Funding Cycle
PCORI Application Guidelines
Improving Infrastructure for Conducting Patient-Centered Outcomes Research

The National Patient-Centered Clinical Research Network:
- Clinical Data Research Networks (CDRNs)—Phase II
- Patient-Powered Research Networks (PPRNs)—Phase II

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These guidelines apply to the funding cycle for the following PCORI Funding Announcements: The National Patient-Centered Clinical Research Network: Clinical Data Research Networks (CDRNs)—Phase II and National Patient-Centered Clinical Research Network: Patient-Powered Research Networks (PPRNs)—Phase II. Funding announcements, templates, and other resources are available at pcori.org/apply. The Funding Cycle closes on April 7, 2015, at 5:00 p.m. (ET).
About PCORI

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input in order 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 the Patient Protection and Affordable Care Act of 2010 as a nonprofit, nongovernmental organization. PCORI’s purpose, as defined by the act, 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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PCORI Funding Announcement: Improving Infrastructure for Conducting Patient-Centered Outcomes Research
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PCORI Funding Announcement: Improving Infrastructure for Conducting Patient-Centered Outcomes Research
I. About These Guidelines

This document provides key information to help researchers prepare and respond to the following PCORI Funding Announcements (PFAs): The National Patient-Centered Clinical Research Network: Clinical Data Research Networks (CDRNs)—Phase II (http://www.pcori.org/PCORI-PFA-CDRN-Phase-2) and the National Patient-Centered Clinical Research Network: Patient-Powered Research Networks (PPRN)—Phase II (http://www.pcori.org/PCORI-PFA-PPRN-Phase-2).

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

- PCORI’s Applicant FAQs1 cover common questions about PCORI and the application process.
- Programmatic Inquiries: Contact the PCORI Helpdesk via email (sciencequestions@pcori.org), via telephone (202-627-1884), or online (http://www.pcori.org/PFA/inquiry). PCORI will provide a response within three business days; however, we cannot guarantee that all questions will be addressed three business days before a Letter of Intent (LOI) or application deadline.
- For Administrative, Financial, or Technical Inquiries: Contact the PCORI Helpdesk at pfa@pcori.org. PCORI will provide a response within two business days. 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. Consult PCORI’s Policy on Submission of Research Contract Applications.2

Administrative Issues

To ensure a thorough, fair, 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 Department of Contracts Management and Administration are final. Email pfa@pcori.org with any formatting or administrative compliance questions.

Funding Mechanism

PCORI issues contracts, not grants, to fund and administrate meritorious research. Under these contracts, PCORI funds only those projects that demonstrate the highest probability that they will be completed on time and on budget, and will meet all milestones and deliverables. Therefore, applicants

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1 Available at pcori.org/funding-opportunities/applicant-faqs
2 Available at pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications/
should submit realistic budgets and technical proposals without the expectation of receiving cost/no-cost extensions.

As part of its active portfolio management, PCORI provides programmatic oversight throughout the contract period. To review PCORI’s contract terms and conditions, see PCORI Contract for Funded Research Projects.  

II. Who Can Apply

Applications may be submitted by any private-sector research organization, including nonprofit or for-profit organizations, and public-sector research organizations, including, but not limited to, any university, college, hospital, healthcare system, laboratory, manufacturer, or unit of local, state, or federal government. The Internal Revenue Service must recognize all applicant organizations. Organizations may submit multiple applications for funding. Individuals are not permitted to apply. If you have questions about eligibility, contact pfa@pcori.org.

Clinical Data Research Networks (CDRNs)

PCORI anticipates funding up to 13 Phase II CDRNs. These 13 CDRNs are expected to include one or more new applicants. Current CDRNs will apply for continuation funding through this PFA in competition with new applicants. To be competitive, existing CDRNs are expected to have achieved the Phase I requirements described in the PFA. The current CDRN applicants are also expected to have participated in the planning phase (not necessarily the final application) of at least one of the three Phase I demonstration projects. Performance against Phase I milestones will contribute heavily to the scoring of the applications of existing CDRNs. Current CDRNs are not required to re-apply with exactly the same institutions or personnel as in Phase I, and are encouraged to evaluate the optimal partnerships for their CDRNs for Phase II, given PCORnet’s overall goals. In evaluation of Phase I achievements, it may be acceptable to PCORI that not all constituent organizations within a CDRN have met 100 percent of the Phase I requirements—for example, some partners within the CDRN may be ready with analysis-ready data, while others are ready to implement efficient clinical trials. However, for such CDRNs, the prospects for completion of all requirements for one million persons or more must be thoroughly described in the application and will be closely scrutinized for strength and viability.

New applicants (i.e., applicants not funded during Phase I) must provide an explicit plan and compelling evidence to demonstrate that, within six months of the date of the initiation of funding, their proposed CDRN will be able to meet these same requirements as Phase I CDRNs for a population of at least one million persons. In particular, new applicants must demonstrate their capacity to capture complete longitudinal data, including full capture of data from medical and pharmacy claims, as well as EHR data for a population of at least one million persons within six months. New applicant CDRNs that capture complete health plan enrollment and claims data should also state whether and how they may have

3 Available at pcori.org/assets/2013/09/PCORI-PFA-Contract-for-Funded-Research-Projects.pdf
access to claims data for some persons who may receive care in delivery systems of other, current CDRNs and whether there is ability to partner with these CDRNs to create complete, longitudinal data. Robust documentation to that effect, including key leadership support, will be required.

**Patient-Powered Research Networks (PPRNs)**

PCORI anticipates funding up to 22 PPRN networks, which are expected to include one or more applicants that were not funded under Phase I. Current PPRNs will apply for continuation funding through this PFA in competition with new applicants. To be competitive, existing PPRNs are expected to have achieved the Phase I requirements described in the PFA. Performance against Phase I milestones will be factored into reviews of existing PPRNs. Applicants should ensure their partnerships are optimal to meet the overall PCORNet goals. Current PPRNs are not required to bring in exactly the same partners or same personnel as in Phase I. All applications will be reviewed based on merit.

New applicants (i.e., applicants not funded during Phase I) must provide an explicit plan and compelling evidence to demonstrate that, within six months—at most—of the date of the initiation of funding, their proposed PPRN will be able to meet the same requirements as Phase I PPRNs. New applicants should make explicit the maturity of their existing network, its membership, and resources that will allow the new entrant to meet Phase I goals and establish partnerships with current or new PCORnet networks within six months. In particular, new applicants must demonstrate their current and existing capacity to enroll participants, capture patient-generated data, involve patients fully in the governance of their network, and participate as subjects in clinical research. PCORI will also entertain new PPRN applications from organizations or communities of individuals joined for reasons other than a shared disease or condition. For example, individuals could organize around a general interest in health or healthcare, or around interests in research on common symptoms (e.g., pain or fatigue). Other communities may represent vulnerable or underserved communities (e.g., women, minorities, employee groups, etc.). Such applicants must describe the goals of the organization and of participation in PCORnet; they must also demonstrate their capacity to recruit and retain members, involve members in governance, collect patient-generated data, and participate in research as research subjects.

**Note:** A Principal Investigator (PI) may submit only one LOI per PFA as the primary PI. While a PI may submit an LOI to other PFAs, the research topic or project must be distinct. LOIs with scientific overlap or those that appear to be duplicate submissions will be removed during the LOI screening process.

**III. How to Apply**

Follow the instructions provided in these guidelines and in the [PCORI Online System](https://pcori.fluxx.io) to submit an LOI and application, including all required documents. All required documents must be submitted through the PCORI Online System; failure to do so may result in the removal of the application from the review process.

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4 Available at pcori.fluxx.io
process. Consult your specific PFA for more information regarding the review process of LOIs and applications.

To submit an application or to register your organization in our system, you will need a Data Universal Numbering System (DUNS) number and an Employer Identification Number (EIN). If necessary, you can apply for a DUNS number and/or an EIN. Individual consultants are not required to provide a DUNS number.

Step 1: Register

To apply for PCORI funding, an applicant (PI or PI designee) must register in the PCORI Online System. To register, your name, an email address, a password, and a security question and answer are required. The email address provided will be your username. Carefully consider who initially creates the application, as this person will have permanent access to the application. PCORI strongly encourages that only the PI creates the application.

Step 2: Submit a Letter of Intent (LOI)

An LOI is required for new and resubmitted applications, and it must be submitted before completion of an application. Download the PFA-specific LOI template in the PCORI Funding Center. Note that LOIs that exceed the PFA-specific page limit will not be reviewed. Do not upload additional documents as part of your LOI, such as letters of endorsements or support, as they are not requested at this stage; their inclusion will result in LOI rejection without review. To submit an LOI, upload the completed PFA-specific LOI into the PCORI Online System and complete the required fields. For detailed instructions on how to navigate the system, consult the PCORI Online System User Manual: Start a Letter of Intent.

Step 3: Begin Full Application Process

Note: Only applicants selected to submit a full application should begin this process.

Applicants will be notified by February 3, 2015, if they have been invited to submit a full application.

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5 Available at dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number/
6 Available at irs.gov/Businesses/Small-Businesses-&-Self-Employed/Apply-for-an-Employer-Identification-Number-(EIN)-Online
7 Available at http://www.pcori.org/funding/opportunities
8 Available at pcori.org/assets/2013/10/PCORI-Online-Start-a-LOI.pdf
The application process includes sections within the PCORI Online System, and all sections must be completed before submission. Log in to PCORI Online to view the full list of questions—in the Project Information tab—that require completion before submission.

You can return to complete your application as many times as needed; however, to save your work before exiting, you must go to the Save and Review section, by clicking on the navigation pane on the left side of your screen; proceed to click the “Save and Review” button on the center of the page.

**Step 4: Complete Required Documents**

Required templates are available in the PCORI Funding Center. Be sure to download the correct PFA-specific templates, as they may vary between PFA and cycle. Note:

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

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

- **Header:** Include the PI’s full name on every page in the top left corner of the page header.
- **Margins:** Use at least half-inch margins. The header may fall within the top margin, but the body text should not begin closer than one half-inch from the edge of the page.
- **Font:** Use size 11 Arial, Calibri, or Times New Roman for the main body of the text. Figures and captions may have smaller type.
- **Page Numbers:** Each page must be numbered consecutively for each PDF upload.
- **Spacing:** Use single spacing.

**Step 5: Upload Required Documents**

Follow the application checklist included in these guidelines to enter required information and upload required documents into the PCORI Online System in the correct order. To combine documents into a single PDF, applicants must use Adobe Acrobat Professional.

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9 Available at pcori.org/apply
10 See adobe.com for more information on Adobe Acrobat Professional.
Step 6: Submit for Authorization

After all required information has been entered and all required documents have been uploaded, click “Submit to AO” to forward the application to your Administrative Official (AO) for him or her to authorize and submit. **The AO may not be the same individual as the lead PI or co-PI.** Only the AO may approve the final application for official submission to PCORI. Ensure that the AO approves and submits the application to PCORI before the submission deadline. It is the responsibility of the PI to inform the AO when the application is ready for submission. Following the submission of an application, both the AO and the PI will receive an email confirming that it has been received.

IV. When to Apply

Deadlines for each funding cycle are noted in the PCORI Funding Center and in each funding announcement. Deadlines are at 5:00 p.m. ET on the due date.

Any system or technical issues with the PCORI Online System that hinder the on-time submission of an application must be reported to PCORI before the stated deadline. PCORI reserves the right to extend deadlines due to such issues.

Problems with computer systems at the applicant’s organization; failure to follow instructions in the PCORI Online System, these guidelines, or a specific PFA; and failure to complete all required user profiles by the submission deadline are not considered system issues and may result in rejection of your LOI or application. Consult PCORI’s Policy on Submission of Research Contract Applications\(^\text{11}\) for further information.

V. What to Include

Applicants are encouraged to review this entire section and to print and complete the provided application checklist to ensure that the LOI and application are submitted correctly and completely. All required templates can be downloaded from the PCORI Funding Center.\(^\text{12}\)

\(^{11}\) Available at pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications

\(^{12}\) Available at pcori.org/apply
## Application Checklist

<table>
<thead>
<tr>
<th>Letter of Intent</th>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
</thead>
<tbody>
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### Letter of Intent
- **PI and Contact Information**
- **Network Information**
- **PFA-Specific LOI Template**

#### Submission Method
- Enter into PCORI Online System
- Save file as “LOI_PI_Last Name.pdf” and upload

#### Length/Limit
- N/A

### Application
- **PI and Contact Information**
- **Project Information**
- **Key Personnel**
- **Milestones Template**
- **Technical Proposal Template**
- **People and Places Template**
- **Budget Template**

#### Submission Method
- Enter into PCORI Online System
- Enter into PCORI Online System
- Enter into PCORI Online System
- Save file as “Milestones_PI_Last Name.pdf” and upload
- Save file as “TechnicalProposal_PI_Last Name.pdf” and upload as a single file
- Save as “PeoplePlaces_PI_Last Name.pdf” and upload
- Combine and save as “Budget_PI_Last Name.pdf” and upload

#### Length/Limit
- N/A
- 3,000 characters/spaces
- As needed
- As needed
- As noted below
- As indicated in each template
- As needed
- 25 pages
- As noted below
- 5 pages per individual
- 5 pages per individual
- 15 pages
- As needed

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PCORI Funding Announcement: CDRN and PPRN Phase II Application Guidelines
• Budget Justification (prime and subcontractors)
• Federally Negotiated or Independently Audited Indirect Cost Rate Letter (prime and subcontractors)
• Fringe Benefit Rate Policy Verification Document (prime and subcontractors)

☐ Letters of Support

Save as “Letters_PI Last Name.pdf” and upload as a single file

As needed
Letter of Intent (LOI)

An LOI must be submitted before the completion of your application. Enter information in the required fields in the PCORI Online System.

Upon receipt of LOIs, PCORI program staff will screen them for programmatic fit and overlap with projects in the existing portfolio. Those applicants whose LOIs do not meet expectations for progress in meeting Phase I goals and ability to meet Phase II goals will not be invited to submit full applications. LOIs will also be reviewed for programmatic fit and balance. Applicants will receive an email notification accepting or declining their LOIs three full weeks after the LOI deadline.

PI and Contact Information

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

Principal Investigator (PI)

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

B. Activities
   • Assumes responsibility and accountability for network execution, organization conduct, and compliance
   • Manages day-to-day operation of the network
   • Acts as lead network representative of the organization/institution
   • Serves as PCORI lead point of contact

Administrative Official (AO)

A. Description
   • Responsible for matters related to the award and administration of the contract
• Cannot be the PI
• The AO’s signature certifies that the organization/institution will be accountable both for the appropriate use of funds awarded and for the performance of the PCORI-supported project or activities resulting from the contract.

B. Activities
• Manages contract activation, renewals, milestones, and additional required materials
• Oversees submission of the contract activation, renewals, milestones, and additional required materials
• Certifies contract compliance of all applicable assurances and certifications referenced in the application

Financial Official (FO)

A. Description
• Responsible for required annual expenditure reports

B. Activities
• Completes and certifies the required yearly expenditure reports
•Executes accounting of contract funds and submission of invoices and payment details

PFA-Specific LOI Template

Download the PFA-specific LOI template from the Funding Center for the PPRN PFA and CDRN PFA. Provide a thorough description that allows the scientific community to understand the proposed network, including a description of its ability as a network to conduct research and its ability to meet Phase I goals and plans for Phase II goals, without reviewing the full application. Consult the PFA for specific instructions on how to complete the LOI. Any LOIs that exceed the page limit (excluding references and the required table) will not be reviewed. All references must be included as in-text citations or listed at the end of the LOI. Do not upload additional documents, such as letters of endorsements or support, as part of your LOI, as they are not requested at this stage. Their inclusion will result in LOI rejection without review.

To submit an LOI, save the completed PFA-specific LOI as a PDF, upload it into the PCORI Online System, and complete the required fields.

Full Application Requirements

⚠️ The following sections are applicable only if you have been invited to submit a full application. Applicants will be notified of this decision via email by February 3, 2015.

PI, Contact Information, and Network Information

Review information carried over from your LOI and update in the PCORI Online System, as needed.
Project Information

Enter the following information directly into the PCORI Online System.

Public Abstract

Enter into the PCORI Online System. Provide a description of your project, written in lay language that the general public will understand. Include the following:

- Concisely describe the network and its mission.
- Provide a brief background on why this project is important to patients.
- Explain how patients and other stakeholder partners will help make the project successful.

Keep in mind that this summary should be comprehensible to a variety of audiences and will be reviewed by patient and stakeholder reviewers during Merit Review. Public abstracts from proposals that are awarded a contract will be posted on PCORI’s website.

Log in to PCORI Online to view the full list of questions in this section that require completion before submission.

Key Personnel

Enter key personnel information into the PCORI Online System. Keep the following guidelines in mind as you complete this section:

- Applications can include one PI and multiple co-PIs (see PFA for specific requirements).
- PIs can serve in other applications in other roles (e.g., as co-investigators or consultants).
- Investigators may serve as PI on only one application per cycle for any individual PFA. An individual who is a PI may, however, participate in other applications (from the same or other organizations) in a different role, such as co-PI, co-investigator or consultant.
- PPRN applicants should indicate the key personnel who are mentoring early-career investigators. Co-PIs should consider mentoring up to two such investigators. This would be an opportunity for the co-PIs to train early-career investigators on conducting patient-centered research with a patient community. A brief plan for mentoring early-career qualified investigators in Phase II will be considered a value in the review process and should be included in the key personnel section. A more detailed mentoring plan can be included as an appendix.
- PCORI identifies key personnel as any individual who is considered critical to the project’s scientific development and execution in a measurable way, regardless of whether salary is requested, and whose absence from the project would have a significant impact on the approved scope.
- 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.

13 Available at http://www.pcori.org/content/glossary
• Project directors and project managers are considered key personnel. At least one senior project manager or project director is required at minimum 50-percent effort (see PFA for specific requirements).
• Anyone who could be replaced without significantly affecting the direction or conduct of the project should not be listed as key personnel.
• In your application, you will be asked to identify the primary patient and stakeholder partner on the project; PCORI is interested in highlighting the work of key patient and stakeholder partners on projects. In the event your project is awarded a contract, the primary patient or stakeholder partner(s) will be named in a public announcement along with the PI and research or academic institution.
• If your project is awarded, PCORI will need to approve additional or replacement key personnel (listed in the submitted application) during contract negotiation and post-contract execution, as detailed in contract terms and conditions. To review PCORI’s contract terms and conditions, consult PCORI’s Standard Contract for Funded Research Projects.

**Milestones Template**

Each network will adhere to the same set of milestones. These global milestones will be provided by PCORI for Phase II applicants after the LOI stage. Applicants invited to submit full applications will utilize the global Milestones Template for Phase II. Complete the PFA-specific Milestones Template (found in the Funding Center) and upload the document as a pdf into the PCORI Online System. Milestones are concrete, specific events or accomplishments that are documented by deliverables.

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

Note: Applicants are required to describe project milestones and a timeline for completion in the milestones template. Milestones are specific deliverables and attached to a timeline.

**Technical Proposal Template**

Complete all required sections and upload as a single PDF into the PCORI Online System. The Technical Proposal template includes: Technical Strategy, Protection of Human Subjects, Consortium Contractual Arrangements, References, and optional Appendices.

The sections of the technical strategy are:

PART I: Executive Summary (1 page)

PART II: Technical Proposal (page limits as required in the Technical Proposal templates)

- A. Demonstration of Successful Achievement of Phase I infrastructure Requirements
- B. Proposed Plans for the Statement of Work in Phase II
- C. Staffing and Organizational Requirements
D. Proposed Budget

A more detailed outline of the technical strategy, including required components and page numbers, can be found in the PPRN Technical Proposal template or the CDRN Technical Proposal template.

Adherence to PCORI Methodology Standards

All PCORI proposals must adhere to relevant PCORI Methodology Standards and, in particular, to the Standards for Data Networks as Research-Facilitating Infrastructures.

To help reviewers quickly identify the adherence to a particular standard, applicants should cite each methodology standard within their proposals as the standard is addressed.

Protection of Human Subjects

This component (up to five pages) is included in the technical proposal. The awardee institution or organization bears ultimate responsibility for safeguarding the rights and welfare of human subjects in PCORI-supported activities.

Describe the protection of human subjects. For additional guidance, consult Section 5.0 “Human Subjects Research Policy” from the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, issued by the US Department of Health and Human Services (HHS). Consult the Required Education of Key Personnel on the Protection of Human Subject Participants requirement, below, as you complete this section.

Consortium Contractual Arrangements

This component is included in the Technical Proposal template. Describe the proposed research projects that will be performed by subcontracted organizations. Explain the strengths, expertise, and resources that these partners bring to the overall project to ensure successful submission of contract deliverables, in accordance with the milestones schedule.

Keep the following in mind as you complete this section:

- While signed subcontract agreements are not required at the time of application submission to PCORI, you should explain how you will facilitate the execution of these agreements upon receipt of an award.
- The submission of an application signifies that programmatic and administrative personnel from your organization and from all proposed subcontract organizations that will be involved in this project are aware of your organization’s subcontract agreement policy and that all involved organizations are prepared to establish the necessary interorganizational agreement(s) consistent with that policy.

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15 Available at grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#5_4_IRB_Approval
• If applicable, subcontract personnel should be included under the Key Personnel section.
• Budget information for subcontracted organizations should be included in the Detailed Budget, Budget Summary for Entire Project, and Budget Justification sections.

References Cited

This component (up to 10 pages) is included in the Technical Proposal template. Throughout the entire Technical Proposal, applicants should use in-text citations to reference published materials and at the end, list the full bibliographical citation of each reference cited. Each reference must include the names of all authors (in the same sequence in which they appear in the publication); the article title; and the journal or book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied on in preparing any section of the application. Citations that are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference. References should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to the proposed research so that the 10-page limit is not exceeded. Websites should be 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 Technical Proposal template. You may provide additional materials that you deem useful to support your study (e.g., survey instruments and interview guides). Supplemental material—such as biographies, technical diagram, data dictionaries, publications, and projects abstracts—may be submitted in the form of appendices. Note that reviewers are not required to review this section during Merit Review.

People and Places Template

Professional Profile/Biosketch and Patient/Stakeholder Partner Biosketch

These components are included in the People and Places template. Complete a profile/biosketch section (up to five pages per individual) for each person listed as key personnel (including PI, co-investigator, or other significant contributors), copying the tables provided in this section, as needed. Note that you may submit a National Institute 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 the Patient/Stakeholder Partner Biosketch version in lieu of the Professional Profile/Biosketch one. At a minimum, each profile must include the person’s name, title, and degrees; it must not exceed five pages. PCORI is especially interested to learn how each individual’s previous experience, past performance, and training in the field of (patient-centered outcomes research) PCOR has prepared him or her to conduct this research. The backgrounds, relevant experiences, and roles of patient and stakeholder partners should also be described.
Applicants should assemble a research team that is best poised to complete the work. Applicants should demonstrate that the study team’s experience, leadership approach, governance, and organizational structure are appropriate for the project and will serve to achieve the project goals.

Project Performance Site(s) and Resources

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

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

Budget Template

Complete all required sections and upload the Budget template into the PCORI Online System as a single PDF. Do not upload separate budget files for subcontractors; include all subcontractor budget files within the prime applicant’s PDF budget upload.

Detailed Budget for Each Year of the Project Period

Complete a detailed budget for each year of the project for the prime applicant and any subcontractor(s) proposed in your application. For example, if your study is for three years, the prime applicant must complete a detailed budget for Year 1, Year 2, and Year 3. The subcontractor should follow this model and complete a detailed budget for each year of the proposed study. An Additional Personnel form, provided within the template after each Detailed Budget Year section, should only be used after all the personnel rows for each budget detail year have been completed. Maximum project periods are stated in each PFA. Consult the CDRN\textsuperscript{16} and PPRN\textsuperscript{17} specific Application Review Guidance for details on the required budget descriptions.

A. Personnel Costs

- Personnel Costs: Include the base salary for each scientific or technical staff member, employee patient or stakeholder partner, or other personnel on your project, if these members are not accounted for in Section B: Consultant Costs.
- Allowable Costs: PCORI will pay compensation for personnel as long as the costs are consistent with and do not exceed what the applicant would normally pay under its own policy. Such compensation may include salaries and fringe benefits. Consult Appendix 1: Allowable and Unallowable Costs for more information.
- Salaries: Include wages earned by an employee, and fringe benefits may include insurance and retirement plans.
- Level of Effort: Personnel contributing to a PCORI-funded research project are expected to monitor their total percentage of effort across all funding (PCORI or other) and may not exceed

\textsuperscript{17} Available at http://www.pcori.org/sites/default/files/PCORI-PFA-PPRN-Application-Review-Guidance.pdf
100 percent. Effort must be reported by the percentage of time over the course of the project year. 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. List the base salary for such persons in the Budget Justification and Detailed Budget sections. If salary support is not being requested, use $0 for base salary.

- 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 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 section, applicants must provide a verification of the fringe-benefit rate policy for the prime organization and all subcontractors. If funded, PCORI will verify these costs with the applicant and any subcontractors.

B. Consultant Costs

- Consultant costs apply to those individuals who are not employees of the applicant organization or under a subcontract agreement as members of the contracted staff.
- Payments to nonemployee patient and stakeholder representatives should be included as consultant costs in the budget.
- Consultant costs must be expressed in an hourly rate.
- Consultant costs must be reasonable and justified within the Budget Justification section.
- Provide total cost of consultant(s), as well as names, expected number of hours, and hourly rates.
- 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 the negotiated rate. 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 that exceed $1,000. You will be asked to provide further details for each of these costs in the Budget Justification section.
- For all supply costs, provide computations for how applicants arrived at the specific number.
D. Travel Costs

- Travel may include any domestic or international travel by study personnel or consultants directly related to and necessary for the project and within the limits explained below. As a matter of policy, PCORI uses the Federal Travel Regulations as the guidelines for per diem and reimbursement.
- 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, symposiums, and similar events. Scientific travel is capped at $10,000 over the full project period, including costs for applicant organization and subcontractor personnel.
  - Programmatic travel includes travel needed for the conduct of the project (i.e., focus groups, consultants, and others). While there is no cap on programmatic travel funds, PCORI closely reviews all travel costs for reasonableness. Consult your PFA for PCORnet required programmatic travel.
  - Airline costs cannot exceed the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare.
- For each category of travel (scientific and programmatic), include the number of trips and a brief description of the trips, to include the number of people traveling and the dates or duration of the stay.
- In the Budget Justification section, 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 and necessary for achieving programmatic objectives.

F. Other Expenses

- Indicate general categories—such as printing costs, publication costs, and nonconsulting service contracts—and include an amount for each category.
- Use this section to include direct costs that cannot be accounted for in other budget categories. For example, these costs may include study subjects’ travel costs or participation incentives.
- In the space provided, include a detailed explanation for all costs that exceed $1,000. Applicants must provide further detail for each of these costs in the Budget Justification section.

G. Equipment Costs

- Equipment costs include tangible items that have a per-unit cost of $5,000 or more and a life of more than five years.
- Up to three quotes for each item of proposed equipment can be included with the Budget Justification section.
- Costs must be reasonable and necessary for the project. Equipment must not be available or accessible at a lower cost.
• Equipment costs will be analyzed and must be approved by PCORI during the award negotiation phase for projects that are funded.

H. Subcontractor Costs

• This category includes all consortium and contractual costs. A subcontractor arrangement is required if the criteria listed below are met.
  o The subcontractor PI’s effort on the project is calculated as part of his or her “professional time” for his or her employer organization.
  o The subcontractor will be using significant resources (e.g., office space, supplies, computer, and personnel) at his or her own organization when working on the PCORI-funded project.
• Subcontracted organizations must adhere to all budget policies detailed in these guidelines, including allowable and unallowable costs.

I. Indirect Costs

• Indirect costs for the project may be calculated according to the applicant’s federally negotiated or independently audited indirect cost rate; however, PCORI limits the total indirect costs at 40 percent of personnel, consultant costs, travel, supplies, other expenses, and on the first $25,000 of all subcontractor costs combined (direct and indirect).
• Applicants who do not have a federally negotiated indirect cost rate may assess up to 10 percent of indirect costs.
• Foreign applicants will use the same calculation to determine their own indirect cost cap, but they are eligible for no more than 10 percent.
• Applicants and subcontractors may assess only their indirect costs, not to exceed 40 percent (or 10 percent for foreign organizations and for those without a federally negotiated rate), on the first $25,000 of all subcontractor costs combined (direct and indirect). Subcontractors with a third-tier subcontractor must follow this budget guideline.
• Submit a copy of the applicant’s and each subcontractor’s federally negotiated or independently audited indirect-cost rate letter. Include these copies after the Budget Justification section, in a single file of budget materials uploaded to PCORI Online.

Budget Summary for Entire Project
Complete a budget summary for the entire project for the prime applicant and each subcontracted organization. Keep in mind the guidance in the previous section. See Appendix 1 to review acceptable and unacceptable uses of PCORI funding.

Budget Justification
Complete a Budget Justification section for the prime applicant and each subcontracted organization for the entire project. Provide sufficient detail to explain the basis for costs, the reason(s) why the costs are necessary to the project, and the reason(s) for major cost variances.
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 amounts of funding and the period during which it will be available. Use additional pages as needed.

**Letters of Support**

Letters of support are required with the full application. Combine and save all letters of support as one PDF file and upload into the PCORI Online System. Letters of support are required from all key personnel, addressed to the PI or institution, to demonstrate the commitment of key personnel (e.g., PI, co-investigators, consultants, patient and stakeholder partners, stakeholder organizations, and subcontractor sites). Letters of support are also required from collaborating networks. See the CDRN- and PPRN-specific PFAs for PCORnet collaboration requirements. A letter from the leadership of your department or organization affirming support to disseminate and implement research findings, if appropriate, is also highly recommended. Consultants should also write letters of support, verifying the work to be performed and the negotiated rate. There is no limit on the number of letters of support submitted.

Letters of support are not required from personnel who are not contributing in a substantive, measurable way to the scientific development or execution of the project, such as research assistants.
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 personnel listed in the application as key personnel. The policy and FAQs are available from the NIH website.\(^{18}\)

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

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

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his or her institution. The Office for Civil Rights\(^ {19}\) 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.\(^ {20}\)

Award Funding Conditions

PCORI reserves the right to discontinue funding for awardees who fail to meet the mutually agreed-upon milestones at any time during the contract. Proposed milestones should be presented in the application, but final milestones will be negotiated in the post-award period before the beginning/activation of the funding period.

Co-funding

PCORI partners with various other national research organizations to leverage additional funds. The PCORI National Patient-Centered Clinical Research Network is open to co-funding from other organizations. Therefore, applicants to PCORI programs are urged to explore all potential funding sources, including other private organizations, government initiatives, and consortia.

\(^ {18}\) Available at grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html
\(^ {19}\) Available at hhs.gov/ocr
\(^ {20}\) Available at grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html
Dissemination and Data Sharing

In accordance with its enacting legislation, PCORI is committed to the publication and dissemination of all information and materials developed using PCORI funding. All recipients of PCORI contracts must agree to these principles and must take steps in order to facilitate availability of data and samples.
Appendix 1: Allowable and Unallowable Costs

Acceptable uses of PCORI contract funds are those that directly support the proposed research project, including collection and analysis of data and obtaining relevant data sets. Overall, costs include salaries and fringe benefits for study investigators and other project staff (including patient and stakeholder partners), consultant fees, travel for investigator meetings, travel that is clearly project related, supplies, equipment, subcontract agreements, and other direct research expenses and indirect costs. Unallowable costs should not be included as direct costs. The examples listed below are unallowable under PCORI contracts. This is not an all-inclusive list of unallowable costs.

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

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<th>Allowable Costs</th>
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<td>Equipment</td>
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