
   • The FO completes and certifies expenditure reports on behalf of the organization.
   • The FO accounts for contract funds and submits invoices and payment details.

Key Personnel

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

Note the following:

• Applications can include up to two PIs.
• PIs can serve in other roles (e.g., dual-PI, co-PI, co-investigator, or consultant) on other applications.
• If applicable, applicants must explain the rationale for including two PIs in the Leadership Plan Template.
• Consultants and personnel from collaborating organizations may be included as key personnel if they meet the definition. See PCORI’s Glossary for “Consultant” and “Subcontractor” definitions.
• Applicants are required to identify the patient and other stakeholder partners, whether individuals or organizations, that will assist in conducting the project. If your project is funded, these partners will be named on the PCORI website along with the PI and the recipient organization. They may also be recognized in other PCORI communications, such as press releases, or mentioned in response to requests for information. By providing the names of the partnering individuals and organizations, you acknowledge 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. If a patient or other stakeholder partner wishes to remain anonymous, please contact us at pfa@pcori.org for additional guidance on how to recognize such partners appropriately.
• After merit review, PCORI may request current, pending, and other support documentation from all key personnel. This material must be submitted prior to award.
• If awarded, the addition or replacement of key personnel listed in the submitted application requires PCORI’s approval during contract negotiation and post–contract execution.
PFA-Specific LOI Template

Download and complete the Improving Methods for Conducting PCOR LOI Template from the PCORI Funding Opportunities web page. Please provide only the information requested on the template. Do not include supplemental materials (e.g., supporting journal articles, Letters of Support) or additional information not requested in the template (e.g., responses to reviewer comments or Resubmission Letters). Statements in gray italics denote the specific information required for each response. Replace the gray italics and any instructional text with your response, but retain the bold headings. Any additional template modifications will result in the disqualification of your LOI.

Be sure to provide sufficient details to allow the scientific community to understand the project—including the aims and study design—without reviewing the full application. Any LOI that exceeds two pages (excluding the reference list) will not be reviewed. PCORI suggests including all references as in-text citations using AMA citation style, but other citation styles are acceptable. Figures and general tables are allowed and will be included in the two-page count. (Note: All LOI Templates should follow the formatting guidelines provided in Step 4.)

Be sure to delete the template cover page before submitting an LOI. To submit an LOI, save the completed PFA-specific LOI as a PDF. Label your LOI file using the following nomenclature: “PI Last Name_(five-digit LOI number)_LOI.pdf.” PCORI Online will automatically generate an LOI number, which will be visible at the top of the web page once you save the LOI. Click “Review & Submit” to review your submission, and then click “Submit.” Navigate back to the LOI and Application dashboard in PCORI Online where you can see your LOI number and track your status. Once your LOI is submitted, you cannot edit it.

Application Requirements

The following sections are applicable only if PCORI invites you 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:

- PI (Contact PI and PI #2)
- 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 the 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 methodological gap the research is designed to address. Describe how the proposed research will advance methods for patient-centered outcomes research/comparative clinical effectiveness research (PCOR/CER) and the importance of this research to the relevant stakeholders (e.g., patients, clinicians, and policy makers).

- **Objectives**: Describe the research objective(s) and list the specific aims that will address the identified methodological gap.

- **Study Design or Approach**: Describe in detail the methodological work that is planned for each of the specific aims and the ways in which it addresses the identified methodological gap. Include, as applicable, the following elements:
  - Study design
  - Study population and sample size
  - Primary data collection methods
  - Data sources and data sets
  - Analytic methods
  - Evaluative framework (including choice of methodological comparators)

- **Outcomes (projected) and Anticipated Impact**: Identify and explain the specific anticipated contributions and applications of the methodological advancement to PCOR/CER, as well as the patients and/or other stakeholders who will benefit from it.

- **Study Design**: Please fill in the study details in each section, referring to the guidance provided.
  - **Goal**: Describe the study aims.
  - **Approach**: Describe the overall approach – use of a data set, modeling, mixed methods, multiple stages, whatever best fits.

For examples of completed Study Design tables, see:

- Improving Learning Healthcare Systems Using Randomization Methods
- Developing New Methods to Conduct Stepped-Wedge Studies

Public Abstract

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

- The methodological problem your project seeks to solve, including how the problem is currently addressed, what is lacking in existing methods, and how the proposed solution may improve on them.
The study designs, data sets, or research settings in which the proposed new methods or solutions could be applied

Study aims and each step you will take to address these aims

How you will test your solution, such as with simulated or historic data. Use plain language to describe statistical processes and clearly define all technical terms

Planned outputs of your project, such as software or recommendations for other researchers

Who will be able to use the results of this project, and how

Stakeholder engagement: what types of stakeholders are represented, and in what ways are they involved in the study

If your project is approved for funding, the PCOR Translation Center will edit your summary to ensure it is consistent with PCORI style. The final version will be sent to you for sign-off.

For examples of completed public abstracts, see:

- Making Case-Control Studies More Reliable for Comparing Treatment Outcomes
- Developing Methods for Record Linkage that Protect Patient Privacy

**Milestones Template**

Applicants must complete the [Methods Milestones Template](#) and upload it as an Excel file, not as a PDF, in PCORI Online, in the designated upload field. Follow the instructions in the Milestone Template and complete all required sections. Based on “Milestone - Deliverable Name” (Column B) and the “Description” (Column C), applicants must provide the “Due Date” (Column D). Consider the guidance information in Column E as you determine the “Due Date.”

Milestones are concrete, specific events or accomplishments that may be documented by deliverables. They include only the activities that the PCORI contract supports. For Methods projects, some examples of milestones include completion of theoretical development, simulation studies, or empirical analyses; development of protocols; establishing project-specific databases. See Appendix 1: Example Milestones for a more complete list. If applicable, milestones may also include activities dedicated specifically to engagement, such as the recruitment of all patient/stakeholder research partners. As part of Merit Review Criterion 3, Scientific Merit (research design, analysis, and outcomes), reviewers evaluate the submitted milestone schedule to assess feasibility of the study plan.

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, the following:

- PCORI Progress Reports
- Study Protocol
- Copies of Institutional Review Board (IRB) approval
- Registration of the trial on ClinicalTrials.gov
- Data Safety and Monitoring Plan
- Recruitment Plan
- Engagement Plan
- Abstracts accepted or presentations made
- Manuscripts accepted for publication
- Copies of drafts of instruments, data dictionaries, educational materials, manuals, or other project deliverables
- Reports of plans to adopt research findings in practice
- Charts, tables, graphs, or other summaries of preliminary data
- Other documents or materials, as appropriate

**Note:** Milestones must include specific deliverables associated with a timeline and include project objectives that will be accomplished at specific times during the proposed project. PCORI encourages applicants to provide three to six milestones per six-month reporting period.

**Budget**

Complete all required sections in PCORI Online, including the Peer Review Budget section, and upload the Subcontractor Detailed Budget Template for each subcontractor and the Budget Justification Template to PCORI Online in their designated fields.

**Detailed Research Project Budget for Each Year of the Research Project Period**

For each program year, complete a Detailed Budget entered into PCORI Online for the prime applicant proposed in your application. For example, if your study lasts two years, the prime applicant must complete a Detailed Budget for Year One and for Year Two. You must enter all personnel information in the Project Personnel tab that corresponds to that year in the Budget tab. The applicant may add additional rows for personnel as needed. Following the example of a two-year study, applicants may delete the unused Years Three through Five Detailed Budget tabs. However, applicants may not add additional years. Each PFA states the maximum project periods. Note the following:

**A. Personnel Costs**

- **Personnel Costs:** These include the base salary for each scientific and technical staff member, employee patient or stakeholder partner, or other personnel on your project who are or are not accounted for in Section B: Consultant Costs. Provide a clear distinction between individuals who are key personnel and those considered “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. Provide documentation to support the fringe benefits within the Budget Justification.

• Level of Effort: Personnel who contribute to a PCORI-funded research project must monitor their total percentage of effort across all of their active funding, so that it does not exceed 100 percent. Before submitting the application to PCORI, the AO must certify that individual personnel will not exceed 100 percent effort, if funded. You must report effort by the percentage of time over the course of the project year. If you are not requesting salary support, use $0 for the base salary.

• All personnel who dedicate effort to the project must be listed on the Personnel Budget with their level of effort, even if they are not requesting salary support. List the base salary for each person in the Budget Justification and the Detailed Budget. Describe the individual’s specific functions in the Budget Justification. 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, excluding fringe benefits. An individual who earns less than $200,000 must 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 Justification upload, applicants must provide a verification of the fringe benefit rate policy for the prime organization.

  **Note:** 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 must be included in the budget as consultant costs.

• Provide the total cost of the consultant(s), as well as name(s), expected number of hours, and hourly rate.

• Include the daily consultant fee, travel expenses, nature of the consulting effort, and the reasons that the proposed project requires consultants. Note any overlap in duties with personnel.

• Consultant costs must be reasonable and justified within the Budget Justification.

• Include Letters of Support from each consultant, 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 be 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 in the Budget Justification for all costs exceeding $1,000.

- For all supply costs, provide computations for the way that applicants arrived at the specific number.

**Note:** 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. If these items are proposed as essential for performing the research project, the following must be provided in the Budget Justification:

- Detailed explanation of why purchasing these items is necessary to complete the proposed research project
- Statement verifying that the requested items are not currently available for the PI’s use
- 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 should be devoted to programmatic activities necessary to conduct the project, such as focus groups, project team meetings, or data collection. Requests for travel to present at conferences or symposiums that are related to the topical areas of the project may also be included, but should be limited in number, and strongly justified. PCORI closely reviews all travel costs to ensure they are reasonable.

- Travel costs must be itemized per trip and must include the number of trips and a brief
description of each one, including the number of people traveling and dates or duration of the stays.

- 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.

- In the Budget Justification Template, 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 necessary for achieving programmatic objectives.

E. Other Expenses

- Indicate and include general categories such as printing, publication, illustration costs, and non-consulting 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 computer core services, data warehousing, or participant incentives.

- In the space provided, include a detailed explanation in the Budget Justification for items that exceed $1,000. Applicants must provide additional detail for each of these costs.

F. Equipment Costs

- Equipment costs include those for tangible items that have a per-unit cost of $5,000 or more and a useful life greater than one year.

- You must include with the Budget Justification up to three quotes for each item of proposed equipment.

- 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. PCORI must approve equipment disposition.

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 personnel’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 or deliverable they will be supporting on the 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, and other expenses and on the first $25,000 of each subcontract.
- Applicants that do not have a federally negotiated or independently audited 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.
- While consortium indirect costs must be noted in the prime applicant’s direct cost budget, consortium indirect costs are not included in the applicant’s direct-cost budget cap.

I. Engagement Costs

- The budget should account for patient and other stakeholder partner (individual and organizational) compensation. For additional guidance, review PCORI’s Compensation Framework.
- Awardees should also consider costs of patient and other stakeholder expenses, project staff, engagement event and/or meeting costs, and incorporating partner feedback. For additional guidance, review PCORI’s Budgeting for Engagement Activities document.

Detailed Peer-Review Budget for Peer-Review-Related Costs

The detailed Peer-Review Budget must include costs related to the Peer-Review Process. 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.

- Costs associated with the Peer-Review Process are limited to personnel, consultants, and subcontractors.
- A Budget Justification must be included for the Peer-Review Budget.
- The Budget Summary must include the Peer-Review Budget.
- The PI has full discretion in identifying peer-review support personnel.
- The PI must dedicate measurable effort in support of the Peer-Review Process.
- Applicants must identify the peer-review support staff role within the budget at the time of submission.

Budget Summary for Entire Project

A Budget Summary for the entire project for the prime applicant is created within PCORI Online when
the budget is entered into the system. Review this information prior to submission. See Appendix 2: Allowable and Unallowable Costs to review acceptable and unacceptable uses of PCORI funding.

Subcontractor Detailed Budget Template

Complete the Subcontractor Detailed Budget Template for each subcontractor organization, then combine the files into a single PDF file and upload it to PCORI Online in the designated field. For each project year, complete a Detailed Budget for each subcontractor organization proposed in your application. All personnel information must be entered in the Personnel tab corresponding to that year in this template. Add additional rows for personnel as needed.

Budget Justification Template

Complete a Budget Justification Template 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, the reason the costs are necessary to the project, and the reason for major cost variances. Include information about budgeting for engagement, including financial compensation of patient and other stakeholder partners, costs of patient and other stakeholder expenses, project staff, engagement event and/or meeting costs, and incorporating partner feedback. Note that some projects employ or assign an individual responsible for coordinating or managing all project-related patient and other stakeholder engagement. This person should be listed as a full-time equivalent under personnel, consultant, or subcontractor costs. Explain the basis for travel costs, and describe how the travel is related to the proposed research and necessary for achieving programmatic objectives.

Describe the specific role and tasks each research team member will perform, along with the impact on the Project Plan. PCORI will evaluate each member’s contribution as listed in the Budget Justification to validate meaningful contributions and assess whether overlap in responsibilities occurs. Provide a clear distinction between individuals who should be key personnel and those who should be classified as “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.
Research Plan Template

Complete all required sections in the [Methods Research Plan Template](#) and upload as a single PDF to PCORI Online. The Research Plan includes the following: Research Strategy, Research Team and Environment, Dissemination and Implementation Potential, Protection of Human Subjects, Consortium Contractual Arrangements, References Cited, and an Appendix (optional).

Research Strategy

In this component of the Research Plan (up to 12 pages), applicants must describe their Research Strategy and work plan in detail, and demonstrate how the proposed study responds to this PFA. This component addresses the following sections: (A) Objectives, (B) Background, (C) Significance, (D) Study Design or Approach, and (E) Engagement Plan.

Per the PFA, applicants proposing use of an existing research network infrastructure (e.g., the National Patient-Centered Clinical Research Network [PCORnet]), research consortia, or related data resources (e.g., electronic medical records data from healthcare delivery systems or administrative claims data from public or commercial insurers) should address this with sufficient specificity in the Research Plan, as appropriate. Applicants should also refer to the PCORI Methodology Standards for Data Networks as Research-Facilitating Structures.

As applicable, applicants must 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.

As instructed in the Research Plan Template, complete the [PCORI Methodology Standards Checklist](#) to summarize adherence to the relevant PCORI Methodology Standards. Do not address standards that are not applicable to your study.
PCORI program staff and the research team will review relevant standards and plans for adherence during the contract negotiation phase for applications that are awarded funding.

As part of the Research Plan, applicants should describe patient and stakeholder engagement (Section E). The Engagement Plan should be tailored to each research application’s specific aims, methods, and targeted end-users. Investigators should provide a clear and concise justification for both the patients and/or other stakeholders they intend to engage and the activities in which they intend to engage those individuals. Applicants are encouraged to review PCORI’s Engagement Rubric. This resource is not intended to be comprehensive or prescriptive; instead, it provides a variety of options to incorporate engagement, where relevant, into the research process. Section E (Engagement Plan) may not exceed 1 page of the 12-page Research Strategy limit. Additionally, the Engagement in Health Research Literature Explorer14, a searchable, catalogued resource for peer-reviewed literature, can help identify publications about engagement that are specifically relevant to your work.

However, PCORI recognizes that patient engagement may not be appropriate in all cases, especially in highly technical methods projects. Please keep in mind that where it may not be appropriate to engage patients in the methodological research process, it may still be important to engage other stakeholders (data architects, clinicians, domain experts, health services researchers with different expertise than members of the research team, policy makers, etc.) in the methodological research process. Investigators must provide a justification if they think that it is not appropriate to engage patients or other stakeholders in a proposed research project.

Please provide all key personnel professional and partner profiles/biosketches and detailed site descriptions within the People and Places Template as a separate PDF.

**Justification of Assumptions**

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

**Research Team and Environment**

Within the Research Team and Environment component (two pages), applicants should describe the resources, facilities, collaborations, and other support available to ensure the project’s success. Include (as applicable):

- Complementary and integrated expertise and experience of the research team
- Study site selection and governance structures
- Logistical support (e.g., administrative management and oversight) and best practices training

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14 Available at http://www.pcori.org/literature/engagement-literature
• Financial support (e.g., protected time for research with salary support)
• Institutional and community investment in the success of the research (e.g., access to and support of organized peer, patient, and stakeholder groups)

Dissemination and Implementation Potential

In this component (up to one page), applicants should describe (A) their plans for making results available to study participants (as applicable) and (B) possible barriers to disseminating and implementing their work in other settings and any other study limitations that could have an impact on the usability of findings (e.g., propriety issues, applicability, scalability, and appropriate settings of care).

Beyond making results available to study participants (as applicable), PCORI does not support awardees budgeting efforts or resources for the conduct of dissemination and implementation work at this juncture. For projects that produce important findings, PCORI will consider subsequent applications for funding to support dissemination and implementation efforts through separate PFAs and other mechanisms.

Note: PCORI encourages researchers to submit documentation of any implementation agreement with the sponsoring organization confirming that the organization will implement successful interventions on a large scale. PCORI will view this agreement as a positive factor during merit review. Please include this with the Letters of Support PDF document as the last item.

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, which was issued by the U.S. Department of Health and Human Services (Department of HHS). Please refer to the Required Education of Key Personnel on the Protection of Human Subject Participants requirement as you complete this section.

Consortium Contractual Arrangements

In this component (up to five pages), describe the proposed research projects that subcontracted organizations will perform. 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 responsible for the project and must adhere to the contract’s terms and conditions. The prime applicant should negotiate his or her subcontracts accordingly.
• Signed subcontract agreements are not required at the time of application submission to PCORI.
• Submitting an application to PCORI signifies that programmatic and administrative personnel from your organization and from all proposed subcontract organizations involved in the project

are aware of your organization’s subcontract agreement policy and are prepared to establish the necessary interorganizational agreement(s) consistent with that policy.

- If applicable, include subcontract personnel under key personnel.
- Include budget information for subcontracted organizations 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 Research Plan, applicants should use in-text citations to reference published materials. In this section, list the full bibliographical citation for 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, the volume number, the page numbers, and the year of publication. Include only bibliographic citations. PCORI suggests following AMA style when providing citations for source materials used to prepare any section of the application, but other citation styles are acceptable. Citations that are publicly available in a free, online format may include URLs or PubMed ID numbers along with the full reference. *Limit references to relevant and current literature.* Be concise and select only those literature references pertinent to the proposed research, so that you do not exceed the 10-page limit. Reference websites in the standard URL format (i.e., [http://www.pcori.org](http://www.pcori.org)) along with the date on which the link was last accessed.

Appendix (Optional)

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

Methodology Standards Checklist

Applicants must complete the [PCORI Methodology Standards Checklist](#) and upload it as an Excel file to PCORI Online, in the designated upload field. Applicants must complete Column D of the checklist, using the drop-down menu options to indicate whether each PCORI Methodology Standard applies to their proposed research. Applicants must complete the subsequent columns, as appropriate, following the instructions in the checklist. If the standard applies, in Column E provide the page number and section of your Research Plan where the text illustrates how you addressed the standard. Last, in Column F, indicate whether your study may deviate from the standard and provide a rationale. Refer to the [PCORI Methodology Report](#) for explanations of the standards.

Adherence to PCORI Methodology Standards

Applicants are required to adhere to [PCORI Methodology Standards](#) and accepted best practices. PCORI Methodology Standards include 65 individual standards that fall into 16 categories. The first five categories are cross-cutting and relevant to most patient-centered outcomes research (PCOR) studies. Researchers must refer to all of these standards when planning and conducting their research projects.

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These five categories are:

1. Standards for Formulating Research Questions
2. Standards Associated with Patient-Centeredness
3. Standards on Data Integrity and Rigorous Analyses
4. Standards for Preventing and Handling Missing Data
5. Standards for Heterogeneity of Treatment Effect

In addition to these five sets of standards, the first standard listed under “Standards for Causal Inference Methods”—(CI-1)—is cross-cutting and applicable to all PCOR studies.

The 11 other standards categories will be applicable to certain study designs and methods. The standards in each of these categories must be used for guidance when they are relevant to a study. These other categories are:

6. Standards for Data Registries
7. Standards for Data Networks as Research-Facilitating Structures
8. Standards for Causal Inference Methods
9. Standards for Adaptive and Bayesian Trial Designs
10. Standards for Studies of Medical Tests
11. Standards for Systematic Reviews
12. Standards on Research Designs Using Clusters
13. Standards for Studies of Complex Interventions
14. Standards for Qualitative Methods
15. Standards for Mixed Methods Research
16. Standards for Individual Participant-Level Data Meta-Analysis (IPD-MA)

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

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, dual-PI, co-investigator, consultant, or other significant contributors), copying the tables provided in this section as needed. Please note that you may submit the most recently posted 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 degree(s). PCORI is especially interested to learn how each individual’s previous experience, past performance, and training in the field of PCOR has prepared him or her to conduct this research. You should also describe the backgrounds, relevant experiences, and roles of patient and stakeholder partners.

Applicants should assemble a research team that is suited to complete the work. Applications should demonstrate that the study team’s experience, leadership approach, governance, and organizational structure are appropriate for the project and will aid in achieving 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 as planned, within budget, and on time.

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

**Leadership Plan (required if proposing a Dual-PI Application)**

Depending on the nature of the proposed study, a collaborative and multidisciplinary team may be required. PCORI permits applicants to name a maximum of two PIs within an application. The PIs may be from the same or different institutions. Each PI is accountable and responsible for the conduct of the award and for ensuring that all awarded milestones, deliverables, and reports are completed in accordance with the award terms and conditions.

If proposing a dual-PI application, one PI must be designated as the Contact PI. The Contact PI must be employed by the applicant institution and listed first within the application. Although PCORI will recognize both PIs, the Contact PI is responsible for submitting the application and for communications between the PIs and PCORI, including coordinating meetings with PCORI staff.

Applicants proposing a dual-PI application, must include a Leadership Plan (up to five pages) as the first section of the People and Places Template. The Leadership Plan must (A) describe the governance and organizational structure of the leadership team and the research project; (B) delineate the administrative, technical, scientific, and engagement responsibilities for each PI and the rationale for submitting a dual-PI application; (C) discuss communication plans and the process for making decisions on scientific and engagement direction; and (D) describe the procedure for resolving conflicts.

**Note:** Only the Contact PI may submit the application to PCORI.

**Letters of Support**

Save all Letters of Support as a single PDF file and upload it 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 the
reviewers missing key information. 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., dual-PI, co-investigators, consultants, patient and stakeholder partners, and stakeholder organizations) to the proposed project. Letters of Support are not required for personnel who are not contributing in a substantive, measurable way to the project’s scientific development or execution. Letters of Support should reflect the involvement and material contribution the signatory parties will provide and confirm the commitment to collaboration.

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

Letters of Support should be organized as follows:

- **Letters of Organizational Support**: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organizational official, that confirms the institutional support of the proposed project; space to conduct the research; equipment; and other resources available for the project, including staff. PCORI also strongly encourages you to provide a letter from the department or organization leadership 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 the origin of the study topic and the role of the partners in defining the question, comparators, goals and outcomes, and so on. PCORI also strongly encourages 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 all consultants 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 that confirm such access, signed by the person with approval authority. 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 (adding rows as needed) and include the page number for each letter in the single PDF file.

**Resubmission Letter**

An applicant may resubmit an application that was not funded but that did complete PCORI’s merit review process (i.e., the applicant received a summary statement). See the [Resubmission Policy](#) for more information.
Submitting an LOI is a requirement of resubmissions unless the applicant has received an Invitation to Resubmit. Resubmitted applications require completion and submission of a one-page Resubmission Letter. The Resubmission Letter provides an opportunity for applicants to give a high-level overview of how the application has been strengthened in its scientific merit and responsiveness to the current PFA. Simply responding to previous reviewers’ concerns is not sufficient; the application must be programmatically responsive and demonstrate methodological rigor and patient-centeredness. The Resubmission Letter will inform the merit reviewers’ understanding of the ways in which the applicant has made efforts to strengthen the application, and reviewers will evaluate the application based on its responsiveness to the PFA and the merit review criteria.

Applicants that previously submitted a dual-PI application and are now proposing a single-PI application, or that wish to make a change in the previous PI team, must address the rationale for the change within the Resubmission Letter.

PCORI evaluates all applications using the same merit review criteria found in the program-specific PFA.

VI. 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 individuals listed as key personnel in the application. The policy and FAQs are available on the NIH website.17

**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” (e.g., PCORI-XXXX-XXXX). Clinical trials must be registered before enrollment of the first patient. All trials that meet the definition on the NIH database18 (see “Data Element Definitions”) are required to register, if funded.

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

Funded evidence-synthesis studies must be registered at PROSPERO.19 Funded patient registries must be registered at https://patientregistry.ahrq.gov/.

18 Available at https://www.clinicaltrials.gov/.
19 Available at http://www.crd.york.ac.uk/PROSPERO/.
Standards for Privacy of Individually Identifiable Health Information

On August 14, 2002, the Department of HHS issued a final modification to the Standards for Privacy of Individually Identifiable Health Information, the “Privacy Rule.” 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 Department of 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 Rights20 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.21

Award Funding Conditions

At any time during the contract, PCORI reserves the right to discontinue funding for awardees that fail to meet the mutually agreed-upon milestones. Applicants’ proposed milestones will be finalized in contract negotiations and prior to execution. Please see PCORI’s Standard Contract Template for more information.

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 that is already funded through another funding entity. By submitting the application to PCORI, the AO is certifying that no overlap in funding exists 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 publishing and disseminating 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 data availability.

PCORI encourages openness in research and making research data available for purposes of replication and reproducibility. As such, if an award is made, the awardee will be expected to adhere to PCORI’s Policy for Data Management and Data Sharing. The policy articulates PCORI’s requirement that certain Awardees make the underlying data and data documentation (e.g., study protocol, metadata, and analytic code) from their PCORI-funded research projects available to third-party requestors.

A full data management and data sharing plan is not required at the time of application. If an award is made—specifically for the Pragmatic Clinical Studies and the targeted PFA studies—the awardee is required to develop and maintain such a plan, which is described in detail in the PCORI Methodology Standards for Data Integrity and Rigorous Analyses, specifically Standard IR-7. This plan must be appropriate for the nature of the research project and the types of research project data, and consistent with applicable privacy, confidentiality, and other legal requirements. The policy includes details about what data certain Awardees will be expected to deposit into a PCORI-designated data repository and when that data would be available for third-party requests.

For research awards funded under a Broad funding announcement (Addressing Disparities, Assessment of Prevention, Diagnosis, and Treatment Options, Communication and Dissemination Research, Improving Healthcare Systems, and Improving Methods), the policy calls for awardees to maintain the Full Data Package for seven years. PCORI may, in selective cases, notify the PI of its intent to provide funds for the deposition of the Full Data Package in a PCORI-designated repository in circumstances where PCORI requests such deposition.

The information here is meant for informational purposes only and does not attempt to be an exhaustive representation of the Policy for Data Management and Data Sharing. Refer to the Policy in its entirety for additional information.
Appendix 1: Example Milestones

Milestones are significant events, tasks, or outcomes that occur over the course of each project and signify study progress. The completion of each milestone is intended to mark progress toward the project goals and ensure that the project is on schedule and likely to be completed within the contract period. As part of Merit Review Criterion 3, reviewers evaluate the submitted milestone schedule to assess the feasibility of the study plan.

In general, and at the discretion of your PCORI project team if awarded, the following are examples of milestones and deliverables to be submitted to PCORI. You may reference this list as you complete this section of your application:

Required:

- Awardees must submit a PCORI Progress Report in PCORI Online at least every six months.

Within first six to nine months of an executed contract, as applicable:

- Develop, finalize, and submit copy of study protocol in accordance with the PCORI Methodology Standards.
- Submit IRB approval in PCORI Online (Continuing approval submitted annually).
- Select and register project at appropriate site for the study design (ClinicalTrials.gov, RoPR, or other as approved by PCORI before study start date).
- Submit updated Recruitment Plan
  - Elements in the recruitment plan should, at a minimum, include the following: timeline; total target sample size for primary analysis; name and # study sites; historical patient volume and estimated eligible N across study sites; estimated yield/consent; estimated loss to follow up/attrition; and estimated monthly enrollment.
- Begin recruitment: Site(s) activated and screening for study enrollment.
- Enroll first patient. From this point forward, submit monthly enrollment update to PCORI including cumulative and interval recruitment, accrual, and retention for the overall study (e.g., number eligible, approached, consented, enrolled, retained).
  - Monthly enrollment updates are not required in the milestones schedules, but awardee must include milestones to enroll and retain 25, 50, 75 and 100 percent of targeted sample size (include target N of patients per reporting period) throughout the duration of the project.

Within the first 12 to 15 months of an executed contract, as applicable:

- Submit 100 percent of the IRB approvals across sites to PCORI.
- Submit status report detailing executed subcontract agreements across sites.
- Seventy-five percent of the sites must have started recruiting patients.
- The 25 percent cumulative enrollment target has been met.
• Programmatic Evaluation Materials are due to PCORI. For projects with a duration of four or more years, awardee must submit document that demonstrates study progress and feasibility based on metrics provided by PCORI at the time that contract is executed. In general, the Programmatic Evaluation will encompass the first 12 to 15 months of the contract, with materials due to PCORI ~15 months.

Remainder of Contract, as applicable:

• Primary Completion Date
  o An estimated Primary Completion Date must be provided when registering the study in ClinicalTrials.gov. For studies that are not clinical trials or non-prospective observational studies registered on ClinicalTrials.gov, the Awardee and PCORI shall agree on a Primary Completion Date as a milestone that precedes the agreed-upon date to submit a Draft Final Research Report.
• Results submitted to ClinicalTrials.gov or applicable database
  o Awardee ensures results are submitted to ClinicalTrials.gov or other database. For ClinicalTrials.gov, the generated tables are a required section in the Draft Final Research Report. Results must be submitted to ClinicalTrials.gov no later than submission of the Draft Final Research Report.
• Draft Final Research Report Submission
• Draft Final Research Report Revisions
  o Upon receipt of written summary, and as applicable, PI will make revisions and submit revised Draft Final Research Report and disposition of comments table for acceptance in accordance to PCORI policy and process.
• Submit Final Progress Report
• Approval/sign off of the Lay Abstract
  o No later than 90 days beyond the date PCORI accepts the Final Research Report

If awarded, a contractual milestone schedule will be negotiated and finalized with the PCORI project team. Additional reporting, such as monthly enrollment updates, 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 collecting and analyzing data and obtaining relevant data sets. Because PCORI primarily funds 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, when 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 when 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 spent 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 necessary for conducting the research project
- Supplies
- Equipment
- Subcontracts
- Expenses related to conducting engagement activities with patients and/or other stakeholders
- Other direct research expenses
- Indirect costs

A funding applicant must specifically request costs related to conducting the research project through itemization on the Detailed Budget. PCORI will consider this request 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:

- Typically, IRB fees are included in an organization's indirect cost pool. However, PCORI will allow this expense as a direct cost if the costs are not included as part of the indirect cost rate. By submitting the application, the PI and AO certify that their institution treats IRB fees as direct costs, and the fee is allocable to the study. IRB fees are subject to audit.
- In general, PCORI will not cover costs for study interventions that constitute the procedures, treatments, interventions, or other standard clinical care (“patient care”) that is being proposed for comparison in the research project (“patient care costs”). The host healthcare delivery system, third-party payer, product manufacturer, developer of the intervention, or other interested party should cover the patient care costs.
• The willingness of one or more stakeholder groups to cover patient care costs 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 indicate that the stakeholder groups will use the research study’s findings. (Such support 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 copayment 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 to implement or monitor 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 collecting and monitoring study subject data that would not normally be performed in the course of patients receiving the patient care evaluated in the research project.

PCORI will review all proposed costs. Costs must be deemed allowable, allocable, and directly necessary for 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. For more information, see PCORI Cost Principles.

<table>
<thead>
<tr>
<th>Allowable Costs</th>
<th>Unallowable Costs</th>
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</thead>
<tbody>
<tr>
<td>Personnel salaries &amp; benefits</td>
<td>Bad debts/losses</td>
</tr>
<tr>
<td>Consultant fees</td>
<td>Interest of bad debts</td>
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<tr>
<td>Travel cost</td>
<td>Advertising</td>
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<tr>
<td>Equipment</td>
<td>Excessive airfare</td>
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<tr>
<td>Supplies</td>
<td>Donations</td>
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<tr>
<td>Other</td>
<td>Alcohol drinks</td>
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<tr>
<td>Applicant indirect costs</td>
<td>Fundraising</td>
</tr>
<tr>
<td>Subcontractor direct &amp; indirect</td>
<td>Student housing and stipends</td>
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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 that 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>
</table>
| An application or LOI will be automatically rejected if any of the following apply:  
   • Exceeds the specified page limit (LOI)  
   • Exceeds the specified period of performance outlined in the PFA  
   • Exceeds the maximum budget specified in the PFA  
   • Has adjusted margins or font size (LOI)  
   • Does not include or has an incomplete Research Strategy | PCORI will modify an application by removing all pages that exceed stated limits. | Unless automatically rejected or modified, PCORI may request that the applicant submit missing documents or correct noncompliant ones. |

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