



## PCORI 2021 Broad PFA Submission Instructions

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These instructions apply to the 2021 Funding Cycle for the following PCORI Funding Announcements (PFAs): Assessment of Prevention, Diagnosis, and Treatment Options; Improving Healthcare Systems; Communication and Dissemination Research; and Addressing Disparities. Funding announcements, templates, deadlines, and other resources are available at [pcori.org/apply](https://www.pcori.org/apply).

Assessment of  
Prevention,  
Diagnosis, and  
Treatment Options

Improving  
Healthcare  
Systems

Communication &  
Dissemination  
Research

Addressing  
Disparities

## **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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### **Standing 2021 Broad PFA**

Starting with Cycle 1 2021, PCORI posted all submission materials for the Broad and Methods PFAs and opened PCORI Online for the Letter of Intent (LOI) phase of application submission at the start of the Cycle Year (i.e. Cycles 1-3 of any given year). In addition to the PFAs, the Submission Instructions, applicant templates and resources, and cycle deadlines were also be posted on PCORI’s website and available in PCORI Online. Applicants may submit an LOI for any of the available cycles up until the LOI deadline for that cycle. PCORI will strive to make only necessary administrative updates to the Submission Instructions and applicant templates throughout the Cycle Year.

To maintain responsiveness to health research needs and stakeholder interests, PCORI may revise the details of a priority area, address policy changes, and add or remove Special Areas of Emphasis (SAEs) in a PFA. SAEs aim to encourage applications on a particular healthcare topic—not to restrict applications to only the SAEs. SAEs may include dedicated funds.

Announcement of any updates and any revised documents will be posted on PCORI’s website no later than **four weeks before each cycle’s LOI deadline**. PCORI will also clearly indicate on the PFA webpage if no changes have been made since the Cycle 1 posting.

### **Piloting a Process for Application Deferrals**

Starting with Cycle 1 2021, PCORI began piloting a new application submission deferral process *for the Broad and Methods PFAs only*. Deferrals are available to applicants who submitted an LOI to the Broad or Methods PFAs and are invited to submit a full application. Applicants will be limited to two sequential deferrals, which may cross Cycle Years (e.g., an applicant who is invited to submit a full application for Cycle 2 may defer submission to Cycle 3, and then may potentially again request a deferral to Cycle 1 2022).

To request a deferral, the Principal Investigator (PI) must email [pfa@pcori.org](mailto:pfa@pcori.org) prior to the application deadline, copying the institutional Administrative Official (AO). For a request to be granted, the deferral

request must be submitted before the application deadline and the AO must be included in the request email. As noted above, applicants will be limited to two deferrals. Applicants will be notified of the status of their request within one business day of its receipt.

Under this pilot program, applicants will not need to re-upload their LOI or re-complete application fields for the next cycle to which they deferred within PCORI Online. Deferral requests received after the application deadline will be rejected and applicants will be encouraged to submit a new LOI for the next posted cycle.

Applicants proposing projects that fall under an SAE for a particular cycle should note that if they elect to defer their application submission to a later cycle, the SAEs might change (as stated above). However, for the Broad PFA, any changes to SAEs would not affect application responsiveness determinations.

In addition, if program priority areas or guidance on such topics in a PFA are updated by PCORI, it is possible that a deferred application could be determined to be non-responsive based on the updated information at the time of final submission. See the Broad PFA for programmatic details, requirements, and a summary of changes

## 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 Announcements (PFAs):

- Addressing Disparities
- Assessment of Prevention, Diagnosis, and Treatment Options
- Improving Healthcare Systems
- Communication and Dissemination Research

Researchers who wish to respond to the Improving Methods for Conducting Patient-Centered Outcomes Research (PCOR) PFA can find related information at <https://www.pcori.org/methods>.

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

- See PCORI's [Applicant FAQs](#)<sup>1</sup> for common questions about PCORI and the application process.
- Visit PCORI's [Help Center](#)<sup>2</sup> 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 a Letter of Intent (LOI) or application deadline.
  - **For Programmatic Inquiries:** Contact the PCORI Helpdesk via email at [sciencequestions@pcori.org](mailto: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](mailto:pfa@pcori.org), or phone at 202-627-1885.

It is the applicant's responsibility to submit the letter of intent and application on or before the deadline. Refer to [PCORI's Policy on Funding Application Submission](#).<sup>3</sup>

### 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 Contracts 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.

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

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

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

## Funding Mechanism

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

As part of its active portfolio management, PCORI provides contractual and programmatic monitoring throughout the contract term period. Applicant institutions and the Administrative Officials are advised to carefully review PCORI's standard contract templates provided on the [Awardee Resources](#) page on the PCORI website.<sup>4</sup> Note that international awardees will be issued a contract in U.S. dollars.

Fluctuations in currency exchange rates will have no bearing on the contract value, nor will adjustments be made to accommodate losses or gains associated with such currency fluctuations.

## 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. See PCORI's [Standard Contract Template](#) for more information.

## II. Who Can Apply

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

Nondomestic components of organizations based in the United States and foreign organizations may apply, as long as there is demonstrable benefit to the U.S. healthcare system and U.S. efforts in the area of patient-centered research can be shown clearly. However, PCORI's general preference is that prime awards be made to a U.S.-based organization.

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

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

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<sup>4</sup>Available at <http://www.pcori.org/sites/default/files/PCORI-PFA-Standard-Contract-for-Funded-Research-Projects.pdf/>.

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



**Note:** In general, a Principal Investigator (PI) can submit only one LOI per PFA. However, because PCORI’s Broad PFA included funding opportunities across the four distinct PCORI National Research Priorities, it is permissible for a PI to submit multiple LOIs under different national research priority areas. The research topics and projects must be distinct and responsive to the specific respective national research priority areas, as outlined in the PFA. Moreover, an individual listed as a PI on one LOI may be listed as and serve in another role (e.g., co-PI, co-investigator, or consultant) on other LOIs within the same PFA during the same cycle. A PI may submit multiple LOIs to different program PFAs in a cycle, but the PI must ensure that the research topics and projects are not similar. If a PI submits an LOI to multiple program PFAs, LOIs that exhibit scientific overlap or that appear to be duplicate submissions will be disqualified. PCORI will contact the PI and provide him or her with an opportunity to choose which PFA he or she would like to apply to. This applies to single- and dual-PI submissions.

### III. How To Apply

Applying for PCORI funding is a two-stage process. To submit an LOI and application (if invited), including all required documents, follow the instructions provided in this document and in [PCORI Online](#).<sup>5</sup> 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 a Letter of Intent or 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](#)<sup>6</sup> and [an EIN](#),<sup>7</sup> 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 Research Awards tile to apply for funding. PCORI strongly recommends that only the PI create the LOI/application record, because whoever creates the record will have permanent access to it in PCORI Online.

<sup>5</sup> Available at <https://pcori.force.com/engagement>.

<sup>6</sup> Available at <https://www.test.grants.gov/applicants/organization-registration/step-1-obtain-duns-number.html>.

<sup>7</sup> Available at <https://www.irs.gov/businesses/small-businesses-self-employed/apply-for-an-employer-identification-number-ein-online>.





## Step 2: Submit a Letter of Intent

An LOI is required for new and resubmitted applications. To submit an LOI, log in to [PCORI Online](#), complete the required LOI fields, and upload the completed PFA-specific LOI Template into the system.

PIs can download the LOI Template from the PFA page in the [PCORI Funding Opportunities](#) web page. For formatting instructions, reference Step 4. Each PFA cycle has one LOI Template. Use the same template when applying for any of the Broad PFA topics for that cycle.

For detailed instructions on how to navigate the system, reference the [PCORI Online: Pre-Award User Guide for Research Awards](#).<sup>8</sup>



## Step 3: Begin Application Process

PCORI will notify applicants by the date specified within the PFA as to whether they have been invited to submit an application.

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](#)<sup>9</sup> 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

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<sup>8</sup> Available at <http://www.pcori.org/sites/default/files/PCORI-Online-Pre-Award-User-Guide.pdf>.

<sup>9</sup> Available at <http://www.pcori.org/funding-opportunities/>.

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 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 Professional<sup>10</sup> 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](#).

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<sup>10</sup> See [adobe.com](http://adobe.com) for more information on Adobe Acrobat Professional.



## 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 (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](#) web page and in the PFA. System or technical issues with PCORI Online that affect the on-time submission of an application must be reported to PCORI before the specified deadline. Problems with computer systems at the applicant’s organization or failure to follow instructions in PCORI Online, in the PCORI 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](#)<sup>11</sup> for complete information.

## V. What To Include



**Note:** Only applicants selected to submit an application may begin the application process.

You will be notified by date specified in the Broad PFA, regarding whether PCORI has invited you to submit an application.

Applicants are encouraged to review this entire section. Print and complete the [Submission Checklist](#) to ensure that the LOI and application are submitted correctly. Download all required templates from the [PCORI Funding Opportunities](#)<sup>12</sup> web page.

### Letter of Intent

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

Download and complete the Broad PFA–specific LOI Template from the [PCORI Funding Opportunities](#) web page. Statements in gray italics provide instructions. Replace the gray italics and any instructional text with your responses, but retain the bold headings and question numbers. **Note that any additional template modifications will result in the disqualification of your LOI.**

The content included in this template will be used as the primary source of information for PCORI’s competitive screening process. Focus on including only critical information, as space is limited to two pages. Provide a description that allows the scientific community to understand the project, including

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<sup>11</sup> Available at <http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/>.

<sup>12</sup> Available at <http://www.pcori.org/funding-opportunities/>.

the aims and study design, without reviewing the full application. Review the PFA for maximum project budget (direct costs) and duration information. The two-page limit does not include references. PCORI suggests including all references as in-text citations using AMA style, but other citation styles are accepted. (**Note:** All LOI Templates must follow the formatting guidelines provided in [Step 4](#).)

Do not include supplemental materials (e.g., supporting journal articles, Letters of Support) or additional information not requested in the template (e.g., responses to reviewer comments, Resubmission Letters).

To submit an LOI, save the completed PFA-specific LOI as a PDF. Label your LOI file using the following nomenclature: "PI LastName\_(five-digit LOI number)\_LOI.pdf." [PCORI Online](#) will automatically generate an LOI number, which will be visible at the top of the web page once you save the LOI. Click "Review & Submit" to review your submission, and then click "Submit." Navigate back to the LOI and Application dashboard in PCORI Online, where you can see your LOI number and track your status. Once your LOI is submitted, you cannot edit it.

If program staff determine that the LOI is a better fit for another program, they may transfer the LOI to that program. If that program is interested in inviting the applicant to submit an application, PCORI will notify the applicant and obtain his or her approval to switch programs. PCORI will not invite an applicant to submit an application if the applicant's LOI does not meet program areas of interest or if it substantially overlaps with existing projects in the portfolio. Applicants will receive an email notification accepting or declining their LOI. See the PFA for more information about LOI Review.

### Resubmission Policy

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

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

### 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 peer review-related activities.



- The Contact PI's institution must be the primary institution for the award.
- PIs can participate in other applications (from the same or another organization) in the same or a different role, such as co-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 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](mailto: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.

## VI. Application Requirements



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

- PI (Contact PI and PI #2)
- Institution
- Study design
- Research question(s)
- Specific aims
- Comparators

If you need to change any of this information or have any questions, email [pfa@pcori.org](mailto:pfa@pcori.org).

## PI and Contact Information

Review the information transferred from your LOI, and update as needed.

## Project Information

Enter the following information directly into PCORI Online.

### Technical Abstract

Provide a Technical Abstract within PCORI Online that summarizes your Research Strategy. The abstract must include the following sections:

- **Background and Significance:** State the problem or question the research is designed to address.
- **Study Aims:** Briefly describe the specific aims of the study, including specific research questions and long-term objectives.
- **Study Description:** Describe in detail the study design. Include, as applicable, the following:
  - Overall study design
    - *Identify the study design that most closely matches your project. This list is not exclusive. If your study does not fall into one of these categories, please insert the most appropriate description.*
      - *Randomized controlled trial*
      - *Cluster randomized trial*
      - *Stepped wedge design*
      - *Quasi-experimental study*
      - *Observational: cohort study*
      - *Observational: case-control study*
      - *Observational: cross-sectional study*
  - Main components of the intervention and comparator(s)
    - *Name or briefly describe each intervention/exposure and comparator. Do not use brand names. If “usual care,” define what this will be.*
  - Study population
    - *Describe population studied; including*
      - *Source*
      - *Number of participants/target sample size by arm*
      - *Inclusion criteria (if including age, describe as “adults ages 45-85” or “children age 5 or younger”)*
      - *Demographic information*
      - *Clinical status*
  - Primary and secondary outcomes
    - *Include all primary and secondary outcomes. If study has both primary and secondary outcomes, use this approach:*
      - *Primary: List primary outcomes in series, separated by commas*

- *Secondary: List secondary outcomes in series, separated by commas*
  - Timeframe
    - *Specify the most distant follow-up point for the primary outcomes. (Do not need to specify length of exposure to intervention.) For example:*
      - *18-month follow-up for primary outcomes*
      - *Up to 7-year follow-up from the time of diagnosis (an example of a retrospective cohort study)*
      - *Immediate follow-up for primary outcomes*

For examples of completed Study Design tables, see:

- [Comparing the Benefits and Harms of Medicines for Long-Term Treatment of Blood Clots -- The ALTERNATIVE Study](#)
- [Comparing Treatment Options for Children with Urea Cycle Disorders](#)

### Public Abstract

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

Describe:

- The health condition or problem being studied. Include enough information to provide context for a reader who is unfamiliar with the topic, such as the scope, severity or burden posed by the problem
- The rationale for and importance of the study
- The study's objective(s) and specific aims
- A brief non-technical description of the study design
- Who can use results from this study and how (i.e., what is the decision that results from this study will help end-users make? What will they be deciding between, and in what situation?)
- The patient population and how they will be recruited for the study
- The study intervention(s), making sure to define all study arms/comparators, including what any control or usual care group received, and any acronyms or technical terms used
- All primary and secondary outcomes, the intervals at which they will be measured, and how (e.g., electronic health record data, survey, clinical assessment, etc.)
- Stakeholder engagement: what types of stakeholders are represented, and in what ways are they involved in the study

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

For examples of completed public abstracts, see:

- [Comparing Two Ways to Provide Palliative Care to Older Adults with Serious Illness](#)
- [Comparing Programs to Treat Opioid Use Disorder in Primary Care and Substance Use Clinics](#)



## Milestones Template

Applicants must complete the [Milestones Template](#) and upload it as an Excel file, not as a PDF, in PCORI Online, in the designated upload field. Follow the instructions in the Milestone Template and complete all required sections. For the milestones provided in the template, based on Milestone—Deliverable Name (Column B) and Description (Column C), applicants must provide the Due Date (Column D). Consider the guidance information in Column E as you determine the Due Date, which can be any day of the week. Applicants should insert rows for additional milestones, when and where appropriate as they would correspond to the timing of the milestone.

Milestones are concrete, specific events or accomplishments that are documented by deliverables, associated with a timeline, and must include project objectives that will be accomplished at specific times during the proposed project. PCORI encourages applicants to provide three to six milestones per six-month reporting period, though there is no minimum or maximum. Each reporting period should include the major milestones reflecting the research activities and only those activities that the PCORI contract supports. Some examples of milestones include reaching specific patient accrual targets, developing a survey, commencing the intervention, and establishing project-specific databases. See [Appendix 1: Example Milestones](#) for a more complete list.

As part of Merit Review Criterion 3, Scientific Merit (research design, analysis, and outcomes), reviewers evaluate the submitted milestone schedule to assess the feasibility of the study plan.

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

## Budget

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

## 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.

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

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

additional years. Each PFA states the maximum project periods. Note the following:

A. Personnel Costs

- Personnel costs include the base salary for each scientific and technical staff member, employee patient or stakeholder partner, or other personnel on your project who are or are not accounted for in Section B: Consultant Costs. Provide a clear distinction between individuals who are key personnel and those considered “other” personnel.
- PCORI will reimburse personnel costs that are consistent with and do not exceed what the applicant would normally pay under its own policy. PCORI may request salary verification during the contract activation process. Such compensation may include salaries and fringe benefits. See Appendix 2: Allowable and Unallowable Costs for more information.
- Salaries include wages earned by an employee, and fringe benefits may include insurance and retirement plans. Provide documentation to support the fringe benefits within the Budget Justification.
- Level of Effort: Personnel who contribute to a PCORI-funded research project must monitor their total percentage of effort across all of their active funding, so that it does not exceed 100 percent. Before submitting the application to PCORI, the AO must certify that individual personnel will not exceed 100 percent effort if funded. You must report effort by the percentage of time over the course of the project year. If you are not requesting salary support, use \$0 for the base salary.
- All personnel who dedicate effort to the project must be listed on the Personnel Budget with their level of effort, even if they are not requesting salary support. List the base salary for each person in the Budget Justification and the Detailed Budget. Describe the individual’s specific functions in the Budget Justification. Provide an explanation of how the role supports the project aims and note any overlap in job functions.
- Salary Cap: The PCORI base salary cap for personnel is \$200,000 annualized per individual, per year, excluding fringe benefits. An individual who earns less than \$200,000 must use his or her actual base salary to calculate personnel costs. An individual with a full-time employee base salary of more than \$200,000 must use \$200,000 as the base salary rate in determining the amount of salary and time to charge to the project.
- 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.



**Note:** Personnel costs must account for the level of effort required to initiate and complete the mandated Peer-Review Process. See the [Detailed Peer-Review Budget for Peer-Review-Related Costs](#) section for additional instructions.

B. Consultant Costs

- Consultant costs apply to those individuals who are not employees of the applicant organization

or under a subcontract agreement as members of the contracted staff.

- Payments to nonemployee patient and stakeholder representatives must be included in the budget as consultant costs.
- Provide the total cost of the consultant(s), as well as name(s), expected number of hours, and hourly rate.
- Include the daily consultant fee, 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 research project, the following must be provided in the Budget Justification:

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

#### D. Travel Costs

- Travel may include any domestic or international travel by project personnel or consultants directly related to, and necessary for, the project and within the limits explained below. PCORI uses the Federal Travel Regulations guidelines for per diem and other reimbursements.

- Travel should be devoted to programmatic activities necessary to conduct the project, such as focus groups, project team meetings, or data collection. Requests for travel to present at conferences or symposiums that are related to the topical areas of the project may also be included, but should be limited in number, and strongly justified. PCORI closely reviews all travel costs to ensure they are reasonable.
- Travel costs must be itemized per trip and must include the number of trips and a brief description of each one, including the number of people traveling and dates or duration of the stays.
- Airline or rail costs cannot exceed the customary standard commercial fare (coach or equivalent), or the lowest commercial discount fare. PCORI will not compensate upgrades.
- In the Budget Justification Template, applicants must provide additional detail to explain the basis for the costs listed and describe how the travel is directly related to the proposed research project and necessary for achieving programmatic objectives.

#### E. Other Expenses

- 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, return of results to study participants, 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.

#### I. Engagement Costs

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

#### **Subcontractor Detailed Budget Template**

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

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

PCORI has a legislative mandate to ensure the scientific integrity of the primary research it supports and to make study findings widely available and useful to patients, clinicians, and the general public within a specific timeframe. Accordingly, the PCORI Board of Governors (Board) adopted the [Process for Peer](#)

## [Review of Primary Research and Public Release of Research Findings](#).<sup>13</sup>

The detailed Peer-Review Budget must include costs related to the development and revision of the Draft Final Research Report (DFRR), as part of [PCORI's Peer-Review Process](#). The Peer Review Budget will be completed in PCORI Online and the Subcontractor Detailed Budget Template, as needed. Note that the Total Budget will include the Peer-Review Budget and the Research Project Budget when determining compliance with the Maximum Project Budget in the PFA.

- The DFRR is expected to be submitted 3 months after completion of the milestone for Completion of Data Analysis for All Study Aims and expected to have finished the [Peer Review process](#) and be accepted by PCORI within 6-12 months of submission ([following necessary revisions](#)).
- Costs associated with the Peer-Review Process are limited to personnel, consultants, and subcontractors, who will be assisting the PI in the development of the DFRR and responding to any requested revisions as part of the external review.
- A Budget Justification must be included for the Peer-Review Budget. The PI must dedicate measurable effort in support of the Peer-Review Process. Applicants must identify the peer-review support staff role within the budget at the time of submission.
- The Budget Summary must include the Peer-Review Budget.

### **Budget Summary for Entire Project**

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

### **Budget Justification Template**

Complete a [Budget Justification Template](#) for the prime applicant and each subcontracted organization for the entire Research Project Budget and Peer-Review Budget for all research- and peer-review-related costs. Provide sufficient detail to explain the basis for costs, the reason the costs are necessary to the project, and the reason for major cost variances. Include information about budgeting for engagement, including financial compensation of patient and other stakeholder partners, costs of patient and other stakeholder expenses, project staff, engagement event and/or meeting costs, incorporating partner feedback, and costs associated with the return of aggregate study results to study participants. Note that some projects employ or assign an individual responsible for coordinating or managing all project-related patient and other stakeholder engagement. This person should be listed as full-time equivalent under personnel, consultant, or subcontractor costs. Explain the basis for travel costs, and describe how the travel is related to the proposed research and necessary for achieving programmatic objectives.

Describe the specific role and tasks each research team member will perform, along with the impact on the Project Plan. PCORI will evaluate each member's contribution as listed in the Budget Justification, to validate meaningful contributions and assess whether overlap in responsibilities occurs. Provide a clear

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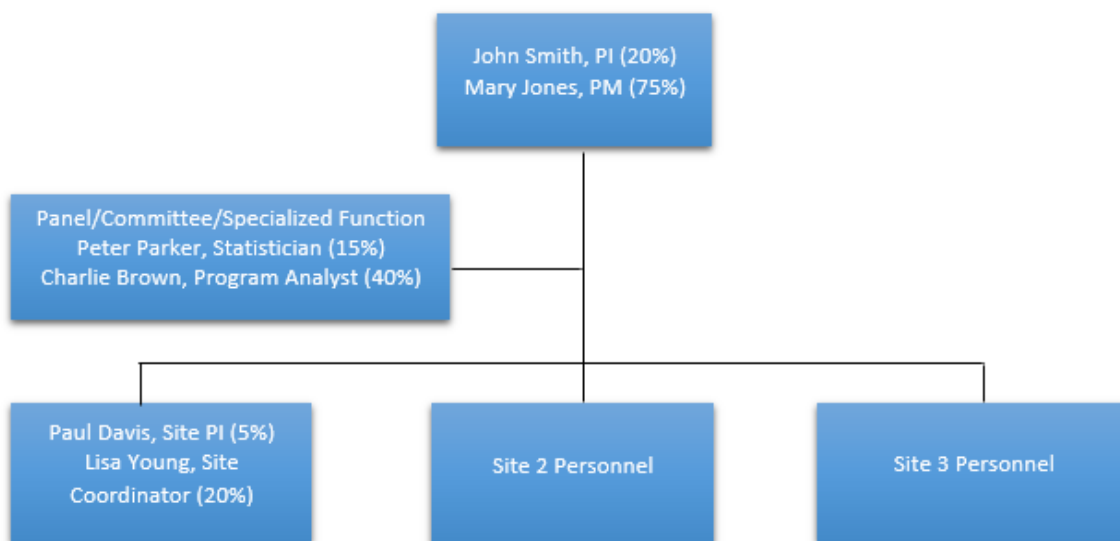
<sup>13</sup> See <http://www.pcori.org/sites/default/files/PCORI-Peer-Review-and-Release-of-Findings-Process.pdf>.

distinction between individuals who should be key personnel and those who should be classified as “other” personnel.

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

Applicants proposing use of an existing research network infrastructure, research consortia, or related data resources must provide documentation supporting the involvement of network leadership throughout the study (e.g., budgets, Budget Justification that covers the costs of the network’s efforts).

Applicants must include an overall organizational chart (example below) indicating the roles and relationships of project personnel and including their titles/functions and percentages of effort. As determined by the needs of the study, this chart must include the project PI, individual site PIs, the Data Coordinating Center, statistical analysis team, advisory panels, DSMB, and personnel coordinating and managing data collection. Provide separate charts as needed for such components as individual sites, the Data Coordinating Center, and so on, if these involve multiple personnel. If the percentages vary by contract year, provide separate charts for each version. The budgetary information provided with the application must reference the organizational figures to facilitate PCORI’s review.



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

### Research Plan Template

Complete all required sections in the [Research Plan Template](#) and upload as a single PDF to PCORI Online. The Research Plan includes the Research Strategy, Research Team and Environment, Dissemination and Implementation Potential, Return of Aggregate Study Results, Protection of Human

Subjects, Consortium Contractual Arrangements, References Cited, and an optional Appendix.

## Research Strategy

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

In addition to following the instructions in the Research Plan Template, applicants should ensure that the Research Plan addresses the following points:

- **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 Research Strategy. Additional best practices, including guidelines for conducting clinical trials developed by other organizations, must be addressed in the application.
- **Addressing a decisional dilemma meaningful to patients.** Applicants should state the specific clinical decision(s) or treatment choice(s) confronted by decision makers and explain how the findings from the proposed research will inform those decisions. State why this decision—such as choosing a specific medication, surgical approach, or care delivery strategy to treat a condition or manage a specific population—is important to patients. Document the uncertainty that patients and other stakeholders face in making this decision.
- **Selection of outcomes that are important to patients and other decision-makers.** Applicants should document how the primary and/or secondary outcomes are relevant and meaningful endpoints to patients and other stakeholders.
- **Detection of meaningful effects.** PCORI specifically seeks studies that are powered to detect meaningful effects. Applicants must justify the proposed sample sizes by explaining the assumptions used in all study power calculations. For example, the application must state all the necessary assumptions, such as the outcome(s) on which the power calculations are based, the estimated difference in the effect size between study arms, the standard deviation of the effect size measure, the type I and II error rates, and any other assumptions. All such estimates must be justified by referring to prior published research or preliminary data.
- **Ensuring valid estimates of intervention effects.** Applicants must specifically discuss their capacity to measure such factors as differential adherence to chosen treatments (or participation in intervention programs) that could result in differences in the effectiveness of the alternative interventions being compared in clinical populations
- **Leveraging existing resources.** Applicants proposing use of an existing research network infrastructure (e.g., PCORnet, the National Patient-Centered Clinical Research Network ), research consortia, or related data resources (e.g., electronic medical records data from healthcare delivery systems or administrative claims data from public or commercial insurers)



should address this with sufficient specificity in the Research Plan, as appropriate. Applicants should also refer to the PCORI Methodology Standards for Data Networks as Research-Facilitating Structures.

- **Engagement with patients and other stakeholders.** Applicants should describe how they will work with patients and other stakeholders on their study and the added value their experience and expertise will bring. In this section, identify the types of stakeholders that will be engaged as research partners, the rationale for selection, including how they represent the diversity of the people affected by the problems this study addresses, and the scope of their involvement. Include the names of patient and other stakeholder partners and their organizations if known at the time of application. If unknown, applicants should describe a plan for identifying and selecting research partners. [PCORI's Engagement Rubric](#), and other [engagement resources](#) available [on PCORI's website](#) can be a helpful resource to guide applicants on engagement approaches to consider in different phases of a research study. Funded studies will be required to submit a full roster and detailed [Engagement Plan](#) at six months after contract execution<sup>14</sup>.

### Research Team and Environment

Within the Research Team and Environment component (up to two pages), applicants must describe the research team's capabilities to accomplish the goals of the proposed research project and the appropriateness of the research environment to conduct the study. Applicants must also describe the following:

- How and why those research sites were selected
- How they tie back to the research project
- The resources, facilities, support, and collaborations available to ensure the project's success
- If multiple sites are involved, prior experience that demonstrates the likelihood of working together successfully (e.g., past data sharing, Institutional Review Board (IRB) reciprocity, or other factors) to facilitate efficient conduct of the study
- Ways in which the project will benefit from the research environment's unique features or from community involvement
- How sites will work together to ensure that milestones will be achieved
- Institutional and community investment in the success of the research, such as the availability of organized peer groups
- Logistical support, such as administrative management and oversight, and best practices training

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<sup>14</sup> Forsythe LP, Carman KL, et al. Patient Engagement in Research: Early Findings From The Patient-Centered Outcomes Research Institute. Health Aff (Millwood). 2019 Mar;38(3):359-367; PCORI Board of Governors Meeting, December 9, 2019. <https://www.pcori.org/sites/default/files/PCORI-Board-Meeting-Presentation-Slides-120919.pdf>, p. 32-69; [Engagement in Health Research Literature Explorer](#); [Updated Engagement Plan](#); [PCORI Methodology Standards on Patient-Centeredness](#)

- Financial support, such as protected time for research with salary support
- Access to and support of patient groups

Provide all key personnel, professional and partner profiles/biosketches, and detailed site descriptions within the [PI Template](#), [Key Personnel Template](#), and [Project/Performance Site\(s\) and Resources Template](#) as a separate PDF upload.

### Dissemination and Implementation Potential

In this component (up to one page), applicants should describe specific opportunities as well as possible barriers to disseminating and implementing their work in other settings. This section should address any study limitations that could have an impact on the usability of findings (e.g., propriety issues, applicability, scalability, and appropriate settings of care).

PCORI does not support awardees budgeting efforts or resources for the conduct of dissemination and implementation work at this juncture. For projects that produce important findings, PCORI will consider subsequent applications for funding to support dissemination and implementation efforts through separate PFAs and other mechanisms.



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

### Return of Aggregate Study Results

In this component (up to one page), applicants should describe how, as awardees, they plan to communicate the aggregate findings from their research to the participants who were enrolled in the study. Note that the proposed activity should return *aggregate* study results (i.e., the overall study findings) to the study participants, and not *individual* results (i.e., participant-specific data, such as genetic or imaging results). Results return may be accomplished by sharing the lay language “Results Summary” that PCORI posts to its website upon completion of the research project, or by distributing a similar summary. Applicants may propose to distribute the study results to study participants by email, mail, newsletter, or other approaches.

In the Detailed Budget tab in PCORI Online and in the [Budget Justification Template](#), specify the costs associated with this return of results to study participants. Studies with fewer than 5,000 participants may budget up to \$2,500. If this amount does not suffice for studies that need to return results to a larger number of participants, applicants may propose a larger amount with justification. Note that the costs associated with the return of results must be included as part of the Total Budget (in PCORI Online) when determining compliance with the Maximum Project Budget in the PFA.

Applicants should consider whether they will need to obtain IRB approval ahead of the study in order to recontact participants at its conclusion. In addition, awardees should make all efforts to ensure that returning results is in accordance with their institution and/or state’s guidelines and laws.

Studies may be exempt from this provision if a return of results is not possible. For example, this provision does not apply to studies that use secondary data or those that use anonymous participants. If applicable, applicants' response to this section should address why the return of results is not feasible.

### Protection of Human Subjects

In this component (up to five pages), describe the protection of human subjects involved in your research. PCORI follows the Federal 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](#),<sup>15</sup> 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 (up to five pages), describe the proposed research projects that subcontracted organizations will perform. Explain the strengths that these partners bring to the overall project to ensure successful submission of contract deliverables in accordance with the milestone schedule.

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 Research Plan Template. Throughout the Research Plan, applicants should use in-text citations to reference published materials. In this section, list the full bibliographical citation for each reference. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article title and journal or book title, the volume number, the page numbers, and the year of publication. Include only bibliographic citations. PCORI suggests following AMA style when providing citations for source materials used to prepare any section of the application, but other citation styles are acceptable. Citations that are publicly available in

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<sup>15</sup> See <http://grants.nih.gov/sites/default/files/supplementalinstructions.docx>.

a free online format may include URLs or PubMed ID numbers along with the full reference. *Limit references to relevant and current literature.* Be concise and select only those literature references pertinent to the proposed research, so that you do not exceed the 10-page limit. Reference websites in the standard URL format (i.e., <http://www.pcori.org>) along with the date on which the link was last accessed.

## Appendix (Optional)

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

## Methodology Standards Checklist

Applicants must complete the [PCORI Methodology Standards Checklist](#) and upload it as an Excel file to PCORI Online in the designated upload field. Applicants must complete Column D of the checklist, using the drop-down menu options to indicate whether each PCORI Methodology Standard applies to their proposed research. Applicants must complete the subsequent columns, as appropriate, following the instructions in the checklist. If the standard applies, in Column E provide the page number(s) of your Research Plan where the text illustrates how you addressed the standard. Last, in Column F, indicate whether your study may deviate from the standard and provide a rationale. Indicate “Not Applicable (N/A)” if particular standards are not applicable to your study. Refer to the [PCORI Methodology Report](#) for explanations of the standards.

## 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 Dual-PI information and Leadership Plan, if applicable)
- 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. PCORI permits applicants to name a **maximum of two** PIs within an application. The PIs may be from the same or different institutions. Each PI is accountable and responsible for the conduct of the award and for ensuring that all awarded milestones, deliverables, and reports are completed in accordance with the award terms and conditions.

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

Complete a Profile/Biosketch (up to five pages per individual) for the PIs, and as appropriate the dual-PI. Combine the profile/biosketches and into a single PDF file. The Contact PI profile/biosketch should be the first item in this upload. If applicable, attach the Leadership Plan to this file as the last item in this upload. Upload the file to the designated field in PCORI Online.

### **Leadership Plan (Required if Proposing a Dual-PI Application)**

Applicants proposing a dual-PI application, must include a [Leadership Plan](#) (up to five pages). The Leadership Plan 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 and the rationale for submitting a dual-PI application; (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). PCORI is especially interested to learn how each individual's previous experience, past performance, and training in the field of PCOR has prepared him or her to conduct this research. You 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 project, including capacity, capability, characteristics, proximity, and extent of availability to the project.

## 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., dual-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 Research Plan involves access to patient populations, data sets, or additional resources, include a Letter of Support that confirm such access, signed by the person with approval authority. If access cannot be confirmed at the time of contract negotiation, PCORI reserves the right to withhold funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.

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

### **Resubmission Letter**

An applicant may resubmit an application that was not funded but that did complete PCORI's merit review process (i.e., the applicant received a summary statement). See the [Resubmission Policy](#) for more information.

Resubmitted applications require completion and submission of a one-page [Resubmission Letter](#). The Resubmission Letter provides an opportunity for applicants to give a high-level overview of how the application has been strengthened in its scientific merit and responsiveness to the current PFA. Simply responding to previous reviewers' concerns is not sufficient; the application must be programmatically responsive and demonstrate methodological rigor and patient-centeredness. The Resubmission Letter will inform the merit reviewers' understanding of the ways in which the applicant has made efforts to strengthen the application, and reviewers will evaluate the application based on its responsiveness to the PFA and the merit review criteria.

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

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

## Appendix 1: Example Milestones

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

The following are examples of milestones and deliverables to be submitted to PCORI. You may reference this list as you complete this section of your application.

Required:

- Awardees must submit a PCORI Progress Report in PCORI Online at least every six months.
- A final progress report is due at the end of the period of performance.

Within first six to nine months of an executed contract:

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

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

- Submit 100 percent of the IRB approvals across sites to PCORI.



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

**Remainder of Contract:**

- Research deliverables and findings (e.g., instruments, data dictionaries, abstracts and manuscripts)
- Primary Completion Date
  - This follows the NIH definition pertaining to the primary outcome. The NIH definition of Primary Completion Date is the date when the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome. This milestone should be relocated so that it falls chronologically based on when the study expects to complete data collection for the primary aim. This date must precede the estimated submission date of the Draft Final Research Report (DFRR).
  - An estimated Primary Completion Date must be provided when registering the study in ClinicalTrials.gov. For studies that are not clinical trials or non-prospective observational studies registered on [ClinicalTrials.gov](https://clinicaltrials.gov), the Awardee and PCORI shall agree on a Primary Completion Date as a milestone that precedes the agreed-upon date to submit a DFRR.
- Completion of Data Collection for All Study Aims
  - Completion of Data Collection milestone should ideally occur before Completion of Data Analysis for All Study Aims milestone; however, may be the same date.
- Completion of Data Analysis for All Study Aims
  - Completion of Data Analysis for All Study Aims Date must be on or before date of submission of Final Progress Report. It should be scheduled to be due three (3) months prior to submission of DFRR.
- Results submitted to ClinicalTrials.gov or applicable database
  - Awardee ensures results are submitted to ClinicalTrials.gov or another database.
  - This should occur no later than 12 months from Primary Completion Date for applicable studies. PCORI encourages and recommends the first submission to clinicaltrials.gov be within 6 months of Primary Completion Date, as applicable.
  - For ClinicalTrials.gov, the generated tables are a required section in the DFRR. Results must be submitted to ClinicalTrials.gov no later than submission of the DFRR.
- Last Submission of Results to ClinicalTrials.gov (if applicable)
  - The specific timing of multiple milestones for submissions to ClinicalTrials.gov may vary, depending on the number of study aims (some milestones may occur after the milestones for Completion of Data Collection for All Study Aims and Completion of Data

Analyses for All Study Aims). The complete and final submission of results to ClinicalTrials.gov must appear one month before the DFRR Submission milestone.

- DFRR Submission
  - This date should be 3-4 months after the completion of Data Analysis for All Study Aims milestone. Submit DFRR according to these [instructions](#).
- DFRR Revisions
  - This date should be 6 months after “DFRR Submission”. Upon receipt of written summary, and as applicable, PI will make revisions and submit revised DFRR and disposition of comments table for acceptance in accordance to PCORI policy and process.

If awarded, a contractual milestone schedule will be negotiated and finalized with the PCORI project team. Additional reporting, such as monthly enrollment updates, may be required.

## Appendix 2: Allowable and Unallowable Costs

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

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

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





A funding applicant must specifically request costs related to conducting the research project through itemization on the Detailed Budget. PCORI will consider this request in the course of making an award. The following principles and requirements generally apply to PCORI's evaluation of the proposed budget and determination of allowable costs and should guide applicants in preparing their Detailed Budgets:

- Typically, IRB fees are included in an organization's indirect cost pool. However, PCORI will allow this expense as a direct cost if the costs are not included as part of the indirect cost rate. By submitting the application, the PI and AO certify that their institution treats IRB fees as direct costs, and the fee is allocable to the study. IRB fees are subject to audit.
- In general, PCORI will not cover costs for study interventions that constitute the procedures, treatments, interventions, or other standard clinical care ("patient care") that are being













proposed for comparison in the research project (“patient care costs”). The host healthcare delivery system, third-party payer, product manufacturer, developer of the intervention, or other interested party must cover the patient care costs.

- The willingness of one or more stakeholder groups to cover patient care costs incurred during the research project, even when one of the comparators is not currently directly covered by insurance, will be taken as a strong endorsement of the research project by the stakeholder group. Such commitments also indicate that the stakeholder groups will use the research study’s findings. (Such support by a stakeholder group must be discussed in the application.)
- Except for specific permission in exceptional circumstances, PCORI will not cover patient care costs.
- PCORI may consider coverage of the co-payment or co-insurance costs of participating study subjects when necessary to preserve blinding in a study or to ensure access to the study for vulnerable populations.
- PCORI will generally cover costs for ancillary tasks necessary to implement or monitor patient care as part of conducting the research project. Examples include costs for obtaining informed consent to participate in the research project; collecting data pursuant to the research protocol; or collecting and monitoring study subject data that would not normally be performed in the course of patients receiving the patient care evaluated in the research project.

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

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.

PCORI’s authorizing law was amended by reauthorization legislation<sup>2</sup> in 2019 to include a new mandate to consider, as appropriate, the full range of clinical and patient-centered outcomes data relevant to patients and stakeholders. The reauthorizing language clarifies that, in addition to the relevant health outcomes and clinical effectiveness, relevant outcomes included within PCORI-funded projects may include the potential cost burdens and economic impacts of the utilization of medical treatments, items, and services when relevant to patients and caregivers or to other stakeholders. The parameters for appropriately including such outcomes are further described in the [Principles for Consideration of the Full Range of Outcomes Data](#).

### Appendix 3: Administrative Actions

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

Automatic Rejection	Modification by PCORI	Appended upon PCORI's Request*
<p>An application or LOI will be automatically rejected if any of the following apply:</p> <ul style="list-style-type: none"> <li>• Exceeds the specified period of performance outlined in the PFA</li> <li>• Exceeds the maximum budget specified in the PFA</li> <li>• Has adjusted margins or font size (LOI)</li> <li>• Does not include or has an incomplete Research Strategy</li> </ul>	<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.