Spring 2015 Funding Cycle
PCORI Application Guidelines for Improving Methods for Conducting Patient-Centered Outcomes Research (PCOR)

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These guidelines apply to the Spring 2015 Funding Cycle for Improving Methods for Conducting Patient-Centered Outcomes Research (PCOR). Funding announcements, templates, and other resources are available at http://www.pcori.org/spring-2015-methods/. The Spring 2015 Funding Cycle closes May 5, 2015, at 5:00 p.m. (ET).
About PCORI

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

PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a nonprofit, nongovernmental organization. PCORI’s purpose, as defined by the act, is to help patients, clinicians, purchasers, and policy makers make better-informed health decisions by “advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions.”

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PCORI Funding Announcements: Methods Application Guidelines
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What Has Changed for the Spring 2015 Funding Cycle:

- Documentation of Assumptions has been renamed as Justification of Assumptions and moved from the PCORI Funding Announcement (PFA) into the Application Guidelines.
- Research Strategy instructions in the Research Template and Application Guidelines have been updated.
- Times New Roman is the only font now accepted.
- There are new LOI Template prescreen questions in the PCORI Online system.
- In the People and Places Template, biosketches may now be up to five pages, per person.
- The use of 10 percent indirect cost rate must be noted in the Budget Justification.
- PCORI is no longer accepting Greater Than Budget and Time Requests.
- Information on resubmissions in Resubmission Letter section has been updated.
- In the People and Places Template, biosketches may now be up to five pages, per person.
- A Letters of Support Table has been added.
- Inpatient and Outpatient Costs within the Detailed Budget for Each Year of the Project Period section has been removed.
- Allowable and Unallowable Costs in Appendix 2 has been updated.
I. About These Guidelines

This document provides key information to help researchers prepare and respond to the Improving Methods for Conducting Patient-Centered Outcomes Research PCORI Funding Announcement (PFA), available at http://www.pcori.org/spring-2015-methods/.

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

- PCORI’s Applicant FAQs\(^1\) cover common questions about PCORI and the application process.
- Visit PCORI’s Help Center\(^2\) for additional applicant resources.
- **For Programmatic Inquiries:** Please contact the PCORI Helpdesk via email (sciencequestions@pcori.org), phone (202-627-1884), or online (http://www.pcori.org/PFA/inquiry). PCORI will provide a response within three business days. However, we cannot guarantee that all questions will be addressed three business days prior to a Letter of Intent (LOI) or application deadline.
- **For Administrative, Financial, or Technical Inquiries:** Please contact the PCORI Helpdesk at pfa@pcori.org. PCORI will provide a response within two business days. Please 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. Please refer to [PCORI's Policy on Submission of Research Contract Applications].\(^3\)

Administrative Issues

To ensure a thorough, fair, and competitive review process, PCORI strictly enforces the formatting and administrative compliance guidelines outlined in the PFA, FAQs, and Application Guidelines. Applicants who fail to submit the required documents or who exceed the stated word limits may be rejected from the merit review process. All rejection decisions made by the Department of Contracts Management and Administration are final. Please email pfa@pcori.org with any formatting or administrative compliance questions.

Funding Mechanism

PCORI issues contracts, rather than grants, to fund and administrate meritorious research. Under these contracts, PCORI funds projects that demonstrate the highest probability of completing on time and within budget, and of meeting all milestones and deliverables. Therefore, applicants should submit

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1 Available at pcori.org/funding-opportunities/applicant-faqs.
3 Available at pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications/.
realistic budgets and Research Plans without the expectation of extending the project period beyond the originally approved period of performance.

As part of its active portfolio management, PCORI provides programmatic oversight throughout the contract period. To review PCORI’s contract terms and conditions, see PCORI Standard Contract for Funded Research Projects. ⁴

II. Who Can Apply

Applications may be submitted by any private-sector research organization, including any nonprofit or for-profit organization; any public-sector research organization, including any university or college hospital or healthcare system; a laboratory or manufacturer; or a 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 there is demonstrable benefit to the US healthcare system, and US efforts in the area of patient-centered research can be clearly shown. Organizations may submit multiple applications for funding. Individuals are not permitted to apply. If you have questions about eligibility, please contact pfa@pcori.org.

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

III. How to Apply

Follow the instructions provided in these guidelines and in the PCORI Online System ⁵ to submit an LOI and invited application, including all required documents. All required documents must be submitted through the PCORI Online System; failure to do so may result in the removal of the application from the review process. To submit an application or to register your organization in our system, you need a Data Universal Numbering System (DUNS) number and an Employer Identification Number (EIN). If necessary, you can apply for a DUNS number ⁶ and/or an EIN. ⁷ Individual consultants are not required to provide a DUNS number.

⁵ Available at pcori.fluxx.io.
⁶ Available at dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number/.
⁷ Available at irs.gov/Businesses/Small-Businesses-&-Self-Employed/Apply-for-an-Employer-Identification-Number-(EIN)-Online.
Step 1: Register

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

Step 2: Submit a Letter of Intent (LOI)

An LOI is required for new and resubmitted applications, and it must be submitted before completion of an application. Download the PFA-specific LOI Template from the Funding Center. Please note that LOIs that exceed the three-page limit will not be reviewed. Do not upload additional documents as part of your LOI, such as letters of endorsement or support, as they are not requested at this stage; their inclusion will result in LOI rejection without review. To submit an LOI, upload the completed PFA-specific LOI as a PDF to the PCORI Online System and complete the required fields. For detailed instructions on how to navigate the system, please see the PCORI Online System User Manual: Start a Letter of Intent. The LOI is due March 6, 2015, by 5:00 p.m. (ET).

Step 3: Begin Full Application Process

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

Applicants will be notified by March 23, 2015, about whether or not to submit a full application.

The application process includes seven sections within the PCORI Online System, and all sections must be completed prior to submission. Please log in to PCORI Online to view the full list of questions in the Project Information tab that require completion prior to submission.

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

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8 Available at pcori.org/assets/2013/10/PCORI-Online-Start-a-LOI.pdf.
Step 4: Complete Required Documents

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

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

All required documents must be formatted as follows:

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

Step 5: Upload Required Documents

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

Step 6: Submit for Authorization

After all required information has been entered and all required documents have been uploaded, click “Submit to AO” to forward the application to your Administrative Official (AO) for him or her to authorize and submit. The PI and the AO may not be the same individual. Only the AO may approve the final application for official submission to PCORI. The AO must approve and submit the application to PCORI prior to the submission deadline. The AO will receive an email from PCORI notifying him or her to log in to the PCORI Online system, accept the terms and conditions, and submit the application to PCORI. PCORI also encourages the PI to inform the AO when the application is ready for submission.

Following the submission of an application, both the AO and the PI will receive an email confirming that it has been received.

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9 Available at pcori.org/apply.
10 See adobe.com for more information on Adobe Acrobat Professional.
IV. When to Apply

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

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

Problems with computer systems at the applicant’s organization; failure to follow instructions in the PCORI Online System, these guidelines, or a PFA; or failure to complete all required user profiles by the submission deadline are not considered system issues. Please see PCORI’s Policy on Submission of Research Contract Applications for further information.

V. What to Include

Note: Only applicants selected to submit an application should begin the application process. You will be notified by March 23, 2015, as to whether your LOI has been selected to submit an application.

Applicants are encouraged to review this entire section and to print and complete the provided Application Checklist to ensure that the LOI and application are submitted correctly and completely. All required templates can be downloaded from the PCORI Funding Center.

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11 Available at pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications.
12 Available at pcori.org/apply.
# Application Checklist

## Letter of Intent

<table>
<thead>
<tr>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter into PCORI Online System</td>
<td>N/A</td>
</tr>
<tr>
<td>Save file as “SP15_(last 5 digits of Request ID)_PI Last Name_LOI.pdf” and upload</td>
<td>3 pages</td>
</tr>
</tbody>
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## Application

<table>
<thead>
<tr>
<th>Submission Method</th>
<th>Length/Limit</th>
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<tr>
<td>Enter into PCORI Online System</td>
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<td>N/A</td>
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<td>Enter into PCORI Online System</td>
<td>6,000 characters/spaces</td>
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<tr>
<td>Enter into PCORI Online System</td>
<td>1,000 characters/spaces each</td>
</tr>
<tr>
<td>Enter into PCORI Online System</td>
<td>3,000 characters/spaces</td>
</tr>
<tr>
<td>Enter into PCORI Online System</td>
<td>As needed</td>
</tr>
<tr>
<td>Enter into PCORI Online System</td>
<td>As needed</td>
</tr>
<tr>
<td>Save file as “Resubmission_PI Last Name.pdf” and upload</td>
<td>3 pages</td>
</tr>
<tr>
<td>Save file as “ResearchPlan_PI Last Name.pdf” and upload as a single file</td>
<td>As noted below</td>
</tr>
</tbody>
</table>

### Research Plan Template

- Research Strategy: 20 pages
- Dissemination and Implementation Potential: 2 pages
- Replication and Reproducibility of Research and Data Sharing: 2 pages
- Protection of Human Subjects: 5 pages
- Consortium Contractual Arrangements: 5 pages
- References Cited: 10 pages
- Appendix (optional): 10 pages

### People and Places Template

- Professional Profile/Biosketch: 5 pages per individual
- Patient/Stakeholder Partner Profile/Biosketch
  5 pages per individual
- Project/Performance Site(s) and Resources
  15 pages

<table>
<thead>
<tr>
<th><strong>Budget Template</strong></th>
<th>Combine and save as “Budget_PI Last Name.pdf” and upload</th>
<th>As needed</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>- Detailed Budget for Each Project Year (prime and subcontractors)</td>
<td></td>
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<tr>
<td></td>
<td>- Budget Summary for Entire Project</td>
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<tr>
<td></td>
<td>- Budget Justification (prime and subcontractors)</td>
<td></td>
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<tr>
<td></td>
<td>- Federally Negotiated or Independently Audited Indirect Cost Rate Letter (prime and subcontractors)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Fringe Benefit Rate Policy Verification Document (prime and subcontractors)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Letters of Support</strong></th>
<th>Save as “Letters_PI Last Name.pdf” and upload as a single file</th>
<th>As needed</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>- Letters of Support Table</td>
<td></td>
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<td></td>
<td>- Letters of Support</td>
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</tbody>
</table>
**Letter of Intent (LOI)**

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

Upon receipt of LOIs, PCORI program staff will screen them for programmatic fit and overlap with projects in the existing portfolio. An applicant whose LOI does not meet program areas of interest or whose LOI substantially overlaps with existing projects in the portfolio will not be invited to submit a full application. Applicants will receive an email notification accepting or declining their LOI within 14 business days after the LOI deadline.

**PI and Contact Information**

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

**Principal Investigator (PI)**

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

**B. Activities**
- The PI assumes responsibility and accountability for research execution, organization conduct, and compliance.
- The PI manages day-to-day management of the research and project.
- The PI acts as lead research representative of the organization/institution.
- The PI serve as the PCORI lead point of contact.

**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/institution will be accountable both for the appropriate use of funds awarded and for the performance of the PCORI-supported project or activities resulting from the contract.

B. Activities
• The AO manages contract activation, renewals, milestones, and additional materials required.
• The AO oversees submission of the contract activation, renewals, milestones, and additional materials required.
• 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 required annual expenditure reports.

B. Activities
• The FO completes and certifies the required yearly expenditure reports.
• The FO accounts for contract funds and submits invoices and payment details.

PFA-Specific LOI Template
Download the Improving Methods for Conducting PCOR LOI Template from the Funding Center. To submit an LOI, upload the completed LOI to the PCORI Online System and complete the required fields. Provide a thorough description that allows the scientific community to understand the project, including the aims and study design, without reviewing the full application. Any LOIs that exceed three pages (excluding references) will not be reviewed. All references must be included as in-text citations with full citations listed at the end of the LOI. Do not upload additional documents, such as letters of endorsements or support, as part of your LOI, as they are not requested at this stage. Their inclusion will result in LOI rejection without review. (Note: All LOI Templates should follow the formatting guidelines listed in Step 4.)

The LOI must include the following sections:
• Background—State the problem or question the research is designed to address and indicate the specific topic in the funding announcement to which the proposed project is responsive. Describe why this is of interest to patients, caregivers, researchers, and/or other stakeholders.
• Objectives—Describe briefly the specific aims of the study, including specific research question(s) and the long-term objectives. Please note that proposals that include objectives to conduct cost-effectiveness analysis in any capacity will be deemed nonresponsive.
• Methods—Provide a concise description of the study design, study population, sample size, and analytical methods that will be employed.
• **Outcomes (Projected) and Anticipated Impact**—Specify the study outcomes and state briefly why these are important to the field of patient-centered outcomes research (PCOR). Please address how this project will help advance PCOR’s mission.

• **Patient and Stakeholder Engagement**—Provide a description of the plan for engaging patients, caregivers, and/or other stakeholders over the course of the project. If you believe that patient and caregiver engagement is not appropriate given the technical nature of the proposed research, consider whether engagement of other stakeholders and/or end users (data architects, clinicians, domain experts, health services researchers with different expertise than members of the research team, policy makers, etc.) in both the methodological process and the dissemination and implementation plans would be of value. Provide a clear and concise justification of both the types of patients, caregivers, and stakeholders that will be engaged and how those individuals will contribute to the research.

To submit an LOI, save the completed PFA-specific LOI as a PDF. Label your LOI file using the following nomenclature: “SP15_(last 5 digits of Request ID)_PI Last Name_LOI.pdf.” Upload the file to the PCORI Online System and complete the required fields.

### Full Application Requirements

The following sections are applicable only if you have been invited to submit a full application.

**PI and Contact Information**

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

**Project Information**

Enter the following information directly into the PCORI Online System.

**Technical Abstract**

Provide a technical abstract that summarizes your research strategy, and enter it into the PCORI Online System. The abstract should include the following sections:

- **Background and Significance:** State the problem or question the research is designed to address.
- **Study Aims:** Briefly describe the specific aims of the study, including specific research question(s) and long-term objectives.
- **Study Description:** Provide a detailed description of the overall study design. Please include, as applicable:
  - Overall study design
  - Main components of the intervention and comparator(s)
  - Study population (source, inclusion criteria, demographic information, clinical status, target sample size by arm)
Primary and secondary outcomes

Project Narratives

Enter into the PCORI Online System. PCORI may use these responses for programmatic triage, to assign applications to the appropriate review panel, and to provide a high-level overview to merit review panel members. In addition to responding to other questions and prompts, within PCORI Online you must fill in the text boxes provided for you to supply the following information (note the 1,000-character limit, including spaces, for each of the bullets listed below):

- Description of study comparators
- Explanation of why this comparison is important
- Number of arms in the proposed trial, if applicable
- Length of follow-up after intervention, if applicable
- Primary and secondary outcomes
- Target sample size for main analysis

Please log in to PCORI Online to view the full list of questions in this section that require completion prior to submission.

Public Abstract

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

- Description of the problem your project seeks to solve
- Outcomes you hope to achieve
- Brief background on why this project is important to patients
- Explanation of how patients and other stakeholder partners will help make the project successful

Keep in mind that this summary should be comprehensible to a variety of audiences and will be reviewed by scientists, patients, and stakeholders during the merit review process. Public abstracts from proposals that are awarded a contract will be posted on PCORI's website.

Key Personnel

PCORI identifies key personnel as any individual who is considered critical to the project’s scientific development and execution in a measurable way, regardless of whether salary is requested, and whose absence from the project would significantly affect the approved scope.

Enter into the PCORI Online System. Keep the following guidelines in mind as you complete this section:
Applications can include one PI and multiple co-PIs.
PIs can serve in other applications in other roles (co-I or consultant).
When naming a co-PI, applicants should explain in the budget justification why a co-PI is needed and his or her role on the project.
Investigators may serve as the primary PI on only one application per cycle for any individual PFA. An individual who is a PI may, however, participate in other applications (from the same or other organizations) in a different role, such as co-I or consultant.
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.
A project staff person who could be replaced without significantly affecting the direction or conduct of the project should not be listed as key personnel.
Applicants will be asked to identify the primary patient and stakeholder partner on the project. PCORI is interested in highlighting the work of key patient and stakeholder partners on research projects. In the event your project is awarded a contract, the primary patient or stakeholder partner(s) will be named in a public announcement along with the PI and research or academic institution, if applicable.
If awarded, the addition or replacement of key personnel (listed in the submitted application) requires approval by PCORI during contract negotiation and post contract execution, as detailed in contract terms and conditions. To review PCORI’s contract terms and conditions, see PCORI’s Standard Contract for Funded Research Projects.

Milestones
Enter into the PCORI Online System and as part of your Research Plan. Explain the projected goals and outcomes to be accomplished during the proposed project. Milestones are concrete, specific events or accomplishments that are documented by deliverables. They should include only activities that are supported by the PCORI contract. Examples of milestones include minutes of major meetings of the research partners (scientists and patient/stakeholder representatives), recruitment of patients or research subjects, survey development, inception of the intervention, and establishment of databases. See Appendix 1: Example Milestones for a more complete list. Milestones should also include activities dedicated specifically to engagement, such as the recruitment of all patient/stakeholder research partners, results of annual surveys of patient/stakeholder partners, or meeting minutes of patient/stakeholder advisory councils.

You must include at least one deliverable to PCORI during each six-month period of the project in addition to PCORI’s reporting requirements, such as semiannual progress or financial reports.

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Interim and final deliverables will be included in your research contract if your proposal is funded. Please 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 may include:

- Copies of Institutional Review Board (IRB) approval
- Abstracts accepted or presentations made
- Manuscripts accepted for publication
- 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 research findings by scientific and consumer groups
- Reports of plans to adopt research findings in practice
- Charts, tables, graphs, or other summaries of preliminary data
- Registration of the trial on ClinicalTrials.gov
- Data and Safety Monitoring Board (DSMB) meeting recommendations
- Other documents or materials, as appropriate

Note: Applicants are required to describe project milestones and a timeline for completion in the Research Plan, under Research Strategy. Milestones entered into the system should be specific deliverables associated with a timeline; whereas, the milestones described within the Research Strategy should include project objectives that will be accomplished at specific times during the proposed project. Applicants must provide between 3 and 10 milestones per six-month period.

Resubmission Letter

If an application does not result in funding, a PI or organization may resubmit an application for a specific PFA. PCORI does not limit the number of resubmissions; however, applicants who wish to reapply must submit a new LOI.

If you are resubmitting an application, you are strongly encouraged to address all of the previous reviewers’ critiques in the Resubmission Letter (up to three pages).

Beginning with the Fall 2014 Merit Review Cycle, program staff may invite applicants to resubmit. Invited applicants will bypass the LOI review stage (Fall 2014 applicants invited to resubmit will bypass the Fall 2015 cycle’s LOI Review), and will submit their full application by the deadline stated in the PFA. Invited applicants will be required to complete the application information by the LOI deadline for the cycle to which they resubmit; instead of submitting an LOI, invited applicants will be required to upload their letter of invitation to resubmit. The specific aims in invited resubmissions should remain the same as in the original application, unless the applicant has explicit and documented approval from the program to which they will resubmit.
An invitation to resubmit is not a guarantee that the application will be selected for funding. Invited applicants must adhere to the updated guidance in the PFA and still compete with other invited applications.

Research Plan Template

Please complete all required sections and upload as a single PDF to the PCORI Online System. The Research Plan Template includes: Research Strategy, Dissemination and Implementation Potential, Replication and Reproducibility of Research and Data Sharing, Protection of Human Subjects, Consortium Contractual Agreements, References Cited, and an Appendix (optional).

Research Strategy

This component (up to 20 pages), included in the Research Plan Template, addresses the following sections: (A) Background, (B) Significance, (C) Study Design or Approach, (D) Project Milestones and Timeline, (E) Research Team and Environment, and (F) Engagement Plan (optional). Please provide all the information requested, as outlined in the template.

While completing Study Design or Approach (Section C), applicants should cite PCORI’s Methodology Standards.

Adherence to PCORI Methodology Standards

Applicants are required to adhere to PCORI Methodology Standards and prevailing accepted best practices. PCORI Methodology Standards include 47 individual standards that fall into 11 categories. The first five categories are cross-cutting and relevant to most PCOR studies. Researchers should refer to all of these standards when planning and conducting their research projects. These categories are:

- Standards for Formulating Research Questions
- Standards Associated with Patient-Centeredness
- Standards on Data Integrity and Rigorous Analyses
- Standards for Preventing and Handling Missing Data
- Standards for Heterogeneity of Treatment Effects (HTE)

Six other categories of standards will be applicable to particular study designs and methods. The standards in each of these categories should be used for guidance when they are relevant to a particular study:

- Standards for Data Registries
- Standards for Data Networks as Research-Facilitating Infrastructures
- Standards for Causal Inference Methods

• Standards for Adaptive and Bayesian Trial Designs
• Standards for Studies of Diagnostic Tests
• Standards for Systematic Reviews

Most of these standards should be considered minimal. Additional best practices, including guidelines for the conduct of clinical trials developed by other organizations, should be addressed in the application.

Research Plans will be reviewed for adherence to relevant methods standards. We ask that you indicate whether each standard is relevant to your Research Plan. Following PCORI’s Methodology Standards, cite each relevant standard and provide a brief statement indicating how your proposed research demonstrates adherence to the standard. Do not address standards that are not applicable to your study.

PCORI program staff will review relevant standards and plans for adherence with the research team during the contract negotiation phase for proposals that are awarded funding.

While completing the Research Team and Environment (Section E) component, applicants should describe:

- How and why those research sites were selected
- How the sites tie back to the research project
- The resources, facilities, support, and collaborations available to ensure the project’s success
- Ways in which the project will benefit from unique features of the research environment or community involvement, or will employ useful collaborative arrangements
- How the sites will work together to ensure milestones will be achieved
- Institutional and community investment in the success of the research, such as the availability of organized peer groups
- Logistical support, such as administrative management and oversight, and best-practices training
- Financial support, such as protected time for research with salary support
- Access to and support of patient groups

As part of the Research Plan, PCORI encourages all applicants to clearly describe patient and stakeholder engagement (Section F) in their research proposals; however, PCORI also recognizes that patient engagement may not be appropriate in all cases, especially in highly technical methods projects. Please keep in mind that where it may not be appropriate to engage patients in the methodological process, it may still be important to engage stakeholders and/or end users (data architects, clinicians, domain experts, health services researchers with different expertise than members of the research team, policy makers, etc.) in both the methodological process and the dissemination and implementation plans. The engagement plan must be tailored to each research proposal’s specific aims, methods, and targeted end users, and PCORI asks that investigators provide a clear and concise justification in the proposal of both
the types of patients and stakeholders they intend to engage and the types of activities in which they intend to engage those individuals. Investigators must provide a justification if they feel that it is not appropriate to engage patients in a proposed research project.

**Justification of Assumptions**

PCORI specifically seeks studies that are sufficiently powered to detect meaningful effects. To that end, applicants must justify the proposed sample sizes by explaining the assumptions used in all study power calculations. For example, the application should clearly state all the necessary assumptions (i.e., the outcome[s] on which the power calculations are based, the estimated difference in the effect size between study arms, the standard deviation of the effect size measure, the type I and II error rates, and any other assumptions). All such estimates must be justified by referring to prior published research or preliminary data.

**Dissemination and Implementation Potential**

This component (up to two pages) is included in the Research Plan Template. Describe the potential for disseminating and implementing the results of your work in other settings.

PCORI is interested in research that can be rapidly disseminated and implemented in clinical and community practice, thus facilitating improvements in patients’ and other stakeholders’ healthcare decision making. Therefore, applications should include a section that describes the potential for impact of disseminating project findings and facilitating their widespread use in practice. Applicants should also describe possible barriers to dissemination and implementation of their work in other settings. Please note, we are asking you to describe the potential for dissemination and implementation. PCORI does not expect you to budget for dissemination and implementation work at this juncture. For projects that produce important findings, PCORI will consider subsequent applications that support dissemination and implementation efforts through separate funding announcements.

PCORI encourages applicants to think creatively about how to disseminate findings. Many patients and relevant stakeholders do not access information about their disease condition from scholarly journals or from attending scientific meetings. Refer to PCORI’s Methodology Standards[^15] for guidance on how to include patient and stakeholder partners in the dissemination process, as relevant.

Researchers are encouraged to submit documentation of any implementation agreement with the sponsoring organization confirming that successful interventions will be implemented by that organization on a large scale. This agreement will be viewed as a positive factor during merit review. Please include this with the Letters of Support PDF document, as the last item.

Replication and Reproducibility of Research and Data Sharing

This component (up to two pages) is included in the Research Plan Template. Describe the ability to replicate and reproduce potentially important findings from PCORI-funded studies in other data sets, clinical settings, and/or populations. This assessment is essential to building confidence in the accuracy of these findings. PCORI will also support policies to promote sharing of study documentation (e.g., study protocol, programming code, and data definitions) so that other researchers may replicate the findings in other populations. Also, propose a method for sharing data, if such activity is later requested. Applicants must describe the following requirements as they complete this template.

**Replication of research findings:** This requirement refers to supporting efforts by other researchers to replicate study findings in other patient populations and data sets. It applies to all applicants, regardless of project size.

Applicants must describe a replication plan that accommodates the following:

- Provision of a complete, final study protocol describing the study population, primary and secondary hypotheses to be tested, sources and methods of measuring exposures, outcomes, and all covariates used in analyses, including data definitions, coding instructions, discussion guides for qualitative research, and the analysis plan. The protocol will usually be expected to be delivered to PCORI with the 12-month progress report, and always within 3 months of the end of the funding period. PCORI will reserve the right to share these materials with appropriate researchers, in consultation with the PI of the study.
- Proposed clinical trials or observational studies should be registered at www.ClinicalTrials.gov.
- Proposed evidence synthesis studies should be registered at [http://www.crd.york.ac.uk/prospero/](http://www.crd.york.ac.uk/prospero/).

**Reproduction of research findings:** This requirement refers to reproducing research findings in the same data set by another researcher(s) not affiliated with the applicant’s research team. The ability to reproduce important findings from the original data is critical to establishing trust in PCORI findings. Therefore, PCORI will require a data-sharing plan (described below). Although the plan described below is required of all such applicants, subsequent data sharing would be requested by PCORI only after review of findings and a decision that the findings warrant the expense and time of data sharing.

PCORI is committed to maximizing the utility and usability of data collected in our funded projects. We may request awardees to prepare documentation to accompany their final data sets that enables others in the research community to use the data for additional or secondary analysis and make the data and documentation available upon request.

The data-sharing plan must:

- State how a complete, cleaned, de-identified copy of the final data set used in conducting the final analyses will be made available.
• Propose a method by which investigators will make this data set available, if requested.
• Propose a budget that would cover costs of data sharing, if requested.

Note: Do not include this plan in the proposed budget of your application. Depending on the nature, uses, and potential impact of the study findings, PCORI will consider whether incremental funding will be made available to assist investigators in complying with data-sharing requests.

Protection of Human Subjects

This component (up to five pages) is included in the Research Plan Template. Describe the protection of human subjects involved in your research. PCORI follows the Federal Policy for the Protection of Human Subjects (45 CFR part 46), including the Common Rule. For more detailed information, please see Section 5 “Human Subjects Research Policy” from the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, 16 issued by the U.S. Department of Health and Human Services (HHS).

Please refer to the Required Education of Key Personnel on the Protection of Human Subject Participants requirement, below, as you complete this section.

Consortium Contractual Arrangements

This component (up to five pages) is included in the Research Plan Template. Describe the proposed research projects that will be performed by subcontracted organizations. Explain the strengths that these partners bring to the overall project to ensure successful submission of contract deliverables, in accordance with the milestone schedule.

Please keep the following in mind as you complete this section:

• Signed subcontract agreements are not required at the time of application submission to PCORI.
• The submission of an application to PCORI signifies that programmatic and administrative personnel from your organization and from all proposed subcontract organizations that will be involved in this project are aware of your organization’s subcontract agreement policy and that all involved organizations are prepared to establish the necessary interorganizational agreement(s) consistent with that policy.
• If applicable, subcontract personnel should be included under Key Personnel.
• Budget information for subcontracted organizations should 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 Research Plan Template. Throughout the entire Research Plan, applicants should use in-text citations to reference published materials. In this section, list the full bibliographical citation of each reference cited. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article title, and journal or book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied on in preparing any section of the application. Citations that are publicly available in a free, online format may include URLs or PubMed ID numbers along with the full reference. References should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to the proposed research so that the 10-page limit is not exceeded. Websites should be referenced in the standard URL format (i.e., http://www.pcori.org) with the date the link was last accessed.

Appendix (Optional)

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

People and Places Template

Professional Profile/Biosketch and Patient/Stakeholder Partner Biosketch

These components are included in the People and Places Template. Complete a profile/biosketch section (up to five pages per individual) for each person listed as key personnel (including PI, co-I, or other significant contributors), copying the tables provided in this section, as needed. Please note that you may submit a National Institutes of Health (NIH)-formatted biosketch in lieu of a PCORI-formatted biosketch. Patient or stakeholder partners serving as key personnel may choose to fill out a Patient/Stakeholder Partner Biosketch in lieu of the Professional Profile/Biosketch. At a minimum, each profile must include the person’s name, title, and degrees; each profile or biosketch may be no more than five pages. PCORI is especially interested to learn how each individual’s previous experience, past performance, and training in the field of PCOR has prepared him or her to conduct this research. The backgrounds, relevant experiences, and roles of patient and stakeholder partners should also be described.

Applicants should assemble a research team that is best poised to complete the work. Applicants should demonstrate that the study team’s experience, leadership approach, governance, and organizational structure are appropriate for the project and will serve to achieve the project goals.
Project Performance Site(s) and Resources

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

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

Budget Template

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

Detailed Budget for Each Year of the Project Period

Complete a Detailed Budget for each year of the project for the prime applicant and any subcontractor(s) proposed in your application. For example, if your study lasts 2 years, the prime applicant must complete a Detailed Budget for Year 1 as well as for Year 2. The subcontractor should follow this model and complete a Detailed Budget for each year of the proposed study. An Additional Personnel Form is provided within the template after each Detailed Budget year. This form should be used only after all the personnel rows for each budget detail year have been completed. Following the example of a 2-year study, you may delete the unused Year 3–5 Detailed Budgets and corresponding Additional Personnel Forms from the template. However, you may not add additional years. Maximum project periods are stated in each PFA. Please keep in mind:

A. Personnel Costs

- Personnel Costs: Include the base salary for each scientific/technical staff member, employee patient or stakeholder partner, or other personnel on your project, if these members are not accounted for in Section B: Consultant Costs.
- Allowable Costs: PCORI will pay compensation for personnel as long as the costs are consistent with and do not exceed what the applicant would normally pay under its own policy. Such compensation may include salaries and fringe benefits. See Appendix 2: Allowable and Unallowable Costs for more information.
- Salaries include wages earned by an employee, and fringe benefits may include insurance and retirement plans.
- Level of Effort: Personnel contributing to a PCORI-funded research project are expected to monitor their total percent effort across all funding (PCORI or others), and may not exceed 100 percent. Effort must be reported by the percentage of time over the course of the project year. All personnel dedicating effort to the project should be listed on the personnel budget with their level of effort, even if they are not requesting salary support. Please list the base salary for each
person in the Budget Justification and Detailed Budget. If salary support is not being requested, use $0 for base salary. Before the application can be submitted, the AO must certify that all key personnel will not exceed 100 percent commitment if funded.

- **Salary Cap:** The PCORI base salary cap for personnel is $200,000 annualized per individual, per year, exclusive of fringe benefits. An individual who earns less than $200,000 should use his or her actual base salary to calculate personnel costs. An individual with a full-time employee base salary 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 and all subcontractors. If funded, PCORI will verify these costs with the applicant and any subcontractors.

### B. Consultant Costs

- Consultant costs apply to those individuals who are not employees of the applicant organization or under a subcontract agreement as members of the contracted staff.
- Payments to nonemployee patient and stakeholder representatives should be included as consultant costs in the budget.
- Consultant costs must be expressed in an hourly rate.
- Consultant costs must be reasonable and justified within the Budget Justification.
- Provide the total cost of consultant(s), as well as names, expected number of hours, and hourly rate.
- For all consultant costs, provide computations for how applicants arrived at the specific number.
- Include a letter of support from all consultants, verifying the work to be performed and the negotiated rate. See the [Letters of Support](#) section for more detailed information.

### C. Supply Costs

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

- Travel may include any domestic or international travel by study personnel or consultants directly related to and necessary for the project and within the limits explained below. As a matter of policy, PCORI uses the Federal Travel Regulations as the guidelines for per diem and reimbursement.
- Travel costs should be itemized per trip and be described as either scientific travel or programmatic travel, as outlined below:
  o Scientific travel includes travel to present at conferences, symposiums, and similar events. Scientific travel is capped at $10,000 over the full project period, including costs for applicant organization and subcontractor personnel.
  o Programmatic travel includes travel needed for the conduct of the project (i.e., focus groups, consultants, and others). While there is no cap on programmatic travel funds, PCORI closely reviews all travel costs for reasonableness.
  o Airline costs cannot exceed the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare.
- For each category of travel (scientific and programmatic), include number of trips and a brief description of the trips to include 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 describe how the travel is directly related to the proposed research and is necessary for achieving programmatic objectives.

E. Other Expenses

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

F. Equipment Costs

- Equipment costs include tangible items that have a per-unit cost of $5,000 or more and a life of greater than 5 years.
- Up to three quotes for each item of proposed equipment can be included with the Budget Justification.
- Costs must be reasonable and necessary for the project. Equipment must not be available or accessible at a lower cost.
- Equipment costs will be analyzed and must be approved by PCORI during the award negotiation phase for funded projects.
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 PI’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, personnel) at his or her own organization when working on the PCORI-funded project.
- Subcontracted organizations must adhere to all budget policies detailed in these guidelines, including allowable and unallowable costs.

H. Indirect Costs

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

Budget Summary for Entire Project

Complete a Budget Summary for the entire project for the prime applicant and each subcontracted organization. Keep in mind the guidance in the previous section. See Appendix 2 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. Provide sufficient detail to explain the basis for costs, the reason why the costs are necessary to the project, and the reason for major cost variances.
Be sure to provide detail to explain the basis for travel costs and describe how the travel is directly related to the proposed research and necessary for achieving programmatic objectives.

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

**Letters of Support**

Save all letters of support as a single PDF file and upload to the PCORI Online System, using the Letters of Support Table as the first page of the file. Please be sure to 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 properly assemble the letters may result in key information being missed by the reviewers. 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 should be addressed to the PI and demonstrate the commitment of key personnel and supporting organizations (e.g., co-PIs, co-Is, consultants, patient and stakeholder partners, stakeholder organizations) to your proposed project. Letters of support are not required for personnel who are not contributing in a substantive, measurable way to the scientific development or execution of the project, such as research assistants. Letters of support should clearly reflect the substantive involvement and material contribution to be provided by the signatory parties, and are meant to substantiate the commitment of collaboration of all forms. The quality of the letters, and how they bolster the proposed research, is paramount to the number of letters provided.

*Please note that PCORI may contact any individuals/organizations included in the letters of support with questions or to confirm support as described in their letters.*

Letters of support should be organized in the following manner, noting that they should support the information provided in the Research Plan:

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organizational official, confirming the institutional support of the proposed project, space to conduct the research, equipment, and other resources available for the project, including staff. A letter from the leadership of your department or organization affirming support to disseminate and implement research findings that are appropriate and warranted for implementation is also highly encouraged.

- **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 should clearly describe the origin of the study topic and the role of the patient partners in defining the question,
outcomes, comparators, goals and outcomes, and so on. Letters from patient or stakeholder partners or partnering organizations affirming support to disseminate and implement research findings that are germane and warranted for implementation are also highly encouraged. Please also include a letter of support for all consultants verifying the work to be performed and the negotiated rate.

- **Letters Confirming Access to Patient Populations, Data Sets, or Additional Resources:** If the proposed research plan involves access to patient populations, data sets, or additional resources, include a letter of support, 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 on the table and include the page number on which the 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 personnel listed as “key personnel” in the application. The policy and FAQs are available from the NIH website.17

**PCORI Public Access Policy**

PCORI contracts require all awardees to adhere strictly to PCORI’s publication policies. These policies will be shared with awardees.

**Registering Clinical Trials**

Funded clinical trials or observational outcomes studies must be registered at ClinicalTrials.gov. PIs are required to use the following naming convention: “PCORI-PCORI application number” (e.g., PCORI-XXXX-XXXXX). Clinical trials must be registered before enrollment of the first patient. All trials that meet the definition on the NIH database18 (see “Data Element Definitions”) are required to register.

Proposed evidence-synthesis studies should be registered at PROSPERO.19

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17 Available at grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.
18 Available at prsinfo.clinicaltrials.gov.
19 Available at crd.york.ac.uk/prospero.
Standards for Privacy of Individually Identifiable Health Information

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

Decisions about 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 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.

Award Funding Conditions

PCORI reserves the right to discontinue funding for awardees who fail to meet the mutually agreed on milestones at any time during the contract. Proposed milestones should be presented in the application, but final milestones will be negotiated in the post-award period before the beginning or activation of the funding period. For more information, please see PCORI’s Standard Contract Template.

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 sponsor. 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.

Dissemination and Data Sharing

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

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20 Available at hhs.gov/ocr.
Appendix 1: Example Milestones

Milestones are significant events, deliverables, tasks and/or outcomes that occur over the course of each project that mark progress toward the project’s overall aims. The completion of each milestone is intended to mark progress toward the project goals and ensure that the project is on schedule and likely to be successfully completed within the contract period. Below is a list of milestone examples you may reference as you complete this section of your application:

- IRB approval
- Documentation of adherence to PCORI’s Methodology Standards
- Recommendations from DSMB meetings every six months
- Start of recruitment (indicate target total)
- Completion of 25 percent of recruitment (indicate the number)
- Completion of 50 percent of recruitment (indicate the number)
- Completion of 75 percent of recruitment (indicate the number)
- Completion of recruitment (indicate the number)
- Questionnaire/tool completion
- Final study protocol
- Notification of posting final protocol on ClinicalTrials.gov
- Conduct baseline assessments or measurements
- Start follow-up assessments or measurements
- Complete follow-up assessments or measurements
- Interim progress reports, every six months
- Final report
- Manuscript submission or notification of publication
- Data sets, analytic data sets, and codebook
- Copies of published manuscripts
- Engagement updates, every six months, noting specific engagement activities that patients and stakeholders participated in during the reporting time period; examples of engagement activities include describing how patients and stakeholders were involved in the development of intervention materials and describing patient and stakeholder involvement and contribution in the early stages of the research project, such as enrollment of research participants, baseline assessments, and the process evaluation component

At the discretion of the Program Officer, milestones listed above may be deemed irrelevant (e.g., recruitment milestones may not be relevant for observational studies) or additional reporting, such as monthly recruitment numbers, may be required.
Appendix 2: Allowable and Unallowable Costs

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

Allowable costs (i.e., those costs that can be included in a proposed Detailed Budget in 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 percentage of effort on conducting the research project (such costs should 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 otherwise necessary for conducting the research project
- Supplies
- Equipment
- Subcontracts
- Expenses related to conducting engagement activities with patients and other stakeholders
- Other direct research expenses
- Indirect costs

Costs related to the conduct of the research project must be specifically requested by a funding applicant through itemization on the Detailed Budget and will be considered by PCORI in the course of making an award. The following principles and requirements generally apply to PCORI’s evaluation of the proposed budget and determination of allowable costs and should guide applicants in preparing their Detailed Budgets:

- In general, costs for study interventions that constitute the procedures, treatments, interventions, or other standard clinical care (“patient care”) that are being proposed for comparison in the research project (“patient care costs”) will not be covered by PCORI. Patient care costs should be covered by the host healthcare delivery system, third-party payer, manufacturer of the product, developer of an intervention, or other interested party.
• The willingness of one or more stakeholder groups to cover patient care costs that will be incurred during the research project, even when one of the comparators is not currently directly covered by insurance, will be taken as a strong endorsement of the research project by the stakeholder group. Such commitments also provide an indication that the stakeholder groups will use the research study’s findings. (Such support for the study by a stakeholder group should be discussed in the application.)

• Except for specific permission in exceptional circumstances, PCORI will not cover patient care costs.

• PCORI may consider coverage of the co-payment or coinsurance costs of participating study subjects when necessary to preserve blinding in a study or to ensure access to the study for vulnerable populations.

• PCORI will generally cover costs for ancillary tasks necessary in the implementation or monitoring of patient care as part of conducting the research project. Examples include costs for obtaining informed consent to participate in the research project, collecting data pursuant to the research protocol, or study subject data collection and monitoring that would not normally be performed in the course of patients receiving the patient care being evaluated in the research project.

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

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