



Cycle 2 2021

PCORI Funding Announcement:
Coordinating Center Functions to Advance Phase 3 of
PCORnet[®], the National Patient-Centered Clinical
Research Network

PCORI Submission Instructions

Published May 4, 2021

This PCORI Funding Announcement (PFA) applies to the funding cycle that closes August 10, 2021, at 5 pm ET. Submission Instructions, templates, and other resources are available at pcori.org/apply.

About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) was authorized by Congress in 2010 and reauthorized for an additional ten years in 2019 as a nonprofit, nongovernmental organization. PCORI's purpose, as defined by our authorizing legislation, is to help patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders make better-informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions” and by promoting the dissemination and uptake of this evidence.

PCORI is committed to transparency and a rigorous stakeholder-driven process that emphasizes patient engagement. PCORI uses a variety of forums and public comment periods to obtain public input to enhance its work. PCORI helps people make informed healthcare decisions and improves healthcare delivery and outcomes by producing and promoting high-integrity, evidence-based information that comes from research guided by patients and other stakeholders.

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I. About These Instructions

This document provides key information to help researchers prepare for and respond to the following Patient-Centered Outcomes Research Institute (PCORI) Funding Announcement (PFA): Coordinating Center Functions to Advance Phase 3 of PCORnet®, the National Patient-Centered Clinical Research Network.

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

- See PCORI's [Applicant FAQs](#)¹ for common questions about PCORI and the application process.
- See the [PCORnet Phase 3 FAQs](#) for specific questions about this funding opportunity.
- Visit PCORI's [Help Center](#)² for additional applicant resources.
 - PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed two business days prior to an application deadline.
 - **For Programmatic Inquiries:** Contact the PCORI Helpdesk via email at sciencequestions@pcori.org, phone at 202-627-1884, or online at <http://www.pcori.org/PFA/inquiry>.
 - **For Administrative, Financial, or Technical Inquiries:** Contact the PCORI Helpdesk via email at pfa@pcori.org, or phone at 202-627-1885.

It is the applicant's responsibility to submit the application on or before the deadline. Refer to [PCORI's Policy on Funding Application Submission](#).³

Administrative Considerations

To ensure a thorough and competitive review process, PCORI strictly enforces the formatting and administrative compliance guidelines outlined in the PFAs, FAQs, and Submission Instructions. Applicants that fail to submit the required documents may be rejected from the merit review process.

All rejection decisions made by the Contract Management department are final. See [Appendix 3: Administrative Actions](#).

Unless otherwise stated in the Submission Instructions, all materials submitted on behalf of an applicant organization are the property of that organization. PCORI will not share or publicize the contents of an organization's application.

Funding Mechanism

PCORI utilizes a contract mechanism, not a grant mechanism, for its awards. PCORI funds projects that demonstrate the highest probability of being completed on time and within budget while meeting all

¹ Available at <http://www.pcori.org/content/faqs-applicants/>.

² Available at <http://help.pcori.org/hc/en-us/>.

³ Available at <http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/>.

milestones and deliverables. *Applicants must submit representative budgets and Technical Proposals that allow the project to conclude within the approved contract term.*

As part of its active portfolio management, PCORI provides contractual and programmatic monitoring throughout the contract term period.

Award Funding Conditions

At any time during the contract, PCORI reserves the right to discontinue funding for awardees that fail to meet the mutually agreed upon milestones. Applicants' proposed milestones will be finalized in contract negotiations and prior to execution.

II. Who Can Apply

Applications may be submitted by current Prime organizations of Clinical Research Networks (CRNs) currently participating in PCORnet and organizations of the current Coordinating Center currently funded to participate in PCORnet, to include any private-sector research organization, including any nonprofit or for-profit organization; any public-sector research organization, including any university or college hospital or healthcare system; any laboratory or manufacturer; or any unit of local, state, or federal government. The Internal Revenue Service must recognize all US applicant organizations. Individuals are not permitted to apply. If you have questions about eligibility, contact pfa@pcori.org.

III. How to Apply

Applying for PCORI funding is a two-stage process. To submit an application, including all required documents, follow the instructions provided in this document and in [PCORI Online](#).⁴ All documents must be submitted through PCORI Online.



Step 1: Register

To apply for PCORI funding, an applicant (PI or PI designee) must register in [PCORI Online](#). 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](#)⁵ and [an EIN](#),⁶ if applicable. To register, you must provide a name, an email address, a password, and a security question and answer. Once signed in, you will be directed to the home screen. Click on the Infrastructure Awards tile to apply for funding. PCORI strongly recommends that only the PI create the application record, because whoever creates the record will have permanent access to it in PCORI Online.

⁴ Available at <https://pcori.force.com/engagement>.

⁵ Available at <https://www.test.grants.gov/applicants/organization-registration/step-1-obtain-duns-number.html>.

⁶ Available at <https://www.irs.gov/businesses/small-businesses-self-employed/apply-for-an-employer-identification-number-ein-online>.



Step 2: Submit a Letter of Intent

An LOI is required to submit an application. An LOI is required for each scope of work that you are applying for; however, LOIs will not be competitively reviewed by PCORI Staff. To submit an LOI, log in to [PCORI Online](#), complete the required LOI fields.

For detailed instructions on how to navigate the system, reference the [PCORI Online: Pre-Award User Guide for Research Awards](#).⁷



Step 3: Begin Application Process

The application consists of multiple sections in [PCORI Online](#), all of which you must complete before submission. Log in to PCORI Online to view the full list of questions.



Step 4: Format and Complete Required Templates

Required templates are on the [PCORI Funding Opportunities](#)⁸ web page. Find the PFA to which you are applying and download the correct PFA-specific templates, because they vary among PFAs and cycles. Keep the following in mind:

- Do not reorganize sections within the templates.
- Do not alter the templates' main header questions within your submission.
- You may delete instructional text.
- Adherence to font size, type density, line spacing, and text color requirements is necessary to ensure readability and fairness.

You must format all required documents as follows:

- **Header:** Include the PI's full name in the top-left corner of every page.
- **Font:** Use Calibri size 11 font for body text and size 8 font for figures, tables, and captions.
- **Type Density:** Must be no more than 15 characters per linear inch (including characters and spaces).
- **Line Spacing:** Use single spacing. Must be no more than six lines per vertical inch.
- **Text Color:** No restriction. Though not required, black or other high-contrast colors are

⁷ Available at <http://www.pcori.org/sites/default/files/PCORI-Online-Pre-Award-User-Guide.pdf>.

⁸ Available at <http://www.pcori.org/funding-opportunities/>.

recommended since they print well and are legible to the largest audience.

- **Margins:** Use at least half-inch margins. The header may fall within the top margin, but the body text may not begin closer than a half-inch from the edge of the page.
- **Page Numbers:** Number each page consecutively for each PDF upload. Begin each section of an uploaded document with page 1.
- **Page Limit:** This varies based on the document.
- **File Name Format:** This varies based on the document. Applicants must adhere to the file naming standards noted in the [Submission Checklist](#).
- **References:** PCORI suggests including all references as in-text citations using American Medical Association (AMA) citation style, but other citation styles are acceptable.
- Legibility is of paramount importance. Applications that include attachments that do not conform to the minimum requirements listed above may be withdrawn from consideration.



Step 5: Upload Required Documents

Follow the [Submission Checklist](#) to enter required information. Upload required documents to PCORI Online in the correct order and required file name format. When instructed, use Adobe Acrobat Professional⁹ to combine documents into a single PDF file for upload.

Avoid scanning text documents to produce the required PDFs. It is best to produce documents using your word-processing software and then convert the documents to PDF. Scanning paper documents may hamper automated processing of your submission for review, analysis, and reporting, as well as the legibility of the file.

Though it may be necessary to letters of support or other signed documents on business letterhead, this is not an acceptable file format for most submission templates. Applicants must follow the detailed file name format and file upload type described in the [Submission Checklist](#).

Within the Templates & Uploads tab, click “Choose file” to select a file from your computer, and click “Upload.” For detailed instructions, refer to the Templates & Uploads section of the [PCORI Online: Pre-Award User Guide for Research Award](#).



Step 6: Submit for Authorization

Once you have completed and uploaded all required information, select “Review & Submit,” and then select “Submit” to forward the application to your Administrative Official (AO) to authorize and submit. The AO must approve and submit the final application for official submission to PCORI before the 5 pm

⁹ See [adobe.com](https://www.adobe.com) for more information on Adobe Acrobat Professional.

(ET) deadline. **PCORI Online will email the AO, but the PI should notify the AO when the application is ready for review, AO approval, and submission.** The PI and the AO may not be the same individual. Both the AO and the PI will receive an email confirming that PCORI has received the application.

IV. When to Apply

Deadlines for each funding cycle are noted in the [PCORI Funding Opportunities](#) webpage and in the PFA. System or technical issues with PCORI Online that affect the on-time submission of an application must be reported to PCORI before the specified deadline. Problems with computer systems at the applicant's organization or failure to follow instructions in PCORI Online, in the PCORI



Submission Instructions, or in PFAs are not valid issues warranting consideration of a deadline extension. See PCORI's [Policy on Submission of Research Contract Applications](#)¹⁰ for complete information.

V. What to Include—Application Requirements

Applicants are encouraged to review this entire section. Print and complete the Submission Checklist to ensure that the application are submitted correctly. Download all required templates from the [PCORI Funding Opportunities](#)¹¹ web page.

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

- The PI is responsible for the project's engagement, scientific, and technical aspects, and related activities.
- The Contact PI's institution must be the primary institution for the award.
- PIs can participate in other applications (from the same or another organization) in a different role, such as co-investigator or consultant. Refer to the [Who Can Apply](#) section for specific instructions.
- If electing to submit an application with two PIs, you must designate one as the Contact PI. The Contact PI is responsible for submitting the application and will serve as PCORI's

¹⁰ Available at <http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/>.

¹¹ Available at <http://www.pcori.org/funding-opportunities/>.

primary point of contact for all communication. **No more than two PIs can be named on an application.**

B. Activities

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

Administrative Official (AO)

A. Description

- The AO is responsible for matters related to the award and administration of the contract.
- The AO cannot be the PI.
- The AO's signature certifies that the organization will be accountable for appropriately using the funds awarded and for performing the PCORI-supported project.

B. Activities

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

Financial Official (FO)

A. Description

- The FO is responsible for all required financial reporting.

B. Activities

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

Key Personnel

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

Note the following:

- Applications can include up to two PIs.
- PIs can serve in other roles (e.g., dual-PI, co-PI, co-investigator, or consultant) on other applications.
- If applicable, applicants must explain the rationale for including two PIs in the Leadership Plan Template.
- Consultants and personnel from collaborating organizations may be included as key personnel if they meet the definition. See [PCORI's Glossary](#) for “Consultant” and “Subcontractor” definitions.
- Applicants should identify patient and other stakeholder partners, whether individuals or organizations, if known. If all partners have not been confirmed by the time of application, then applicants, if funded, must submit updated partner information to PCORI as part of the Updated Engagement Plan milestone per Appendix 1. (Note: Patient and stakeholder partners will be publicly listed on the PCORI website and may be included on public communications. In providing the names of partners, applicants acknowledge that partners have consented to the disclosure of their names to PCORI and to making their names publicly available. If a patient or other stakeholder partner chooses to remain anonymous, contact pfa@pcori.org for guidance.)
- After merit review, PCORI may request current, pending, and other support documentation from all key personnel. This material must be submitted prior to award.
- If awarded, the addition or replacement of key personnel listed in the submitted application requires PCORI’s approval during contract negotiation and post–contract execution.

Project Information

Enter the following information directly into PCORI Online.

Technical Abstract

Provide a Technical Abstract within PCORI Online that summarizes your Technical Strategy. In the technical proposal, applicants should describe fulfillment of the PCORnet Coordinating Center functional scope of work to advance Phase 3 of PCORnet.

The Technical Proposal must include the following sections:

- Executive Coordinating Center Summary
- Technical Approach (Criterion 1)
- Project Management Plan (Criterion 2)
- Demonstrated Experience (Criterion 3)

Public Abstract

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

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.

Budget

Complete the [Budget Summary and Budget Justification Template](#) for the Prime Institution. See [Appendix 1: Allowable and Unallowable Costs](#) to review acceptable and unacceptable uses of PCORI funding.

Provide sufficient detail to explain the basis for costs, the reason the costs are necessary to the project, and the reason for major cost variances. Include information about budgeting for project staff and meeting costs. Explain the basis for travel costs and describe how the travel is related and necessary for achieving programmatic objectives.

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

Specify any other sources of funding, currently available or anticipated, to support the proposed project. Include funding amounts and the period during which the funding will be available. Use continuation pages as needed.

If selected for funding, additional information must be provided to PCORI, including the Prime Institution's and Subcontractors' detailed budgets.

This PFA may consider budgets greater than outlined in the PFA. Any budget exception requests must be approved by PCORI prior to submission. To submit a budget exception request, email pfa@pcori.org.

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 by emailing pfa@pcori.org.

Detailed Budget for Each Year of the Project Period

Only the budget summary should be included in the application. The information below is guidance for developing your detailed budget by year. A detailed budget will be required if selected for funding.

All personnel information must be entered in the Project Personnel tab corresponding to that year in this template. Add additional rows for personnel as needed. Note the following:

A. Personnel Costs

- Personnel costs include the base salary for each scientific and technical staff member, employee patient or stakeholder partner, or other personnel on your project who are or are not accounted for in Section B: Consultant Costs. Provide a clear distinction between individuals who are key personnel and those considered "other" personnel.

- PCORI will reimburse personnel costs that are consistent with and do not exceed what the applicant would normally pay under its own policy. PCORI may request salary verification during the contract activation process. Such compensation may include salaries and fringe benefits. See Appendix 1: Allowable and Unallowable Costs for more information.
- Salaries include wages earned by an employee, and fringe benefits may include insurance and retirement plans. Provide documentation to support the fringe benefits within the Budget Justification.
- Level of Effort: Personnel who contribute to a PCORI-funded project must monitor their total percentage of effort across all of their active funding, so that it does not exceed 100 percent. Before submitting the application to PCORI, the AO must certify that individual personnel will not exceed 100 percent effort if funded. You must report effort by the percentage of time over the course of the project year. If you are not requesting salary support, use \$0 for the base salary. See the [PFA](#) and [Key Personnel](#) section for PFA-specific requirements.
- All personnel who dedicate effort to the project must be listed on the Personnel Budget with their level of effort, even if they are not requesting salary support. List the base salary for each person in the Budget Justification and the Detailed Budget. Describe the individual's specific functions in the Budget Justification. Provide an explanation of how the role supports the project aims and note any overlap in job functions.
- Salary Cap: The PCORI base salary cap for personnel is \$200,000 annualized per individual, per year, excluding fringe benefits. An individual who earns less than \$200,000 must use his or her actual base salary to calculate personnel costs. An individual with a full-time employee base salary of more than \$200,000 must use \$200,000 as the base salary rate in determining the amount of salary and time to charge to the project.
- Inflation/Cost of Living Adjustments may only be assessed on base salaries less than the \$200,000 salary cap.
- Fringe Benefits: These costs are calculated based on the institution's own policy. In the Budget Justification upload, applicants must provide a verification of the fringe benefit rate policy for the prime organization.

B. Consultant Costs

- Consultant costs apply to individuals who are not employees of the applicant organization or under a subcontract agreement as members of the contracted staff.
- Payments to nonemployee patient and stakeholder representatives must be included in the budget as consultant costs.
- Provide the total cost of the consultant(s), as well as name(s), expected number of hours, and hourly rate.
- Include the daily consultant fee, nature of the consulting effort, and the reasons that the proposed project requires consultants. Note any overlap in duties with personnel.

- Consultant costs must be reasonable and justified within the Budget Justification.
- Include Letters of Support from each consultant, verifying the work to be performed and how the negotiated rate was established. See the Letters of Support section for more detailed information.

C. Supply Costs

- Supplies must be directly allocable and allowable to the proposed project, and not be part of general or administrative use. Supplies are consumable items that are used on a regular basis or other tangible items that do not meet the definition of “equipment.” Include the category of supplies needed and the cost for each.
- Tangible items with per-unit costs of \$5,000 or more are considered equipment and cannot be accounted for under this category.
- Indicate general categories such as mailings, printing, lab, and equipment with less than \$5,000 per-unit costs. Provide detailed explanations in the Budget Justification for all costs exceeding \$1,000.
- For all supply costs, provide computations for the way that applicants arrived at the specific number.



Note: PCORI considers computers, tablets, docking stations, mobile data and protection plans, laboratory and office furnishings, and software to be general office supplies that are not allowable as direct-cost charges. If these items are proposed as essential for performing the scope of work, the following must be provided in the Budget Justification:

- Detailed explanation of why purchasing these items is necessary to complete the scope of work
- Statement verifying that the requested items are not currently available for the PI’s use
- Statement assuring that the items will be purchased in accordance with applicable cost principles
- Items purchased under PCORI-funded projects are not to be used as incentives to recruit or retain graduate students or any other project personnel.

D. Travel Costs

- Travel may include any domestic or international travel by project personnel or consultants directly related to, and necessary for, the project and within the limits explained below. PCORI uses the Federal Travel Regulations guidelines for per diem and other reimbursements.
- Travel should be devoted to programmatic activities necessary to conduct the project, such as focus groups, project team meetings, or data collection. Requests for travel to present at conferences or symposiums that are related to the topical areas of the project may also be included, but should be limited in number, and strongly justified. PCORI closely reviews all travel costs to ensure they are reasonable.

- Travel costs must be itemized per trip and must include the number of trips and a brief description of each one, including the number of people traveling and dates or duration of the stays.
- Airline or rail costs cannot exceed the customary standard commercial fare (coach or equivalent), or the lowest commercial discount fare. PCORI will not compensate upgrades.
- In the Budget Justification Template, applicants must provide additional detail to explain the basis for the costs listed and describe how the travel is directly related to the proposed project and necessary for achieving programmatic objectives.
- Applicants should budget for travel to Washington, DC, for two in-person Steering Committee meetings per year starting in year 2 (4 in total); each network must budget for one attendee per meeting; total costs should not exceed \$1,000 per person, per meeting, or \$6,000 total over three years

E. Other Expenses

- Use this section to include direct costs that cannot be accounted for in other budget categories. For example, these costs may include computer core services, data warehousing, or participant incentives, publication, illustration costs, and non-consulting service contracts (when applicable).
- In the space provided, include a detailed explanation in the Budget Justification for items that exceed \$1,000. Applicants must provide additional detail for each of these costs.

F. Equipment Costs

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

G. Subcontractor Costs

- This category includes all consortium and contractual costs. The prime awardee must issue a subcontract agreement to a collaborator if the criteria listed below are met:
 - The subcontractor personnel'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, and other expenses and on the first \$25,000 of each subcontract.
- Applicants that do not have a federally negotiated or independently audited indirect cost rate may assess up to 10 percent indirect costs, to be noted in the Budget Justification.
- Foreign applicants are eligible for no more than 10 percent indirect costs.
- A copy of the prime applicant's federally negotiated, or independently audited, indirect cost rate letter must be submitted with the application. Include these copies in a single file with the Budget Justification.
- If funded, the indirect cost rate submitted at the time of application is what PCORI will utilize during contract negotiations. If there is a change in the indirect cost rate once a project is executed, and the awardee wishes to charge a different rate, they must contact their PCORI Contract Administrator and provide a copy of the new federally negotiated rate or independently audited rate. PCORI may allow a change in the rate charged, but the awardee will need to reallocate within their existing, approved budget. PCORI will not allow additional funds to offset any increases in indirect costs and the rate increase cannot result in a reduction in scope of the approved project.
- While consortium indirect costs must be noted in the prime applicant's direct cost budget, consortium indirect costs are not included in the applicant's direct cost budget cap.

Technical Proposal Template

Complete all required sections in the [Technical Proposal Template](#) and upload as a single PDF into the PCORI Online. The Technical Proposal Template includes: Technical Strategy, Investigators and Environment, Protection of Human Subjects, Consortium Contractual Arrangements, References, and Clinical Research Network Data Contributing Partners.

Technical Strategy

The sections of the technical strategy are:

- A. Executive Network Summary (4 pages)
- B. Approach for Phase 3 (page limits are listed per merit review criteria)
 - i. Technical Approach (6 pages) (Criterion 1)
 - ii. Project Management Plan (4 pages) (Criterion 2)
 - iii. Demonstrated Experience (4 pages) (Criterion 3)

A more detailed outline of the technical strategy, including required components and page numbers,

can be found in the [Technical Proposal Template](#).

In addition to following the instructions in the Technical Proposal Template, applicants should ensure that the Technical Proposal addresses adherence to the PCORI Methodology Standards. Applicants should provide sufficient information to allow reviewers and PCORI staff to determine whether the proposed research adheres to the relevant standards, and then complete the [Methodology Standards Checklist](#) to help reviewers quickly identify where information related to adherence is located within the Technical Proposal.

Protection of Human Subjects

In this component (up to five pages), describe the protection of human subjects involved in your network. PCORI follows the Federal Regulation for the Protection of Human Subjects ([45 CFR part 46](#)), including the Common Rule. For more detailed information, see Section 5, “Human Subjects Research Policy,” from the [Supplemental Grant Application Instructions for All Competing Applications and Progress Reports](#),¹² which was issued by the U.S. Department of Health and Human Services (Department of HHS). 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, describe the proposed activities that will be performed by subcontracted organizations. Explain the strengths that these partners bring to the overall project.

Keep the following in mind as you complete this section:

- The prime applicant is responsible for the project and must adhere to the contract’s terms and conditions. The prime applicant must negotiate his or her subcontracts accordingly.
- Signed subcontract agreements are not required at the time of application submission to PCORI.
- Submitting an application to PCORI signifies that programmatic and administrative personnel from your organization and from all proposed subcontract organizations involved in the project are aware of your organization’s subcontract agreement policy and are prepared to establish the necessary interorganizational agreement(s) consistent with that policy.
- If applicable, include subcontract personnel under key personnel.
- Include budget information for subcontracted organizations in the Detailed Budget, Budget Summary for Entire Project, and Budget Justification.

References Cited

This component (up to 10 pages) is included in the Technical Proposal Template. Throughout the Technical Proposal, applicants should use in-text citations to reference published materials. In this section, list the full bibliographical citation for each reference. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article title and journal or book title, the volume number, the page numbers, and the year of publication. Include only

¹² See <http://grants.nih.gov/sites/default/files/supplementalinstructions.docx>.

bibliographic citations. PCORI suggests following AMA style when providing citations for source materials used to prepare any section of the application, but other citation styles are acceptable. Citations that are publicly available in a free online format may include URLs or PubMed ID numbers along with the full reference. *Limit references to relevant and current literature.* Be concise and select only those literature references pertinent to the network infrastructure and activities, so that you do not exceed the 10-page limit. Reference websites in the standard URL format (i.e., <http://www.pcori.org>) along with the date on which the link was last accessed.

Project Team

Applicants must assemble a team that is suited to complete the work. Applications must demonstrate that the study team's experience, leadership approach, governance, and organizational structure are appropriate for the project and will aid in successfully achieving the project goals.

Applicants will complete and upload two separate key personnel files:

- PI Template (includes PI information)
- Key Personnel Template (includes all other key personnel on project, including co-investigators, consultants, or other significant contributors)

For each person listed as key personnel (including PI, dual PI, co-investigator, consultant, or other significant contributors, as noted in the sections below), complete a Profile/Biosketch section (up to five pages per individual). Note that you may submit the most recently posted National Institutes of Health (NIH)-formatted biosketch in lieu of a PCORI-formatted biosketch. Patient and stakeholder partners serving as key personnel may choose to complete the Patient and Stakeholder Partner Profile/Biosketch form in lieu of the Professional Profile/Biosketch.

PI Template

Applicants must complete the [PI Template](#) for the lead researcher(s). Depending on the nature of the proposed study, a collaborative and multidisciplinary team might be required. The Contact PI must be employed by the prime applicant institution and listed first within the application. Although PCORI will recognize both PIs, the Contact PI is responsible for submitting the application and for communications between the PIs and PCORI, including coordinating meetings with PCORI staff.

The PIs may be from the same or different institutions. Each PI is accountable and responsible for the conduct of the award and for ensuring that all awarded milestones, deliverables, and reports are completed in accordance with the award terms and conditions.

Complete a Profile/Biosketch (up to five pages per individual) for the PI(s). Combine the profile/biosketches and into a single PDF file. The PI profile/biosketch should be the first item, followed by a dual-PI, and then, include the Leadership Plan if you are proposing multiple PIs. Upload the file to the designated field in PCORI Online.

Leadership Plan (If proposing dual PIs)

The [Leadership Plan](#) (up to five pages) must (1) describe the governance and organizational structure of

the leadership team and the research project; (2) delineate the administrative, technical, scientific, and engagement responsibilities for each PI; (3) discuss communication plans and the process for making decisions on scientific and engagement direction; and (4) describe the procedure for resolving conflicts.

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

Key Personnel Template

The [Key Personnel Template](#) must include all biosketches/profiles for the remaining study team members identified as key personnel. Complete a Profile/Biosketch section (up to five pages per individual) for each person listed as key personnel, copying the tables provided as needed. At a minimum, each profile must include the person's name, title, and degree(s). This must include at least one senior project manager or project director with a significant track record in managing large multi-site projects of this nature, and he or she should be dedicated at minimum 50 percent effort. PCORI is especially interested to learn how each individual's previous experience, past performance, and training in the field of PCOR has prepared him or her to assist in completing the Phase 3 scope of work. You must also describe the backgrounds, relevant experiences, and roles of patient and stakeholder partners.

Project/Performance Site(s) and Resources Template

The [Project/Performance Site\(s\) and Resources Template](#) may not exceed 15 pages. Demonstrate in detail that the proposed facilities have the appropriate resources required to conduct the project as planned, within budget, and on time.

Applicants must provide a description of the facilities they will use during the contract period, including capacity, capability, characteristics, proximity, and extent of availability to the network.

Letters of Support

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

All Letters of Support must be addressed to the PI and demonstrate the commitment of key personnel and supporting organizations (e.g., PI, co-PI, co-investigators, consultants, patient and stakeholder partners, and stakeholder organizations) to the proposed project. Letters of Support are not required for personnel who are not contributing in a substantive, measurable way to the project's scientific development or execution. Letters of Support must reflect clearly the involvement and material contribution to be provided by the signatory parties and are meant to confirm the commitment of collaboration. PCORI may contact any individuals or organizations included in the Letters of Support with questions or to confirm support as described in the letters.

Letters of Support must be organized as follows:

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organizational official, that confirms the institutional support of the proposed project; space to conduct the research; equipment; and other resources available for the project, including staff. PCORI also strongly encourages you to provide a letter from the department or organization leadership affirming support to disseminate research findings that are appropriate and warranted for implementation.
- **Letters of Collaboration:** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. Letters of Support from patient and stakeholder partners must describe clearly the origin of the study topic and the role of the partners in defining the question, comparators, goals and outcomes, and so on. PCORI also strongly encourages letters from patient or stakeholder partners or partnering organizations affirming support to disseminate and implement research findings that are germane and warranted for implementation. Include a Letter of Support for each consultant verifying the work to be performed and the negotiated rate.
- **Letters Confirming Access to Patient Populations, Data Sets, or Additional Resources:** If the proposed Technical Proposal involves access to patient populations, data sets, or additional resources, include a Letter of Support that confirm such access, signed by the person with approval authority. If access cannot be confirmed at the time of contract negotiation, PCORI reserves the right to withhold funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.

List all letters in the [table](#) (adding rows as needed), and include the page number on which each letter can be found in the single PDF file.

Appendix 1: Allowable and Unallowable Costs

Acceptable uses of PCORI contract funds are those that directly support the proposed project.

Allowable costs (i.e., those 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 project:

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

PCORI will review all proposed costs. Costs must be deemed allowable, allocable, and directly necessary for the successful execution of the proposed project. A notification of pending award is subject to budgetary review and successful contract negotiation. The actual award amount may vary. For more information, see [PCORI Cost Principles](#).

Allowable Costs			
 PERSONNEL SALARIES & BENEFITS	 TRAVEL COST	 SUBCONTRACTOR DIRECT & INDIRECT	 APPLICANT INDIRECT COSTS
 CONSULTANT FEES	 EQUIPMENT	 SUPPLIES	 OTHER

Commonly Disallowed Costs	Unallowable Costs		
 DATA PLANS (TABLETS AND OTHER MOBILE DEVICES)	 ADVERTISING	 DONATIONS	 INTEREST OF BAD DEBTS
 DOCKING STATIONS	 EXCESSIVE AIRFARE	 FUNDRAISING	 ENTERTAINMENT
 DOUBLE MONITORS	 ALCOHOLIC BEVERAGES	 PERSONAL EXPENSES	 LOSSES ON OTHER GRANTS
 ELECTRONICS PROTECTION PLANS	 ALUMNI ACTIVITIES	 STUDENT HOUSING AND STIPENDS	 MEMBERSHIPS
 OFFICE FURNITURE	 BAD DEBTS/ LOSSES	 IDLE FACILITIES	 LOBBYING
 REPLACEMENT OF ITEMS PURCHASED ON AN EXISTING PCORI AWARD		 RENT	

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 2: Administrative Actions

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

Automatic Rejection	Modification by PCORI	Appended upon PCORI's Request*
<p>An application will be automatically rejected if any of the following apply:</p> <ul style="list-style-type: none"> • Exceeds the specified period of performance outlined in the PFA • Exceeds the maximum budget specified in the PFA • Does not include or has an incomplete Technical Proposal 	<p>PCORI will modify an application by removing all pages that exceed stated limits.</p>	<p>Unless automatically rejected or modified, PCORI may request that the applicant submit missing documents or correct noncompliant ones.</p>

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