Cycle 1 2019 Funding Cycle

PCORI Funding Announcement: Implementation of Findings from PCORI’s Major Research Investments

Application Guidelines

Published January 3, 2019
Updated February 1, 2019

These guidelines apply to the Cycle 1 2019 Funding Cycle for the Implementation of Findings from PCORI’s Major Research Investments PCORI Funding Announcement (PFA). Funding announcements, templates, and other resources are available at https://www.pcori.org/funding-opportunities/announcement/implementation-findings-pcoris-major-research-investments-cycle-1. The Cycle 1 2019 Funding Cycle closes April 4, 2019, at 5 pm (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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*Updated on February 1, 2019 to correct that the Subcontractor Detailed Budgets should be combined into one PFD file and uploaded into PCORI Online.
I. About These Guidelines

This document provides key information to help researchers prepare for and respond to the Implementation of Findings from PCORI’s Major Research Investments Patient-Centered Outcomes Research Institute (PCORI) Funding Announcement (PFA), available at https://www.pcori.org/funding-opportunities/announcement/implementation-findings-pcoris-major-research-investments-cycle-1.

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

- See PCORI’s Applicant FAQs for common questions about PCORI and the application process.
- See the Implementation of Findings from PCORI’s Major Research Investments FAQs for specific questions about this funding opportunity.
- Visit PCORI’s Help Center for additional applicant resources.
- For Programmatic Inquiries: Contact the PCORI Helpdesk via email (disseminationquestions@pcori.org). PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed two business days before a Letter of Intent (LOI) or application deadline.
- For Administrative, Financial, or Technical Inquiries: Contact the PCORI Helpdesk at pfa@pcori.org. PCORI will respond 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 at 202-627-1885.

It is the applicant’s responsibility to submit the application on or before the deadline. Refer to PCORI’s Policy on Submission of Research Contract Applications.

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 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. Email 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 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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1 Available at https://help.pcori.org/hc/en-us/categories/200010230-Applicant-Resources
2 Available at http://help.pcori.org/hc/en-us/
3 Available at http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/.
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 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. 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. ⁴ 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. Evidence Eligible as the Focus of Implementation and Who Can Apply

*Eligible Evidence:* Applicants must propose implementation projects that focus on topics PCORI identifies in this PFA, which are drawn from published, peer-reviewed evidence emerging from selected areas of major PCORI investment in comparative clinical effectiveness research.

For the Cycle 1 2019 PFA, PCORI has identified two areas of eligible evidence, each of which is the focus of an important PCORI-funded study.

1. Use of narrow-spectrum versus broad-spectrum antibiotics to treat children’s acute respiratory tract infections.
2. Informed use of self-monitoring of blood glucose for non-insulin requiring patients with type 2 diabetes.

*Eligible Organizations:* 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 US applicant organizations. Nondomestic components of organizations based in the United States and foreign organizations may apply, as long as the project shows demonstrable benefit to the US healthcare system and US efforts in the area of patient-centered research. Organizations may submit multiple funding applications. Individuals are not permitted to apply. For questions about eligibility, contact disseminationquestions@pcori.org.

*Eligible Applicants:* This is an Open Competition funding opportunity that seeks to draw on the expertise, creativity, and capacity of a broad applicant pool, including implementation experts and diverse stakeholder partners. As such, PCORI does not require applicants to have been associated with the PCORI-funded studies described above, nor need they have received any previous PCORI funding.

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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. You must submit all documents through PCORI Online. Be sure that you are applying to the PFA titled “Implementation of Findings from PCORI’s Major Research Investments.” Refer to the specific PFA for more information about the review process for 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 and an EIN, if applicable.

Step 1: Register

To apply for PCORI funding, an applicant (PI or PI designee) must register in PCORI Online. 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 Dissemination & Implementation 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 page. For formatting instructions, reference Step 4.

To submit an LOI, 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.

Step 3: Initiate Application Process

PCORI will notify applicants by the date specified in 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.

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5 Available at https://pcori.force.com/engagement.
6 Available at https://www.test.grants.gov/applicants/organization-registration/step-1-obtain-duns-number.html
7 Available at https://www.irs.gov/businesses/small-businesses-self-employed/apply-for-an-employer-identification-number-ein-online
8 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 on the [PCORI Funding Opportunities page](http://www.pcori.org/funding-opportunities/). 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.

You must format all required documents as follows:

- **Header**: Include the PI’s full name in the top-left corner of every page and the original PCORI Contract Number.
- **Font**: Use Calibri size 11 font. 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**: 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.
- **References**: PCORI suggests including all references as in-text citations using American Medical Association (AMA) citation style, but other citation styles are acceptable.

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 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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9 Available at [http://www.pcori.org/funding-opportunities/](http://www.pcori.org/funding-opportunities/).
10 See 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 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 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, 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 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 February 14, 2019, regarding whether PCORI has invited you 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 web page.

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11 Available at http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/.
12 Available at http://www.pcori.org/funding-opportunities/.
## Application Checklist

<table>
<thead>
<tr>
<th>Letter of Intent</th>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Letter of Intent (LOI)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Contact Information</td>
<td>Enter into PCORI Online</td>
<td>N/A</td>
</tr>
<tr>
<td>• Pre-Screen Questionnaire</td>
<td>Enter into PCORI Online</td>
<td>N/A</td>
</tr>
<tr>
<td>• PI Information</td>
<td>Enter into PCORI Online</td>
<td>N/A</td>
</tr>
<tr>
<td>• Project Information</td>
<td>Enter into PCORI Online</td>
<td>N/A</td>
</tr>
<tr>
<td>• Project Personnel</td>
<td>Enter into PCORI Online</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Templates &amp; Uploads: LOI Template</th>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Save file as “PI LastName_(five-digit LOI number)_LOI.pdf” and upload</td>
<td>3 pages</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Application</th>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Project Information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Project Summary</td>
<td>Enter into PCORI Online</td>
<td>As needed</td>
</tr>
</tbody>
</table>

| **Budget** | | |
| Enter into PCORI Online | As needed |
| • Detailed Budget for Each Project Year (prime) | | |
| • Budget Summary for Entire Project (prime and subcontractors) | | |

| **Milestones Template** | | |
| Save file as “Milestones_PI LastName.xls” and upload | As needed |

| **People and Places Template** | | |
| Save file as “PeoplePlaces_PI LastName.pdf” and upload | As noted below |
| • Leadership Plan (required if proposing dual-PI application) | 5 pages |
| • Professional Profile/Biosketch | 5 pages per individual |
| • Patient/Stakeholder Partner Profile/Biosketch | 5 pages per individual |
| • Project/Performance Site(s) and Resources | 15 pages |

| **Project Plan Template** | | |
| Save file as “ProjectPlan_PI LastName.pdf” and upload as a single file | As noted below |

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13 Please copy and paste the text from the body of your Project Summary (see Project Summary Template).
- Project Strategy 10 pages
- Protection of Human Subjects (if applicable) 5 pages
- Consortium Contractual Arrangements 5 pages
- References Cited 10 pages
- Appendix (optional) 10 pages

<table>
<thead>
<tr>
<th>Section</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Summary Template</td>
<td>2 pages</td>
</tr>
<tr>
<td>Subcontractor Detailed Budget (for each project year) Template</td>
<td>As needed</td>
</tr>
<tr>
<td>Budget Justification</td>
<td>As needed</td>
</tr>
<tr>
<td>- Budget Justification Template (prime and subcontractors)</td>
<td></td>
</tr>
<tr>
<td>- Federally Negotiated or Independently Audited Indirect Cost Rate Letter (prime)</td>
<td></td>
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<tr>
<td>- Fringe Benefit Rate Policy Verification Document (prime)</td>
<td></td>
</tr>
<tr>
<td>Letters of Support</td>
<td>As needed</td>
</tr>
<tr>
<td>- Letters of Support Table</td>
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<tr>
<td>- Letters of Support</td>
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</tbody>
</table>

*Updated on February 1, 2019 to correct that the Subcontractor Detailed Budgets should be combined into one PFD file and uploaded into PCORI Online.*
**Letter of Intent**

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

Upon receipt of the LOIs, a minimum of two PCORI program staff will administratively screen and review the documents for non-responsiveness. 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 proposes to do any of the following:

- Conduct new research, as opposed to implementing eligible evidence (see Evidence Eligible as the Focus of Implementation section) and evaluating the success of those implementation efforts. Projects proposing to perform CER are **not of interest** under this PFA and will cause an LOI or application to be considered nonresponsive.
- Translate or adapt an intervention or evidence without actively implementing it.
- Develop or validate a new tool for patients or clinicians without the primary purpose of actively implementing eligible evidence. PCORI will consider modification or adaptation of tools and systems previously found to be effective and proposed as the primary mechanism for actively implementing evidence, as long as the modification/adaptation is not the primary activity proposed in the implementation project.
- Conduct activities **primarily** aimed at spreading knowledge and awareness of eligible evidence. These activities fall under PCORI’s definition of “dissemination,” rather than “implementation.”
  - Please see the PCORI Engagement Award: Dissemination Initiative funding opportunity, which focuses on giving organizations and communities the opportunity to propose meaningful dissemination projects aimed at spreading awareness and increasing knowledge of new evidence.
- Use contract funds to pay for the cost of the interventions being implemented in the project. In general, PCORI does not pay for the cost of the interventions being implemented in the projects it funds. Intervention costs include, but are not limited to, salary and time compensation for personnel who are delivering the intervention, as well as equipment and other material costs associated with delivering 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, and so on, 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, this should be clearly described in your LOI. Invited applications must include a detailed justification (in the Budget Justification Template) outlining the importance of the request to the project’s overall success and to the sustainability and implementation once the project is completed (i.e., how these costs will be covered in the future, post-PCORI funding, for implementing the interventions not only at the
sites participating in the study but also in other communities and healthcare settings). Such a justification, however, will not guarantee that PCORI will approve the costs.

**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, 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.**
- The PI 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 (or PIs) assumes responsibility and accountability for project 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 project 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
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, 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 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 pfa@pcori.org for additional guidance on how to recognize such partners appropriately.
• 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 funding is 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 page. Do not include supplemental materials (e.g., supporting journal articles, Letters of Support) or additional information not requested in the template. Statements in gray italics denote how to address the template questions. 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 the disqualification of your LOI.**

PCORI invites only applicants whose LOIs are most responsive to this PFA to submit a full application. 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 (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.

Application Requirements

The following sections are applicable only if PCORI has invited you to submit a full application. PCORI will notify applicants of this decision via email by February 14, 2019.

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
- Implementation approach
- Specific aims

If you need to change any of this information or have any questions, email 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.
**Project Summary**

Please copy and paste the text from the body of your Project Summary (see Project Summary Template). As a reminder, you must also upload your Project Summary as a PDF to the Templates & Uploads section in PCORI Online.

**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. Based on the “Milestone - Deliverable Name” (Column B) and the “Description” (Column C), applicants must provide the “Due Date” (Column D). Consider the guidance information in Column E as you determine the “Due Date.”

Milestones are concrete, specific, documented activities or accomplishments as well as deliverables due throughout the project. Milestones should be associated with the proposed project timeline and reflect all essential/important activities that you will undertake to accomplish your specific project goals.

Examples of milestones include, but are not limited to, the following:

- Copies of Institutional Review Board approval (if applicable)
- Conference/journal abstracts accepted and public presentations made
- Engagement activities, such as stakeholder/advisory meetings, workshops, and so on
- Data collection (including from focus groups/interviews, surveys, and the Electronic Health Record [EHR])
- Evaluation and data analysis activities (e.g., charts, tables, graphs, or other summaries or preliminary data)
- Training activities (e.g., for staff delivering the intervention)
- Activities related to the adaptation of the evidence that if the focus of the implementation project
- Documentation of new or revised processes, protocols, or policies that will lead to changes in practice by those delivering the intervention (e.g., updated clinical procedures/workflows)
- Site visits
- Copies of educational materials, resources, training manuals, or other materials developed in support of your implementation project
- Copies of newsletters that highlight the project from patient/stakeholder partner organizations
- Reports of project endorsement by scientific, consumer, and other stakeholder groups
- Reports of plans to adopt and/or sustain the intervention in practice after the successful completion of this project
• Other documents or materials, as appropriate

If PCORI funds your application, additional interim and final deliverables may be added to your contract during the contract execution process. Note also that PCORI reserves the right to request additional deliverables during the life of the project, and must approve all changes to milestones requested by awardees.

**Note:** Milestones must be associated with a timeline and include project objectives that will be accomplished at specific times during the proposed project.

### 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 the 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 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.

**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 applicable), 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 – Eligible Evidence Proposed for Implementation, (B) Implementation Project Overview, (C) Implementation Project Description, (D) Evaluation, (E) Engagement Plan, and (F) Project Personnel and Environment.

**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, “Human Subjects Research Policy,” from the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, issued by the US Department of Health and Human Services (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:

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• 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, the 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 in any section of the application, but other citation styles are acceptable. Citations that are publicly available in a free, online format may include URLs or PubMed ID numbers along with the full reference. Limit references to relevant and current literature. Be concise and select only those literature references pertinent to the proposed project, so that the 10-page limit is not exceeded. 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 ten 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 nontechnical language that the general public will understand. PCORI will provide this summary to reviewers during the merit review process. PCORI will post on its website Project Summaries from applications that are awarded a contract. The names of the individuals and organizations that compose 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. Note that you will also be required to copy and paste the text from your Project Summary Template into the Project Summary field on the Project Information tab in PCORI Online.
Budget

Complete all required sections in PCORI Online and upload the Subcontractor Detailed Budget Template and Budget Justification Template for each subcontractor to PCORI Online as a single PDF. Do not upload separate budget files for subcontractors; instead, 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 entered in PCORI Online for the prime applicant. 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.

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 one-year project, applicants may delete the unused Year Two Detailed Budget tabs. However, applicants may not 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 who are or are not accounted for in Section B: Consultant Costs. Provide a clear distinction between individuals who are considered key personnel and those considered “other” personnel.

- PCORI will reimburse personnel costs that are consistent with and do not exceed what the applicant would normally pay under its own policy. PCORI may request salary verification during the contract activation process. Such compensation may include salaries and fringe benefits. See Appendix 1: Allowable and Unallowable Costs for more information.

- Salaries include wages earned by an employee, and fringe benefits may include insurance and retirement plans. Provide documentation to support the fringe benefits with the Budget Justification.

- **Level of Effort**: Personnel who contribute to a PCORI-funded research project are expected to 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. 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 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 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, 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.

- **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 the 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 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 cost. Provide detailed explanations in the Budget Justification for all costs that exceed $1,000.

- 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 you propose these items as essential for performing the project, you must provide the following 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 you will purchase the items 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 the trips, 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, 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**

- Indicate and include general categories, such as printing, publication, and illustration costs and non-consulting service contracts (when applicable).
- Use this section to include direct costs that cannot be accounted for in other budget categories. For example, these costs may include computer core 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 in the Budget Justification 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.

**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. PCORI must approve equipment disposition.

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 his or her specific role and the aim or deliverable he or she will be supporting for 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.
- 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.
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. Please review this information prior to submission. See Appendix 1: Allowable and Unallowable Costs to review acceptable and unacceptable uses of PCORI funding.

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.

Budget Justification Template

Complete a Budget Justification Template 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 contributions and assess whether overlap in responsibilities occurs. Provide a clear distinction between individuals who should be key personnel and those who should be classified as “other” personnel.

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

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-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 clearly reflect the involvement and material contribution the signatory parties will provide, and also confirm the commitment of collaboration. PCORI may contact any individuals or organizations included in the Letters of Support to ask 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 project; equipment; and other resources available for the project, including staff.

- **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 implementation effort, as well as their role and specific project responsibilities. Include a Letter of Support for each consultant who verifies 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 that confirms such access, signed by the person with approval authority. If you cannot confirm access at the time of contract negotiation, PCORI reserves the right to withhold funding until the PI has demonstrated support for and access to the relevant population(s) and resources.

List all letters in the table (adding rows as needed) and include the page number for each letter 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.15

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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

On August 14, 2002, the Department of HHS issued a final modification to the Standards for Privacy of Individually Identifiable Health Information, the “Privacy Rule.” 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 provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools related to “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 from NIH.

Award Funding Conditions

At any time during the contract, PCORI reserves the right to discontinue funding for awardees who fail to meet the mutually agreed-on milestones. Applicants’ proposed milestones will be finalized during 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 propose to do so in an LOI and, if invited, submit an application. We recommend that you speak with a Program Officer in advance.

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.

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.

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16 Available at http://www.hhs.gov/ocr/.
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.
PCORI considers computers, tablets, docking stations, mobile data and protection plans, laboratory and office furnishings, and software to be general office supplies that are not allowable as direct-cost charges.
**Appendix 2: Administrative Actions**

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

<table>
<thead>
<tr>
<th>Automatic Rejection</th>
<th>Modification by PCORI</th>
<th>Appended upon PCORI’s Request*</th>
</tr>
</thead>
</table>
| An application or LOI will be automatically rejected if any of the following apply:  
  • Exceeds the specified period of performance outlined in the PFA  
  • Exceeds the maximum budget specified in the PFA  
  • Has adjusted margins or font size (LOI)  
  • Does not include or has an incomplete Project Strategy  
  • Proposes dissemination as its primary project goal | PCORI will modify an application by removing all pages that exceed stated limits. | Unless automatically rejected or modified, PCORI may request that the applicant submit missing documents or correct noncompliant ones. |

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