PCORI Application Guidelines: Health Systems PCORnet Demonstration Project

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These guidelines apply to the Health Systems PCORnet Demonstration Project Limited PCORI Funding Announcement (PFA) that closes on April 19, 2016, at 5 p.m. (ET). Funding announcements, templates, and other resources are available at http://www.pcori.org/2016-health-systems.
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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I. About These Guidelines

This document provides key information to help researchers prepare for and respond to the Limited PCORI Funding Announcement (PFA): Health Systems PCORnet Demonstration Project.

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

- 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), via phone (202-627-1884), or online (http://www.pcori.org/PFA/inquiry). PCORI will provide a response within three business days.
- **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. The application will not be considered complete until all budget documents are submitted. The budget summary, template, and justification documents, must be submitted no later than May 3, 2016, by 5 p.m. (ET). 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 Health Systems PCORnet Demonstration Project Limited 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 application 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 application will not be deemed noncompliant once it is submitted to PCORI. See Appendix 3: Administrative Actions.

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\(^1\) Available at http://www.pcori.org/funding-opportunities/how-apply/faqs-applicants.
\(^2\) Available at https://help.pcori.org/hc/en-us.
\(^3\) Available at pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications/.

Limited PCORI 2016 Funding Announcement Health Systems PCORnet Demonstration Project: Application Guidelines
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 being completed 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*. The budget template and justification documents must be certified by the Administrative Official (AO) and must be submitted in accordance with the published dates and times listed. Applications will continue with the review process prior to the budget document submission.

As part of its active portfolio management, PCORI provides contractual and programmatic monitoring throughout the contract period. To review PCORI’s contract terms and conditions, see the [PCORI Standard Contract for Funded Research Projects](http://www.pcori.org/sites/default/files/PCORI-PFA-Standard-Contract-for-Funded-Research-Projects.pdf). PCORI’s funding contract with the selected Awardee Institution for the Health Systems PCORnet Demonstration Project Limited PFA will be based on PCORI’s sample contract terms and conditions and will have additional provisions appropriate for the specific research project, including its use of PCORnet.

**II. Who Can Apply**

For this limited-competition PFA, PCORI is soliciting applications from organizations or institutions that are part of the PCORnet Clinical Data Research Network (CDRN), working in conjunction with or engaging their health systems leaders. The Internal Revenue Service must recognize all applicant organizations. Organizations or institutions who are a part of the same CDRN may each submit applications for funding as a Principal Investigator/Primary Applicant only once. These organizations or institutions are encourage to participate in other proposals, including as Co-PIs or consultants. Individuals are not permitted to apply. The Awardee Institutions will assume responsibility for the study, including dispersing funds to any and all necessary subcontracts needed to conduct the study. If you have questions about eligibility, please contact [pfa@pcori.org](mailto:pfa@pcori.org).

**III. How To Apply**

To submit an application, including all required documents, please follow the instructions provided in these guidelines and in [PCORI Online](http://pcori.fluxx.io). All documents must be submitted through PCORI Online. Please refer to the specific PFA for more information regarding the review process of applications.

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5 Available at pcori.fluxx.io.
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\(^6\) or an EIN, if applicable.\(^7\)

**Step 1: Register**

To apply for PCORI funding, an applicant (Principal Investigator [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. The email address provided will be the username. PCORI strongly recommends that only the PI create the application record because whoever created the record will have permanent access to it in PCORI Online.

**Step 2: Begin Application Process**

The application sections within PCORI Online must all be completed before submission. Please log in to PCORI Online to view the full list of questions. It is recommended that you log in early in the application development process to be aware of the required questions.

**Step 3: Format and Complete Required Templates**

Required templates are available in the PCORI Funding Center.\(^8\) Find the correct PFA to which you are applying and download the correct PFA-specific templates in the Applicant Resources section because they are unique to this funding announcement. Keep the following in mind:

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

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, tables, and captions may be size 8 font.
- **Page Numbers**: Each uploaded document must be consecutively numbered.

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\(^6\) Available at dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number/.

\(^7\) Available at irs.gov/Businesses/Small-Businesses-&-Self-Employed/Apply-for-an-Employer-Identification-Number-(EIN)-Online.

\(^8\) Available at pcori.org/apply.
• **Spacing**: Use single spacing.
• **References**: Use American Medical Association (AMA) citation style.

**Step 4: 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. Use Adobe Acrobat Professional\(^9\) to combine documents into a single PDF file for upload. To upload, select the name of the required document from the drop-down list. For detailed instructions, refer to the Templates and Uploads section of the [PCORI Online User Manual: Submitting an Application](#).

**Step 5: Submit for Authorization**

Once all required information has been completed and uploaded, select “Submit to AO” to forward the application to your 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.

Please note the budget template and justification documents must be certified by the AO and must be submitted in accordance with the published dates and times listed.

**IV. When To Apply**

Deadlines for each funding cycle are noted in the PCORI Funding Center and in the PFA. System or technical issues with PCORI Online, which 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, 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]\(^{10}\) for complete information.

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\(^9\) See adobe.com for more information on Adobe Acrobat Professional.
\(^{10}\) Available at [http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/](http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/).
V. What To Include

Applicants are encouraged to review this entire section. Print and complete the provided Application Checklist to ensure that the application is submitted correctly. Download all required templates from the PCORI Funding Center.\(^1\)

\(^1\) Available at pcori.org/apply.
# Application Checklist

<table>
<thead>
<tr>
<th>Application</th>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Project Information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Technical Abstract</td>
<td>Enter into PCORI Online</td>
<td>6,000 characters/spaces</td>
</tr>
<tr>
<td>• Public Abstract</td>
<td>Enter into PCORI Online</td>
<td>3,000 characters/spaces</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>□ Research Plan Template</td>
<td>Save file as “ResearchPlan_PI Last Name.pdf” and upload as a single file</td>
<td>As noted below</td>
</tr>
<tr>
<td>• Research Strategy</td>
<td></td>
<td>5 pages</td>
</tr>
<tr>
<td>• Engagement Plan</td>
<td></td>
<td>2 pages</td>
</tr>
<tr>
<td>• Evaluation Plan</td>
<td></td>
<td>2 pages</td>
</tr>
<tr>
<td>• Dissemination and Implementation Potential</td>
<td></td>
<td>2 pages</td>
</tr>
<tr>
<td>• Replication and Reproducibility of Research and Data Sharing</td>
<td></td>
<td>2 pages</td>
</tr>
<tr>
<td>• Protection of Human Subjects</td>
<td></td>
<td>5 pages</td>
</tr>
<tr>
<td>• Consortium Contractual Arrangements</td>
<td></td>
<td>5 pages</td>
</tr>
<tr>
<td>• References Cited</td>
<td></td>
<td>10 pages</td>
</tr>
<tr>
<td>• Appendix (optional)</td>
<td></td>
<td>25 pages</td>
</tr>
<tr>
<td>□ People and Places Template</td>
<td>Save as “PeoplePlaces_PI LastName.pdf” and upload as a single file</td>
<td>As noted below</td>
</tr>
<tr>
<td>• Professional Profile/Biosketch</td>
<td></td>
<td>5 pages per individual</td>
</tr>
<tr>
<td>• Patient/Stakeholder Partner Biosketch</td>
<td></td>
<td>5 pages per individual</td>
</tr>
<tr>
<td>• Project/Performance Site(s) and Resources</td>
<td></td>
<td>As needed</td>
</tr>
<tr>
<td>□ Budget Template</td>
<td>Combine and save as “Budget_PI Last Name.pdf” and upload</td>
<td>As needed</td>
</tr>
<tr>
<td>• Detailed Budget for Each Project Year (prime and subcontractors)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Budget Summary for Entire Project</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Budget Justification (prime and subcontractors)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
- Federally Negotiated or Independently Audited Indirect Cost Rate Letter (prime contractor)
- Fringe Benefit Rate Policy Verification Document (prime contractor)

| □ Key Personnel Justification | Save as “Personnel_PI Last Name.pdf” and upload under “Budget” to PCORI Online | As needed |

| □ Letters of Support | Save as “Letters_PI Last Name.pdf” and upload as a single file | As needed |
- Letters of Support Table
- Letters of Support
PI and Contact Information
PCORI refers to three specific roles with particular responsibilities. Please keep the following in mind as you complete your application.

Principal Investigator
A. Description
- Applicants must designate one PI as the Lead PI. The Lead PI is responsible for submitting the application and will serve as PCORI’s primary Point of Contact for all communication.
- The PI is responsible for the project’s engagement and scientific or technical aspects, as well as the project’s peer-review-related activities.
- Applications must include, in addition to the Lead PI, two co-PIs. (Note that only the Lead PI’s name will be published with the contract if the project is funded.)
- The Lead PI’s institution must be the primary institution for the award.
- PIs can participate in other applications (from the same or another organization) in a different role, such as co-investigator or consultant. Refer to the Who Can Apply section for specific instructions.

B. Activities
- The PI assumes responsibility and accountability for research execution, compliance, and organization conduct.
- The Lead PI is responsible for submitting the application, submitting all progress reports, and serving as PCORI’s programmatic and administrative contact. All PCORI communication will be sent to the Lead PI, and it is his or her responsibility to share PCORI communications with the co-PIs.
- The PI manages day-to-day operations of the project.
- The PI acts as the organization’s lead research representative.

Administrative Official
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

A. Description
• The Financial Official (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 must include one Lead PI and at least two co-PIs.
• PIs can serve in other roles (e.g., co-PI, co-investigator, or consultant) on other applications on up to two other applications.
• Applicants must explain in the Budget Justification the rationale for including a co-PI.
• 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. If your project is funded, these partners will be named on the PCORI website along with the Lead PI and the recipient organization. They might 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 stakeholder partner wishes to remain anonymous, please contact us at pfa@pcori.org for additional guidance on how to recognize such partners appropriately.
• Complete the Key Personnel Justification Template and upload under “Budget” to PCORI Online with all other application materials.
• 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.
Application Requirements

Note: The following sections are applicable only if you have been invited to submit an application. Any changes to the following require PCORI’s approval:

- Principal Investigators (Lead PI and co-PIs)
- Institution
- Population overlap with PCORnet Phase II CDRN and Patient-Powered Research Network (PPRN) populations for which the health plan intends to work

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

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:** Briefly describe the clinical or health system burden imposed by the problem or condition under study, and the added value of the proposed research question for the PCORnet health systems that span two or more CDRNs participating in the study.
- **Study Design or Approach:** Briefly describe how the appropriate interventions or comparators have been selected.
- **PCORnet Commons and Engagement:** Briefly describe an ability and willingness to contribute to the PCORnet Commons through the development of shared tools and resources. Describe proposed plans for engaging in discussions about research activities in collaboration with clinicians, health systems leaders, other key stakeholders, and the broader PCORnet community.

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 organization(s) (health system(s)) and mission
- Brief background on why this project is important to patients
- Explanation of how patients and other stakeholder partners will help 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 application review process. Public abstracts from proposals 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.
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 the activities that the PCORI contract supports. 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. Examples of deliverables that might be required following contract execution include but are not limited to:

- Subcontract(s) as necessary with applicable PCORnet Coordinating Centers and participating study sites
- Copies of Institutional Review Board (IRB) approval
- Abstracts accepted or presentations made
- Manuscripts accepted for publication
- Copies of papers 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
- Engagement updates, every three months, noting specific engagement activities that clinicians, systems leaders, and stakeholders participated in during the reporting time period
- 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 include specific deliverables associated with a time line and project objectives that will be accomplished at specific times during the proposed project.

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

Research Plan Template

Complete all required sections in the [Research Plan Template](#) and upload as a single PDF to PCORI Online. This template includes the following: Research Strategy, Engagement Plan, Evaluation Plan, Dissemination and Implementation Potential, Replication and Reproducibility of Research and Data...
Sharing, Protection of Human Subjects, Consortium Contractual Arrangements, References Cited, and Appendix (optional).

Research Strategy

This component (up to five pages), included in the Research Plan Template, addresses the following sections:

A. Background
B. Significance
C. Study Design or Approach
D. Patient Population, if applicable
E. Research Team and Environment

Please provide all of the information requested, as outlined in the template.

While completing the Research Plan section, applicants must cite the PCORI Methodology Standards.

Engagement Plan

This component (up to two pages) should thoroughly describe the plan to engage patients and stakeholders meaningfully in the various phases of the proposed research (Planning the Study, Conducting the Study, and Disseminating the Study Results).

Evaluation Plan

This component (up to two pages) should thoroughly describe a robust plan for evaluating the impact of the research project. A model for key evaluation pieces, questions, and measureable outcomes, both short and long term, should be included to formatively assess ongoing activities to improve health systems and PCORnet infrastructure through a collaborative review process.

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 and impact of disseminating project findings and facilitating their widespread use in practice. Applicants should describe 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 the findings (e.g., proprietary issues, applicability, scalability, and appropriate settings of care).

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 the PCORI Methodology Standards and the Engagement

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Rubric, which can be found in the PCORI Funding Center, for guidance on how to include patient and stakeholder partners in the dissemination process, as needed. Applicants should also 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 the organization will implement successful interventions on a large scale. This agreement will be viewed as a positive factor during application 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 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 later requested. 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 research 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; and 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 is usually 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 reserves the right to share these materials with appropriate researchers, in consultation with the study’s PI.

**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. Although the plan is required of all applicants, PCORI would request subsequent data sharing only after reviewing the findings and deciding that they 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 that enables others in the research community to use the data for additional or secondary analysis, and may also request that awardees make the data and documentation available upon request.
The data-sharing plan must:

- Address data management and sharing and the methods that investigators will use to make study data sets available in a manner that is consistent with applicable privacy, confidentiality and other legal requirements, if requested
- Propose a budget that would cover the 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.

**Adherence to PCORI Methodology Standards**

All PCORI proposals must adhere to relevant PCORI Methodology Standards, including the Standards for Data Networks as Research-Facilitating Infrastructures. To help reviewers quickly identify the adherence to a particular standard, applicants should cite each PCORI Methodology Standard within their proposals as the standard is addressed.

**Protection of Human Subjects (if applicable)**

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, titled “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 (DHHS). 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 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.
- 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, subcontract personnel should be included under key personnel.

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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 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, journal, or book title; and the 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. 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 referenced in the standard URL format (i.e., http://www.pcori.org) with the date the link was last accessed.

Appendix (Optional)

This component (up to 25 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 expert review panel reviewers are not required to evaluate this section.

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-investigator, 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. As mentioned above, 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 has prepared him or her to conduct this research. The backgrounds; the relevant experiences related to large data infrastructure projects, to patient and stakeholder engagement, and to the conduct or support of comparative clinical effectiveness research (CER); and roles of patient and stakeholder partners should also be described.

Applicants should assemble a research team that is suited 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 aid in achieving the project goals.
Project Performance Site(s) and Resources

This component is included in the People and Places Template. In this section, 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.

Budget Template

Complete all required sections, including the Peer-Review Budget section, and submit the Budget Template and Budget Justification to pfa@pcori.org as a single PDF in accordance with the published dates and times listed. Do not upload separate budget files for subcontractors; include all subcontractor budget files within the prime applicant’s PDF budget upload. The budget template and justification documents must be certified by the AO and must be submitted in accordance with the published dates and times listed. Applications will continue with the review process prior to the budget document submission.

Key Personnel Justification

Please complete the Key Personnel Justification Template and upload under “Budget” to PCORI Online with all other application materials.

Detailed Budget for the Research Project Period

Complete a Detailed Budget for the project for the prime applicant and any subcontractor(s) proposed in your application. The subcontractor should follow the same process and complete a Detailed Budget for each year of the proposed study. An additional personnel form is provided within the template.

All personnel information should be entered in the Personnel tab corresponding to that year in the Budget Template. The applicant may add additional rows for personnel as needed. Applicants may delete the unused Year Two–Five Detailed Budget tabs. However, applicants are not permitted to add additional years. Maximum project periods are stated in each PFA. 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 not accounted for in Section B: Consultant Costs.
- PCORI will reimburse for personnel costs that are consistent with and do not exceed what the applicant would normally pay under the institution’s 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 with the Budget Justification.
• Level of Effort: Personnel contributing to a PCORI-funded research project are expected to monitor their total percent 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 all individual 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. Minimum Full-Time Equivalents (FTEs) are required for PIs if submitting for this limited PFA. The minimum FTEs can be found in the PFA. 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 levels 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. 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.

  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 neither employees of the applicant organization nor under a subcontract agreement as members of the contracted staff.
• Payments to nonemployee patient and stakeholder representatives should be included in the budget as consultant costs.
• Provide the total cost of consultants, as well as names, expected number of hours, and hourly rate.
• Include the daily consultant fee, travel expenses, nature of the consulting effort, and explanation of why the proposed project requires consultants. Note any overlap in duties with personnel.
• Consultant costs must be expressed in an hourly rate.
• Consultant costs must be reasonable and justified within the Budget Justification.
• For all consultant costs, provide computations for how applicants arrived at the specific number.
Include a letter of support for 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, or equipment less than $5,000 per-unit cost. Provide detailed explanations for all costs exceeding $1,000 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 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 costs should be itemized per trip and described as either scientific travel or programmatic travel, as outlined below:
  - Scientific travel includes travel to present at conferences, symposia, 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 conducting the project (i.e., focus groups, project team, meetings, and 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 the number of trips and a brief description of the trips, including 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 to 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 warranties, computer services, data warehousing, or participant incentives.
- In the space provided, include a detailed explanation for items exceeding $1,000. Applicants must provide additional 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.

Subcontractor Costs

- This category includes all consortium and contractual costs. A subcontractor arrangement is required if the following criteria are met:
  - The subcontractor PI’s effort on the project is calculated as part of his or her “professional time” for his or her employer organization.
  - 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, other expenses, and $25,000 of all combined subcontractor costs.
- Applicants who 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.

In the event that an indirect cost rate agreement is more restrictive than that of PCORI’s accepted indirect cost application, PCORI will allow 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 must include costs related to the Peer-Review Process. Please complete a Detailed Budget for the Peer-Review Process. (See the 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 the Peer-Review Process are limited as follows:
  - PI’s level of effort for completing the Peer-Review Process is limited to a maximum of 20 percent level of effort for 90 days.
  - Support staff’s level of effort for completing the Peer-Review Process is limited to a maximum of 100 percent for one 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 of the PI's level of effort and 50 percent of the 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 included within the prime institution’s budget.

Budget Summary for Entire Project

Complete a Budget Summary of the entire project for the prime applicant and each subcontracted organization. Keep in mind the guidance in the previous section. See Appendix 2: Allowable and Unallowable Costs to review acceptable and unacceptable uses of PCORI funding. The budget summary and justification documents must be certified by the AO and must be submitted in accordance with the published dates and times listed. Applications will continue with the review process prior to the budget document submission.

Budget Justification

Complete a Budget Justification for the prime applicant and each subcontracted organization for the 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.

Justify the costs associated with in-patient and outpatient care. Also 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.

Applicants are also asked to 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 the expert review panel 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 might 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 Lead PI and demonstrate the commitment of key personnel and supporting organizations (e.g., co-PIs, co-investigators, consultants, patient and stakeholder partners, and stakeholder organizations) to the proposed project. Letters of support are not required for such personnel as research assistants, who are not contributing in a substantive, measurable way to the project’s scientific development or execution. Letters of support should reflect clearly the involvement and material contribution to be provided by the signatory parties; they are meant to substantiate the commitment of collaboration of all forms. The quality of the letters—and the way in which they bolster the proposed research—is more important than the number of letters provided.
Please note that PCORI may contact any individuals or organizations included in the letters of support with questions or to confirm support as described in their letters.

Letters of support should support the information provided in the Research Plan. They 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, which 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 that you provide a letter from department or organization leadership affirming support to disseminate and implement 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 collaboration from patient and stakeholder partners should clearly describe the origin of the study topic and the role of the patient partners in defining the question, outcomes, comparators, goals and outcomes, and so on. PCORI also strongly encourages that you provide 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 also include a letter of support for all consultants, verifying the work to be performed and the 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 resources.

List all letters on the table, and include the page number on which the letter can be found in the single PDF file.

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 key personnel listed in the application. The policy and FAQs are available on the NIH website.¹³

¹³ Available at grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.
PCORI Public Access Policy
PCORI contracts require all awardees to adhere strictly to PCORI’s publication policies. These policies will be shared with awardees.

Standards for Privacy of Individually Identifiable Health Information

DHHS issued a final modification to the Standards for Privacy of Individually Identifiable Health Information, the “Privacy Rule,” on August 14, 2002. The Privacy Rule is a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS 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. Proposed milestones should be presented in the application, but final milestones will be negotiated in the post-award period before the beginning or activation of the funding period.

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 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.

14 Available at hhs.gov/ocr.
Appendix 1: Example Milestones

Milestones are significant events, deliverables, tasks, or outcomes that occur over the course of each project signifying 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. Below is a list of milestone examples you may reference as you complete this section of your application:

- Subcontract(s) as necessary with applicable PCORnet Coordinating Centers and participating study sites
- Copies of Institutional Review Board (IRB) approval
- Abstracts accepted or presentations made
- Manuscripts accepted for publication
- Copies of papers 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
- Engagement updates, every three months, noting specific engagement activities that clinicians, systems leaders, and stakeholders participated in during the reporting time period
- 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

At the Program Officer’s discretion, 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 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, 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 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 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 conducting the research project must be specifically requested by a funding applicant through itemization on the Detailed Budget and PCORI will consider the costs 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 are being proposed for comparison in the research project (“patient care costs”). Patient care costs should
be covered by the host healthcare delivery system, third-party payer, product manufacturer, developer of the 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 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 in implementing or monitoring 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 that the research project evaluates.

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.
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 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 documents.</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.