



## Cycle 2 2017 Funding Cycle

### Limited PCORI Funding Announcement: Dissemination and Implementation of PCORI-Funded Patient-Centered Outcomes Research Results

#### Application Guidelines

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These guidelines apply to the Cycle 2 2017 Funding Cycle for the Dissemination and Implementation of PCORI-Funded Patient-Centered Outcomes Research Results limited PCORI Funding Announcement (PFA). Funding announcements, templates, and other resources are available at <http://www.pcori.org/Cycle-2-2017-dissemination-implementation/>. The Cycle 2 2017 Funding Cycle closes October 25, 2017, at 5 p.m. (ET).



## **About PCORI**

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

PCORI was authorized by Congress in 2010 as a nonprofit, nongovernmental organization. PCORI's purpose, as defined by our authorizing legislation, is to help patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders make better-informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.”

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### **What Has Changed for the Cycle 2 2017 Funding Cycle**

1. Recommendation to submit Draft Final Research Report one to two months prior to application deadline to allow for a review of completeness and acceptability by PCORI was added (see “Timing” in “Overview” table, above, for more details).
2. New language was added regarding PCORI’s expectation that applicants address anticipated reach of their project (see page 6 for more details).
3. New nonresponsiveness criterion was added to highlight that PCORI will not pay for the delivery of the proposed intervention through this funding (see page 7 for more details).
4. Applicants are now asked to fill out and upload a Project Summary Template (see page 16 for details).



## I. About These Guidelines

This document provides key information to help researchers prepare for and respond to the Dissemination and Implementation of PCORI-Funded Patient-Centered Outcomes Research Results limited PCORI Funding Announcement (PFA) available at <http://www.pcori.org/Cycle-2-2017-dissemination-implementation/>.

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

- PCORI's [Applicant FAQs](#)<sup>1</sup> cover common questions about PCORI and the application process.
- Visit PCORI's [Help Center](#)<sup>2</sup> for additional applicant resources.
- **For Programmatic Inquiries:** Contact the PCORI Helpdesk via email ([disseminationquestions@pcori.org](mailto:disseminationquestions@pcori.org)). PCORI will provide a response within three business days. However, we cannot guarantee that all questions will be addressed three business days before a Letter of Intent (LOI) or application deadline.
- **For Administrative, Financial, or Technical Inquiries:** Contact the PCORI Helpdesk at [pfa@pcori.org](mailto:pfa@pcori.org). PCORI will provide a response within two business days. Note that during the week of the application deadline, response times may exceed two business days. Applicants may also call the PCORI Helpdesk (202-627-1885).

It is the applicant's responsibility to submit the application on or before the deadline. Refer to [PCORI's Policy on Submission of Research Contract Applications](#).<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 Application Guidelines. Applicants who fail to submit the required documents may be rejected from the merit review process.

All rejection decisions made by the Contracts Management and Administration department are final. Email [pfa@pcori.org](mailto:pfa@pcori.org) with any formatting or administrative compliance questions to ensure that your LOI or application will not be deemed noncompliant once submitted to PCORI. See [Appendix 2: Administrative Actions](#).

Unless otherwise stated within the Application Guidelines, all submissions on behalf of an applicant organization are the property of that organization. PCORI will not share or publicize the contents of an organization's application.

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<sup>1</sup> Available at <http://www.pcori.org/funding-opportunities/how-apply/have-question/dissemination-and-implementation-limited-pcori-funding>.

<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/>.

PCORI issues contracts, rather than grants, to fund and administer meritorious dissemination and implementation (D&I) efforts. 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 Project 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. To review PCORI's contract terms and conditions, see [PCORI Standard Contract for Funded Research Projects](#).<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.

## II. Who Can Apply

Recipients of PCORI research awards are eligible to respond to this announcement, including Broad PCORI Awards, Pilot Projects Program Awards, Targeted PCORI Awards, Pragmatic Clinical Study Awards, and PCORI-funded demonstration projects occurring within the Patient-Centered Clinical Research Network (PCORnet) infrastructure (e.g., ADAPTABLE and Obesity trials). Applications associated solely with Eugene Washington PCORI Engagement Awards and Pipeline to Proposal Awards are not eligible for this funding announcement. **Note:** *Although eligible to apply, Pilot Projects must still meet all of the PFA requirements in order to be considered responsive. Some of the requirements (e.g., evidence readiness) may be difficult for Pilot Projects to satisfy.*

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.

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. Organizations may submit multiple funding applications. Individuals are not permitted to apply. If you have questions about eligibility, contact [disseminationquestions@pcori.org](mailto:disseminationquestions@pcori.org).

**Note:** Applicants should refer to the PFA Overview chart for specific eligibility requirements.

## III. How To Apply

To submit an LOI and application (if invited), including all required documents, follow the instructions provided in these guidelines and in [PCORI Online](#).<sup>5</sup> All documents must be submitted through PCORI

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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/>.

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



Online. Please be sure that you are applying to the funding announcement titled, “Limited PCORI Funding Announcement: Dissemination and Implementation of PCORI-Funded Patient-Centered Outcomes Research Results.” Refer to the specific PFA for more information regarding the review process of LOIs and applications.

To submit an application or to register your organization in PCORI Online, you need a Data Universal Numbering System (DUNS) number and an Employer Identification Number (EIN). You can [apply for a DUNS number](#)<sup>6</sup> and [an EIN](#),<sup>7</sup> if applicable.



### Step 1: Register

To apply for PCORI funding, an applicant (Principal Investigator [PI] or PI designee) must register in [PCORI Online](#). A name, an email address, a password, and a security question and answer are required to register. 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.



### Step 2: Submit a Letter of Intent

An LOI is required for new and resubmitted applications. Download the PFA-specific LOI Template from the [PCORI Funding Opportunities](#). For formatting instructions, reference Step 4.

To submit an LOI you must go into [PCORI Online](#), complete the required fields, and upload the completed PFA-specific LOI template into the system. 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: Initiate Application Process

**Applicants will be notified** by the date specified in the PFA as to whether or not they have been invited to submit an application.

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

<sup>6</sup> Available at <https://www.dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number/>.

<sup>7</sup> Available at [http://www.irs.gov/Businesses/Small-Businesses-&-Self-Employed/Apply-for-an-Employer-Identification-Number-\(EIN\)-Online/](http://www.irs.gov/Businesses/Small-Businesses-&-Self-Employed/Apply-for-an-Employer-Identification-Number-(EIN)-Online/).

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



## Step 4: Format and Complete Required Templates

Required templates are available in the [PCORI Funding Opportunities](#).<sup>9</sup> Find the PFA to which you are applying and download the correct PFA-specific templates, because they vary from PFA to PFA and cycle to cycle. Keep the following in mind:

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

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

- *Header:* Include the PI's full name on every page in the top-left corner and the original PCORI Contract Number.
- *Font:* Use Calibri size 11. Figures, tables, and captions may have size 8 font.
- *Spacing:* Use single spacing.
- *Margins:* Use at least half-inch margins. The header may fall within the top margin, but the body of the text may not begin closer than a half-inch from the edge of the page.
- *Page numbers:* Each page must be numbered consecutively for each PDF upload. Each section of an uploaded document must begin with page 1.
- *Page limit:* This varies based on document.
- *File name format:* This varies based on document.
- *References:* PCORI suggests including all references as in-text citations using American Medical Association (AMA) citation style, but other citation styles are accepted.



## Step 5: Upload Required Documents

Follow the [Application Checklist](#) included in these guidelines to enter required information. Upload required documents to PCORI Online in the correct order. When instructed, use Adobe Acrobat Professional<sup>10</sup> to combine documents into a single PDF file for upload. Within the Templates & Uploads tab, click "Choose file" to select a file from your computer, and click "Upload." For detailed instructions, refer to the Templates & Uploads section of the [PCORI Online: Pre-Award User Guide for Research Awards](#).

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

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





## Step 6: Submit for Authorization

Once all required information has been completed and uploaded, select “Review & Submit” and then “Submit” to forward the application to your Administrative Official (AO) to authorize and submit. The AO must approve and submit the final application for official submission to PCORI before the deadline. **PCORI Online will email the AO, but the PI should notify the AO when the application is ready for review, AO approval, and submission.** The PI and the AO may not be the same individual. Both the AO and the PI will receive an email confirming that PCORI has received the application.

## IV. When To Apply

Deadlines for each funding cycle are noted in the PCORI Funding Opportunities and in the PFA. System or technical issues with PCORI Online which affect the on-time submission of an application must be reported to PCORI before the specified deadline. Problems with computer systems at the applicant’s organization or failure to follow instructions in PCORI Online, PCORI Application Guidelines, or PFAs are not valid issues warranting consideration of a deadline extension. 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 August 22, 2017, as to whether or not you have been invited to submit an application.**

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

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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/>.

| Letter of Intent   | Submission Method   | Length/Limit   |
|--|---|----------------|
| <input type="checkbox"/> <b>Letter of Intent (LOI)</b>   |   |                |
| <ul style="list-style-type: none"> <li>Contact Information</li> </ul>  | Enter into PCORI Online   | N/A            |
| <ul style="list-style-type: none"> <li>Pre-Screen Questionnaire</li> </ul>   | Enter into PCORI Online   | N/A            |
| <ul style="list-style-type: none"> <li>Resubmission</li> </ul>   | Enter into PCORI Online   | N/A            |
| <ul style="list-style-type: none"> <li>PI Information</li> </ul>   | Enter into PCORI Online   | N/A            |
| <ul style="list-style-type: none"> <li>Project Information</li> </ul>  | Enter into PCORI Online   | N/A            |
| <ul style="list-style-type: none"> <li>Project Personnel</li> </ul>  | Enter into PCORI Online   | N/A            |
| <ul style="list-style-type: none"> <li>Project Personnel Partner</li> </ul>  | Enter into PCORI Online   | N/A            |
| <ul style="list-style-type: none"> <li>Budget/Time Greater Than Request</li> </ul>   | Enter into PCORI Online   | N/A            |
| <input type="checkbox"/> <b>Templates &amp; Uploads: LOI Template</b>  | Save file as "PI LastName_(last four digits of LOI number)_ LOI.pdf" and upload | 3 pages        |
| Application  | Submission Method   | Length/Limit   |
| <input type="checkbox"/> <b>Project Information</b>  |   |                |
| <ul style="list-style-type: none"> <li>Technical Abstract<sup>13</sup></li> </ul>  | Enter into PCORI Online   | As needed      |
| <input type="checkbox"/> <b>Budget</b>   | Enter into PCORI Online   | As needed      |
| <ul style="list-style-type: none"> <li>Detailed Budget for Each Project Year (prime)</li> <li>Budget Summary for Entire Project (prime and subcontractors)</li> <li>Federally Negotiated or Independently Audited Indirect Cost Rate Letter (prime contractor)</li> <li>Fringe Benefit Rate Policy Verification Document (prime contractor)</li> </ul> |   |                |
| <input type="checkbox"/> <b>Milestones</b>   | Enter into PCORI Online   | As needed      |
| <input type="checkbox"/> <b>People and Places Template</b>   | Save as "PeoplePlaces_PI LastName.pdf" and upload                               | As noted below |

<sup>13</sup> This includes all sub-sections from the Description of Results through the Patient and Stakeholder Engagement Plan.

|                          |   |                        |
|--------------------------|---|------------------------|
|                          | <ul style="list-style-type: none"> <li>• Leadership Plan (required if proposing dual-PI application)</li> </ul>           | 5 pages                |
|                          | <ul style="list-style-type: none"> <li>• Professional Profile/Biosketch</li> </ul>  | 5 pages per individual |
|                          | <ul style="list-style-type: none"> <li>• Patient/Stakeholder Partner Profile/Biosketch</li> </ul>                         | 5 pages per individual |
|                          | <ul style="list-style-type: none"> <li>• Project/Performance Site(s) and Resources</li> </ul>                             | 15 pages               |
| <input type="checkbox"/> | <b>Project Plan Template</b><br>Save file as "ProjectPlan_PILastName.pdf" and upload as a single file                     | As noted below         |
|                          | <ul style="list-style-type: none"> <li>• Project Strategy</li> </ul>  | 10 pages               |
|                          | <ul style="list-style-type: none"> <li>• Protection of Human Subjects (if applicable)</li> </ul>                          | 5 pages                |
|                          | <ul style="list-style-type: none"> <li>• Consortium Contractual Arrangements</li> </ul>                                   | 5 pages                |
|                          | <ul style="list-style-type: none"> <li>• References Cited</li> </ul>  | 10 pages               |
|                          | <ul style="list-style-type: none"> <li>• Appendix (optional)</li> </ul>   | 5 pages                |
| <input type="checkbox"/> | <b>Project Summary Template</b><br>Save as "ProjectSummary_PILastName.pdf" and upload                                     | 2 pages                |
| <input type="checkbox"/> | <b>Letters of Support</b><br>Save as "Letters_PILastName.pdf" and upload as a single file                                 | As needed              |
|                          | <ul style="list-style-type: none"> <li>• Letters of Support Table</li> </ul>  |                        |
|                          | <ul style="list-style-type: none"> <li>• Letters of Support</li> </ul>  |                        |
| <input type="checkbox"/> | <b>Resubmission Letter</b> (if appropriate)<br>Save file as "Resubmission_PILastName.pdf" and upload                      | 2 pages                |
| <input type="checkbox"/> | <b>Greater Than Budget/Time Request</b> (if appropriate) <sup>14</sup><br>Save as "GreaterThan_PILastName.pdf" and upload | 3 pages                |

<sup>14</sup> Only complete this template if you indicated your intention to request additional funds or time when you submitted your LOI and you received confirmation that PCORI is willing to consider granting this request.

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

Upon receipt of the LOIs, a minimum of two PCORI program staff will administratively screen and review them for nonresponsiveness. Only applicants whose LOIs are deemed most responsive to this PFA will be invited to submit a full application. Nonresponsive LOIs and those not adhering to administrative guidelines will not be invited to submit a full application. Nonresponsive LOIs may be administratively withdrawn if the project:

- Primarily conducts new research, as opposed to disseminating and implementing research findings obtained from already completed PCORI-funded studies and evaluating the success of those D&I efforts. Projects proposing to perform CER are **not of interest** under this funding announcement, and will cause a LOI or application to be considered nonresponsive.
- Proposes to disseminate and/or implement findings that are not associated with a PCORI-funded comparative clinical effectiveness research or methods study.
- Proposes to translate and/or adapt a research finding without actively disseminating or implementing it.
- Proposes a passive dissemination plan (publications or presentations to heterogeneous audiences) as its primary dissemination method.
- Proposes to develop or validate a new tool or system for patients or clinicians without the primary purpose of actively disseminating or implementing evidence. Modification or adaptation of tools and systems previously found to be effective and proposed as the primary mechanism for actively disseminating and implementing evidence will be considered, as long as their development is not the primary activity proposed.
- Proposes to use contract funds to pay for the cost of the interventions being disseminated in the project. Note: In general, PCORI does not pay for the cost of the interventions being disseminated in the projects it funds. Intervention costs include, but are not limited to, salary and time compensation for personnel that are delivering the intervention as well as equipment and other material costs associated with the delivery of the intervention. These are considered direct patient care costs and PCORI expects these costs to be covered by the healthcare delivery system or other interested payers. PCORI encourages all applicants to find support from sites, payers, stakeholders, etc. in the payment or cost-sharing of the interventions. Only under special circumstances will PCORI consider, as an exception, coverage of patient care intervention costs. If you are requesting the use of PCORI funds for any portion of these costs, your application must include a detailed justification, in the “Budget Justification Template,” outlining the clear importance of the request to the overall success of the project as well as future sustainability and implementation plans for once the project has completed (i.e. how will these costs be covered in the future, post PCORI funding, for implementation of the interventions in not only the sites participating in the study but



also in other communities and health care settings). Providing a justification, however, will not guarantee that the costs will be approved.

## 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

- If electing to submit an application with two PIs, one PI must be designated as the Contact PI. The Contact PI is responsible for submitting the application and will serve as PCORI’s primary point of contact for all communication. **No more than two PIs can be named on an application.**



- The PI(s) is responsible for the project’s engagement, scientific, and/or technical aspects.
- 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 dual-PI, co-investigator, or consultant. Refer to the [Who Can Apply](#) section for specific instructions.

#### B. Activities

- The PI(s) assume(s) responsibility and accountability for research execution, compliance, and organization conduct.
- The Contact PI is responsible for submitting the application, submitting all progress reports, and serving as PCORI’s programmatic and administrative contact. All PCORI communication will be sent to the Contact PI, and it is his or her responsibility to share PCORI communications with PI #2.
- The PI(s) manage(s) day-to-day operations of the project.
- The PI(s) act(s) as the organization’s lead research representative.



**Note: A Letter of Support is required from the PI of the original PCORI-funded research project if he or she is not the proposed PI of the current application.**

### 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 as key personnel 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 the [Glossary](#) for "Consultant" and "Subcontractor" definitions.
- Project Directors, or equivalent, are considered key personnel.
- Applicants are required to identify the patient and stakeholder partners, whether individuals or organizations, that will assist in conducting the project. They may be recognized in PCORI communications, such as press releases, or mentioned in response to requests for information. By providing the names of the partnering individuals and organizations, you acknowledge that you have obtained any required permission or consent from the respective



partners to disclose their names to PCORI and to permit PCORI to make their names publicly available. If a patient or stakeholder partner wishes to remain anonymous, contact us at [pfa@pcori.org](mailto:pfa@pcori.org) for additional guidance on how to recognize such partners appropriately.

- Post-merit review, PCORI may request current, pending, and other support documentation from all key personnel. This material must be submitted prior to award.
- If awarded, the addition or replacement of key personnel listed in the submitted application requires PCORI’s approval during contract negotiation and post-contract execution.

### PFA-Specific LOI Template

Download and complete the PFA-specific LOI Template from the [PCORI Funding Opportunities](#). Do not include supplemental materials (e.g., supporting journal articles and Letters of Support) or additional information not requested in the template (e.g., responses to reviewer comments or resubmission letters). Statements in gray italics denote how the template questions must be addressed. Replace the gray italics and any instructional text with your response, but retain the bold headings and question numbers. **Note that any additional template modifications will result in disqualification of your LOI.**

The LOI Template is for screening purposes only. Focus on including only critical information because space is limited. Provide a description that allows the program staff to understand the project, including the aims and project design, without reviewing the full application. References will not be included within the three-page limit. PCORI suggests including all references as in-text citations using AMA citation style, but other citation styles are accepted. (**Note:** All LOI Templates must follow the formatting guidelines provided in [Step 4](#).)

Be sure to delete the template cover page before submitting an LOI. To submit an LOI, save the completed PFA-specific LOI template as a PDF. Label your LOI file using the following nomenclature: “PI LastName\_ (last five digits of LOI number)\_LOI.pdf.” An LOI number will be generated automatically and visible at the top of the web page in [PCORI Online](#) once the LOI has been saved. 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. You cannot edit after submitting.

### Application Requirements



**The following sections are applicable only if you have been invited to submit a full D&I application. This is contingent upon your submitting your LOI and your Draft Final Research Report (DFRR). Applicants will be notified of this decision via email by August 22, 2017.**

Applications submitted prior to PCORI’s receipt of the DFRR, or for which the DFRR is judged to be incomplete or otherwise inadequate by PCORI, will be administratively withdrawn. Applicants are encouraged to submit their DFRR 1-2 months before the application deadline for this PFA, so that PCORI can perform a preliminary review to determine whether the DFRR is acceptable for submission



to Peer Review. PCORI will provide comments within two weeks of receiving the DFRR to provide the PI an opportunity to address these comments before the PFA's application deadline.

## PI and Contact Information

Review 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 D&I strategy. The abstract must include the sections listed below. PCORI may use these responses to perform programmatic assessment, to assign applications to the appropriate review panel, and to provide a high-level overview to merit review panel members.

- **Background and Significance:** Clearly identify and describe the research finding you aim to disseminate, including the statistical and clinical significance/meaningfulness of the results and their generalizability. Be sure to state how D&I of the research finding will improve health care and outcomes. Describe the evidence gap the original results filled and the importance of the research finding and/or product in the context of the existing body of evidence in the topic area.
- **Project Aims:** Clearly identify the primary objective of your D&I effort. What are the specific aims you will accomplish to meet your overall objective?
- **Project Description:** Provide a detailed description of the proposed D&I approach. Include, as applicable:
  - A brief description of the proposed approach for disseminating the research findings
  - A brief description of the D&I settings and end-users, including how they will be selected and their representativeness
  - A brief description of the measurable process and short-, intermediate-, and longer-term outcomes you will use to capture timely information on the effectiveness of the proposed D&I activities, including impact on the end-user
  - A brief description of the Patient and Stakeholder Engagement Plan

## Milestones

Complete all required sections in the Milestones Tab in PCORI Online. Milestones are concrete, specific events or accomplishments that are documented by deliverables. They include only the activities that the PCORI contract supports.

Interim and final deliverables will be included in your project contract if your application is funded.





Note that PCORI reserves the right to request additional deliverables during the life of the project.

Examples of deliverables that may be required following contract execution include but are not limited to:

- Copies of Institutional Review Board approval (if applicable)
- Abstracts accepted or presentations made
- Meeting minutes from patient/stakeholder advisory panels, committees, or work groups
- Copies of drafts of instruments, data dictionaries, educational materials, manuals, or other project deliverables
- Copies of newsletters highlighting the project from patient/stakeholder partner organizations
- Reports of endorsement of project findings by scientific and consumer groups
- Reports of plans to adopt project findings in practice
- Charts, tables, graphs, or other summaries of preliminary data
- Other documents or materials, as appropriate



**Note: Milestones entered into PCORI Online must include specific deliverables associated with a time line and must include project objectives that will be accomplished at specific times during the proposed project. List at least two deliverables that will be submitted to PCORI during each 12-month period of the project.**

### Resubmission Policy

After submitting their PCORI DFRR, applicants will be eligible to submit an application in response to this PFA for two years. During this period of eligibility, applicants will be allowed **one opportunity** to resubmit an application that completed the merit review process (i.e., the applicant received a summary statement) and was not funded in a previous cycle. Applicants may not resubmit an application for a previously submitted and reviewed application until they have received merit review feedback (summary statement) from the initial submission. All resubmitted applications require submission of a new LOI that must be administratively and programmatically responsive to the PFA. Resubmitted applications must include a Resubmission Letter. Applications that do not meet these requirements will be deemed nonresponsive and withdrawn from merit review. LOIs that are not invited to submit a full application by PCORI do not count as a submission or resubmission.



**Note: To ensure that new LOIs and resubmitted applications are administratively and programmatically responsive, applicants must carefully read and meet all requirements described in the PFA to which they are applying for funding,**

### Project Plan Template

Complete all required sections in the [Project Plan Template](#) and upload as a single PDF to PCORI Online. The Project Plan includes the following: Project Strategy, Protection of Human Subjects (if



needed), Consortium Contractual Arrangements, References Cited, and an Appendix (optional).

### **Project Strategy**

In this component of the Project Plan (up to 10 pages), applicants must describe their project strategy and plan in detail and demonstrate how the proposed project responds to this limited PFA. This component addresses the following sections: (A) Background, (B) Significance, (C) Approach and Evaluation, (D) Engagement Plan, and (E) Dissemination Team and Environment.

### **Engagement Plan**

Outline how stakeholders central to the proposed project are engaged with planning and execution of the project, as well as how patients or their representatives have been engaged to inform the D&I strategy or other relevant aspects of the project. This plan must reflect the PCORI engagement principles of reciprocal relationships, co-learning, partnerships, transparency, honesty, and trust. Clearly identify individuals, organizations, and informal networks you will partner with to disseminate the research findings or products to the end-users. Note their importance to reaching particular end-users. Clearly describe the willingness and readiness of relevant patient and stakeholder groups and leaders of healthcare settings in which D&I will occur to use and embrace this research finding in the context of their groups and organizations.

### **Dissemination Team and Environment**

While completing the Dissemination Team and Environment (Section E) component, applicants must:

- Describe the multidisciplinary team, including appropriate stakeholders and experts to help shape messages to target audiences, provide context for the evidence for adopters, and assess the effects of D&I activities
- Describe the D&I team's capability to accomplish the goals of the proposed D&I project and the appropriateness of the organizational structure and described resources
- Provide all key personnel professional and partner profiles/biosketches and detailed site descriptions within the People and Places Template as a separate PDF upload
- Describe the facilities and resources (e.g., collaborative or partnering arrangements) that will be used to carry out the proposed project
- Demonstrate that there is sufficient institutional support for the proposed project to be successful

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

In this component (up to five pages), describe the protection of human subjects involved in your project. PCORI follows the Federal Policy for the Protection of Human Subjects ([45 CFR part 46](#)), including the Common Rule. For more detailed information, see Section 5, titled "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

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



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 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, subcontract personnel must be included under key personnel.
- Budget information for subcontracted organizations must be included in the Detailed Budget, Budget Summary for Entire Project, and Budget Justification.

### References Cited

This component (up to 10 pages) is included in the Project Plan Template. Throughout the Project Plan, applicants should use in-text citations to reference published materials. In this section, list the full bibliographical citation of each reference. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article title, journal or book title, volume number, page numbers, and year of publication. Include only bibliographic citations. PCORI suggests following AMA style when providing citations for source materials relied on in preparing any section of the application, but other citation styles are accepted. Citations that are publicly available in a free, online format may include URLs or PubMed ID numbers along with the full reference.

*References must be limited to relevant and current literature.* Be concise and select only those literature references pertinent to the proposed project, so that the 10-page limit is not exceeded. Websites must be referenced in the standard URL format (i.e., <http://www.pcori.org>) with the date on which the link was last accessed.

### Appendix (Optional)

This component (up to five pages) is included in the Project 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.*



## Project Summary Template

Complete all required questions in the [Project Summary Template](#) and upload as a PDF to PCORI Online. The Project Summary should be written in non-technical language that the general public will understand. This summary will be provided to reviewers during the merit review process. Project summaries from applications that are awarded a contract will be posted on PCORI's website. The names of the individuals and organizations that comprise the project team will also be posted on PCORI's website, as described in the Key Personnel section above. Your project summary should not exceed two pages.

## People and Places Template

### Professional Profile/Biosketch and Patient/Stakeholder Partner Biosketch

These components are included in the [People and Places Template](#). Complete a profile/biosketch section (up to five pages per individual) for each person listed as key personnel (including PI, co-PI, dual-PI, co-investigator, consultant, or other significant contributors), copying the tables provided in this section as needed. 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. 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 patient-centered outcomes research (PCOR) have prepared him or her to conduct this project. The backgrounds, relevant experiences, and roles of patient and stakeholder partners must also be described.

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

### Project Performance Site(s) and Resources

This component (up to 15 pages) is included in the [People and Places Template](#). Demonstrate in detail that the proposed facilities have the appropriate resources required to conduct the project as planned, within budget, and on time.

Applicants 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.

### Leadership Plan (required if proposing a dual-PI application)

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



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

Applicants must include a [Leadership Plan](#) (up to five pages) as the first page of the People and Places Template. The Leadership Plan must (1) describe the governance and organizational structure of the leadership team and the 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. PCORI will not review the same application by another institution or another PI.

## Budget

Complete all required sections in PCORI Online and upload the [Budget Justification](#) to PCORI Online as a single PDF. Do not upload separate budget files for subcontractors; include all subcontractor budget files within the prime applicant's budget information.

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

For each program year, complete a Detailed Budget for the prime applicant and each subcontracted organization proposed in your application. For example, if your study lasts two years, the prime applicant must complete a Detailed Budget for Year One and for Year Two. The subcontractor must follow the same process and complete a Detailed Budget for each year of the proposed study.

All personnel information must be entered in the Project Personnel tab corresponding to that year in the Budget tab. The applicant may add additional rows for personnel as needed. Following the example of a one-year project, applicants may delete the unused Year Two Detailed Budget tabs. However, applicants are not permitted to add additional years. Maximum project periods are stated in each PFA. Note the following:

#### A. Personnel Costs

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

- **Level of Effort:** Personnel contributing to a PCORI-funded research project are expected to monitor their total percent effort across all of their active funding so that it does not exceed 100 percent. Before submitting the application to PCORI, the AO must certify that individual personnel will not exceed 100 percent effort, if funded. Effort must be reported by the percentage of time over the course of the project year. If salary support is not being requested, use \$0 for the base salary.
- All personnel dedicating 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 Detailed Budget. Describe the individual's specific functions in the Budget Justification. Provide an explanation of the way in which the role supports the project aims and note any overlap in job functions.
- **Salary Cap:** The PCORI base salary cap for personnel is \$200,000 annualized per individual, per year, exclusive of fringe benefits. An individual who earns less than \$200,000 must use his or her actual base salary to calculate personnel costs. An individual with a full-time employee base salary of more than \$200,000 must use \$200,000 as the base salary rate in determining the amount of salary and time to charge to the project.
- **Fringe Benefits:** These costs are calculated based on the institution's own policy. In the budget upload, following the Budget Justification, applicants must provide a verification of the fringe benefit rate policy for the prime organization.

## **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 consultant(s), as well as name(s), expected number of hours, and hourly rate.
- Include the daily consultant fee, travel expenses, nature of the consulting effort and reason(s) 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 the way in which the negotiated rate was established. See the Letters of Support section for more detailed information.

## **C. Supply Costs**



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



**Note:** PCORI considers computers, tablets, docking stations, mobile data and protection plans, 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 project, the following must be provided in the Budget Justification:

- Detailed explanation of why purchasing these items is necessary to complete the proposed project
- Statement verifying that the requested items are not currently available for the PI's use
- Statement assuring that the items will be purchased in accordance with applicable cost principles

Items purchased under PCORI-funded projects are not to be used as incentives to recruit or retain graduate students or any other project personnel.

#### **D. Travel Costs**

- Travel may include any domestic or international travel by project personnel or consultants directly related to, and necessary for, the project and within the limits explained below. PCORI uses the Federal Travel Regulations guidelines for per diem and other reimbursements.
- Travel costs must be itemized per trip as outlined below:
  - Travel includes travel needed to conduct the project. PCORI closely reviews all travel costs for reasonableness.
  - Airline or rail costs cannot exceed the customary standard commercial fare (coach or equivalent) or the lowest commercial discount fare. PCORI will not compensate upgrades.
- Include the number of trips and a brief description of the trips, including the number of people traveling and dates or duration of the stay.



- In the Budget Justification, applicants must provide additional detail to explain the basis for the costs listed and must describe how the travel is directly related to the proposed project and necessary for achieving programmatic objectives.

#### **E. Other Expenses**

- Indicate and include general categories, such as printing, publication, illustration costs, and nonconsulting service contracts, when applicable.
- Use this section to include direct costs that cannot be accounted for in other budget categories. For example, these costs may include warranties, computer services, data warehousing, or participation incentives.
- In the space provided, include a detailed explanation for all costs that exceed \$1,000. Applicants must provide further detail for each of these costs in the Budget Justification.

#### **F. Equipment Costs**

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



**Note:** Title to equipment vests with the recipient organization. PCORI, at its discretion, may require applicants to share or transfer equipment to other PCORI-funded projects within the recipient organization. Equipment disposition must be approved by PCORI.

#### **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 who do not have a federally negotiated or independently audited indirect cost rate may assess up to 10 percent indirect costs, to be noted in the Budget Justification.
- Foreign applicants are eligible for no more than 10 percent indirect costs.
- A copy of the prime applicant's federally negotiated or independently audited indirect cost rate letter must be submitted with the application. Include these copies in a single file with the Budget Justification.
- In the event that an indirect cost rate agreement is more restrictive than that of PCORI's accepted indirect cost application, PCORI will allow the applicant to use the less restrictive rule when calculating indirect costs on submitted budget categories.

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

Complete a Budget Summary for the entire project for the prime applicant and each subcontracted organization. See [Appendix 1: Allowable and Unallowable Costs](#) to review acceptable and unacceptable uses of PCORI funding.

### **Budget Justification**

Complete a [Budget Justification](#) for the prime applicant and each subcontracted organization for the entire Project Budget for all research. Provide sufficient detail to explain the basis for costs, the reason that 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 stakeholder partners and any other engagement costs, such as travel, meeting costs, training, and other costs associated with convening patients and stakeholders. Note that some projects employ or assign an individual responsible for coordinating or managing all project-related patient and stakeholder engagement. This person must be listed as a Full-Time Equivalent under personnel, consultant, or subcontractor costs.

Provide detail to explain the basis for travel costs, and describe how the travel is directly related to the proposed project and necessary for achieving programmatic objectives.

Describe the specific role and tasks each research team member will perform and the impact on the Project Plan. PCORI will evaluate each member's contribution as listed in the Budget Justification to validate meaningful contribution and to assess whether there is overlap in responsibilities. Provide a clear distinction between individuals who should be key personnel and those who should be 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.



**A Letter of Support is required from the PI of the original PCORI-funded research project if he or she is not the proposed PI of the current application.**

Save all Letters of Support as a single PDF file and upload to PCORI Online, using the [Letters of Support Table](#) as the first page of the file. Follow the guidance below and in the table template to enable easy reference for 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-PIs, 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:

- **Letter of Original PI Support (if applicable):** A Letter of Support is required from the PI of the original PCORI-funded research project if he or she is not the proposed PI of the current application. Letters from the original PCORI-funded PI must describe his or her support for the proposed approach and team for disseminating research findings and products.
- **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organizational official, which confirms the institutional support of the proposed project, space to conduct the project, equipment, and other resources available for the project, including staff. PCORI also strongly encourages you to provide a letter from 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 their interest and rationale for involvement in the D&I effort, as well as their role and specific project responsibilities. Also strongly encouraged are letters from patient or stakeholder partners or partnering organizations affirming support to disseminate and implement the designated PCORI-funded research results and products. Include a Letter of Support for each consultant verifying the work to be performed and their negotiated rate.



- **Letters Confirming Access to Patient Populations, Data Sets, or Additional Resources (if applicable):** If the proposed plan involves access to patient populations, data sets, or additional resources, include a Letter of Support, signed by the person with approval authority, confirming such access. If access cannot be confirmed at the time of contract negotiation, PCORI reserves the right to withhold funding until the PI has demonstrated support for and access to the relevant population(s) and/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.

## VI. Additional Requirements

Awardees are required to comply with the following requirements:

### Required Education of Key Personnel on the Protection of Human Subject Participants

PCORI requires all applicants to adhere to the NIH policy on education in the protection of human subject participants in the conduct of research. This applies to all individuals listed as key personnel in the application. The policy and FAQs are available on the [NIH website](#).<sup>16</sup>

### PCORI Public Access Policy

PCORI requires all awardees to adhere strictly to PCORI's publication policies, which will be shared with awardees within the project contract.

### Standards for Privacy of Individually Identifiable Health Information

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

Decisions about the applicability and implementation of the Privacy Rule reside with the researcher and his or her institution. The [Office for Civil Rights](#)<sup>17</sup> provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts is available at [NIH](#).<sup>18</sup>

### Award Funding Conditions

At any time during the contract, PCORI reserves the right to discontinue funding for awardees who

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<sup>16</sup> Available at <http://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

<sup>17</sup> Available at <http://www.hhs.gov/ocr/>.

<sup>18</sup> Available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.



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.

### Co-Funding

PCORI partners with various other research organizations to leverage additional funds for some of its programs. If you currently have a funded project and would like to seek PCORI funding to add a new aim to the study that advances PCORI funding objectives, you may submit an application. We recommend that you speak with a Program Officer in advance.

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

### Collaborations

Collaborative D&I projects may take different forms. At minimum, a collaborative project must involve the partnership of two or more PCORI-funded investigators partnering to disseminate the collective results of two or more PCORI-funded research studies which address a single or closely related condition, population, decision dilemma, or evidence gap. PCORI welcomes collaborative applications and encourages use of the Greater Than Budget/Time Request mechanism (see "Funds Available" in the PFA) to request funds and/or time greater than the limit specified in this announcement that are appropriate and commensurate to the scope of the proposed project. Collaborative projects must have demonstrated support from the PI of each PCORI study whose findings are being disseminated in the collaborative D&I project. Please note that participation in a collaborative project does not preclude individual investigators from submitting a separate, individual D&I application through this mechanism. However, investigators will be expected to provide a strong justification that their individual D&I projects are not duplicative of activities proposed in the collaborative D&I project.

### Dissemination and Data Sharing

PCORI is committed to publishing and disseminating all information and materials developed using PCORI funding, in accordance with its authorizing legislation. All recipients of PCORI contracts must agree to these principles and take steps to facilitate data availability.



## Appendix 1: Allowable and Unallowable Costs

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

- Salaries and fringe benefits for study investigators and other research project staff (including engaged patient and stakeholder research study partners) related to their percentages 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 project
- Supplies
- Equipment
- Subcontracts
- Expenses related to conducting engagement activities with patients and other stakeholders
- Other direct 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, please 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  |  VISAS               |  TUITION                      |  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 who fail to submit required documents or adhere to administrative requirements may be rejected from the merit review process. The chart below explains the reasons for rejection, modification, and appended requests.

| Automatic Rejection   | Modification by PCORI  | Appended upon PCORI's Request*  |
|---|--|---|
| <p>An application or LOI will be automatically rejected if it:</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 (unless accompanied by a Greater Than Budget request)</li> <li>• Has adjusted margins or font size (LOI)</li> <li>• Does not include or has an incomplete Project Strategy</li> <li>• Does not have a PCORI draft final research report submitted for the original PCORI research award (Application)</li> <li>• Proposes passive dissemination as its primary dissemination method</li> </ul> | <p>PCORI will modify an application by removing all pages that exceed stated limits for the following components:</p> <ul style="list-style-type: none"> <li>• LOI</li> <li>• Resubmission Letter</li> <li>• Project Strategy</li> <li>• Protection of Human Subjects</li> </ul> | <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.