Spring 2014 Funding Cycle
PCORI Application Guidelines for Pragmatic Clinical Studies and Large Simple Trials to Evaluate Patient-Centered Outcomes

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Latest Revision July 8, 2014 Research Strategy increased from 15 to 18 pages

These guidelines apply to the Spring 2014 Funding Cycle for the Pragmatic Clinical Studies and Large Simple Trials to Evaluate Patient-Centered Outcomes PCORI Funding Announcement. Funding announcements, templates, and other resources are available at pcori.org/PFA/pragmatic-studies. The Spring 2014 Funding Cycle closes August 8, 2014, 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 law, 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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1.0 About These Guidelines

This document provides key information to help researchers prepare and respond to the PCORI Funding Announcement (PFA): Pragmatic Clinical Studies and Large Simple Trials to Evaluate Patient-Centered Outcomes.

These guidelines may 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.
- **Programmatic Inquires**: Please contact the PCORI Helpdesk via email ([pfa@pcori.org](mailto:pfa@pcori.org)), via phone (202-627-1884), or online ([http://www.pcori.org/PFA/inquiry](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.
- **Administrative, Financial, or Technical Inquiries**: Please contact the PCORI Helpdesk at [pfa@pcori.org](mailto: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. One week prior to an application deadline, applicants may also call the PCORI Helpdesk (202-627-1885). Applicants are asked to plan accordingly.

It is the applicant’s responsibility to submit the application on or before the deadline. To review PCORI’s policy on late submissions, see [PCORI Policy on Submission of Research Contract Applications](http://www.pcori.org/PFA/inquiry).

### Funding Mechanism

PCORI issues contracts, not grants, to fund and administrate meritorious research. Under these contracts, PCORI funds projects that demonstrate the highest probability that they will be completed on time, on budget, and will meet all milestones and deliverables. Therefore, applicants should submit realistic budgets and research plans without the expectation of receiving cost/no-cost extensions.

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 Contract for Funded Research Projects](http://www.pcori.org/PFA/inquiry).

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\(^{1}\) Available at [pcori.org/funding-opportunities/applicant-faqs](http://pcori.org/funding-opportunities/applicant-faqs)

\(^{2}\) Available at [pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications/](http://pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications/)

\(^{3}\) Available at [pcori/assets/2013/09/PCORI-PFA-Contract-for-Funded-Research-Projects.pdf](http://pcori/assets/2013/09/PCORI-PFA-Contract-for-Funded-Research-Projects.pdf)
2.0  Who Can Apply

Applications may be submitted by any private sector research organization, including any non-profit 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. All US applicant organizations must be recognized by the Internal Revenue Service. Non-domestic components of organizations based in the US 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, contact pfa@pcori.org.

3.0  How to Apply

Follow the instructions provided in these guidelines and in the PCORI Online System\(^4\) to submit an LOI and application, including all required documents. All required documents must be submitted using the PCORI Online System and failure to do so may result in the removal of the application from the review process.

**Step 1: Register**

To apply for PCORI funding, you 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 entered will be your username.

**Step 2: Submit a Letter of Intent (LOI)**

An LOI is required and must be submitted prior to completion of an application. To submit an LOI, complete the required fields in the PCORI Online System. For detailed instructions, please see the PCORI Online System User Manual: Start a Letter of Intent.\(^5\)

**Step 3: Begin Full Application Process**

*Note: Only organizations selected to submit a full application should begin this process.*

The application process includes seven sections within the PCORI Online System and all sections must be completed prior to submission. You can return to complete your application as many times as

\(^4\) Available at pcori.fluxx.io  
\(^5\) Available at pcori.org/assets/2013/10/PCORI-Online-Start-a-LOI.pdf
needed. However, you must go to the Save and Review section and click the “Save and Review” button to save your work before exiting.

Required templates and forms are available in the PCORI Funding Center. You may delete any text in a template or form that is not applicable to your proposal.

All required documents must be formatted as follows:

- **Header:** Include the Principal Investigator’s (PI’s) full name on every page in the top left corner of the page header.
- **Margins:** Use half-inch margins or greater. 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 Arial or 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.
- **Spacing:** Use single spacing.

**Step 4: Upload Required Documents**

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

**Step 5: Submit for Authorization**

After all required information has been entered and all required documents have been uploaded, click “Submit” to forward the application to your administrative official (AO) to authorize. The Principal Investigator (PI) and the AO may not be the same individual. Only the AO may approve the final application for official submission to PCORI. Please ensure that the AO approves and submits the application to PCORI prior to the submission deadline. Following the submission of an application, the AO and PI will receive an email confirmation.

**4.0 When to Apply**

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

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6 Available at pcori.org/apply
7 See adobe.com for more information on Adobe Acrobat Professional.
PCORI Online System issues that threaten the on-time submission of an application must be reported to PCORI prior to the stated deadline and PCORI will investigate reports of system issues on a case-by-case basis. 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 PCORI funding announcement, 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.

5.0  What to Include

*Note: Only organizations selected to submit a full application should begin this process.*

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

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8 Available at pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications
9 Available at pcorg.org/apply
## 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</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• PI and Contact Information</td>
<td>Enter into PCORI Online System</td>
<td>N/A</td>
</tr>
<tr>
<td>• Technical Abstract</td>
<td>Save as “TechnicalAbstract_PI Last”</td>
<td>5 pages</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Application</th>
<th>Submission Method</th>
<th>Length/Limit</th>
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<tbody>
<tr>
<td><strong>PI and Contact Information</strong></td>
<td>Entered previously as part of the Letter of Intent</td>
<td>N/A</td>
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<tr>
<td><strong>Project Information</strong></td>
<td></td>
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</tr>
<tr>
<td>• Technical Abstract</td>
<td>Enter into PCORI Online System</td>
<td>6,000 characters/space</td>
</tr>
<tr>
<td>• Project Narratives</td>
<td>Enter into PCORI Online System</td>
<td>1,000 characters/space</td>
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<tr>
<td>• Public Abstract</td>
<td>Enter into PCORI Online System</td>
<td>6,000 characters/space</td>
</tr>
<tr>
<td><strong>Key Personnel</strong></td>
<td>Enter into PCORI Online System</td>
<td>As needed</td>
</tr>
<tr>
<td><strong>Milestones</strong></td>
<td>Enter into PCORI Online System</td>
<td>As needed</td>
</tr>
<tr>
<td><strong>Research Plan</strong></td>
<td>Save file as “ResearchPlan_PI Last”</td>
<td>As noted below</td>
</tr>
<tr>
<td>• Research Strategy</td>
<td></td>
<td>18 pages</td>
</tr>
<tr>
<td>• Dissemination and Implementation Potential</td>
<td></td>
<td>2 pages</td>
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<tr>
<td>• Reproducibility and Transparency of Research</td>
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<td>2 pages</td>
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<tr>
<td>• Protection of Human Subjects</td>
<td></td>
<td>5 pages</td>
</tr>
<tr>
<td>• References Cited</td>
<td></td>
<td>10 pages</td>
</tr>
<tr>
<td>• Consortium Contractual Arrangements</td>
<td></td>
<td>5 pages</td>
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<tr>
<td>• Appendix (optional)</td>
<td></td>
<td>10 pages</td>
</tr>
<tr>
<td><strong>Engagement Template</strong></td>
<td>Save as “Engagement_PI Last Name.pdf”</td>
<td>4 pages</td>
</tr>
<tr>
<td><strong>People and Places Template</strong></td>
<td>Save as “PeoplePlaces_PI Last Name.pdf”</td>
<td>As noted below</td>
</tr>
<tr>
<td>• Professional Profile/Biosketch</td>
<td></td>
<td>4 pages per individual</td>
</tr>
</tbody>
</table>
Letter of Intent (LOI)

A LOI must be submitted prior to the completion of your application. Letters of Intent will be screened for responsiveness and fit to program goals. Evaluation criteria include: importance and relevance of the topics to PCORI priorities; clarity and credibility of applicants’ responses to the LOI questions, as well as their justification of the need for a large pragmatic study; and programmatic fit and balance, taking into consideration whether the particular proposal significantly overlaps with previously funded studies or concurrent proposals or, conversely, whether the particular proposal fills a gap in the portfolio of proposals with certain characteristics, including disease category, topics, priority population, methodologies, and other variables.

Only Letters of Intent deemed most responsive to this PFA will be invited to submit a full application. Notification of request to submit full application will occur no later than April 7, 2014.

PI and Contact Information

Review information carried over from your LOI, and update as needed. 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
   - Responsible for scientific or technical aspects
   - Applications can include multiple co-PIs
   - Applicants must designate one PI as a primary contact
   - The PI’s institution must be the primary institution for the award unless prior approval was granted prior to the application deadline
   - Investigators may serve as PI on only one application per cycle for any individual PCORI PFA
   - PIs can participate in other applications (from the same or other organizations) in a different role, such as co-PI, co-investigator or consultant

B. Activities
   - Assume responsibility and accountability for research execution, organization conduct, and compliance
• Oversee day-to-day management of the research and project
• Act as lead research representative of the organization/institution
• Serve as PCORI lead point of contact

Administrative Official (AO)
A. Description
• 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 application

B. Activities
• Manage contract activation, renewals, milestones, and additional materials required
• Oversee submission of the contract activation, renewals, milestones, and additional materials required
• Certify contract compliance of all applicable assurances and certifications referenced in the application

Financial Official (FO)
A. Description
• Responsible for required annual expenditure reports

B. Activities
• Complete and certify the required yearly expenditure reports
• Execute accounting of contract funds and submission of invoices and payment details

Technical Abstract

Upload into the PCORI Online System. Please address the following questions.

1. What is the precise question or choice that your research is designed to address?
2. Is the question germane to one of the PCORI priority topics, Institute of Medicine’s (IOM’s) Top 100 Questions, and/or the Agency for Healthcare Research and Quality (AHRQ) Future Research Needs projects? (Note: Other high-priority topics will also be considered.)
3. Why is this particular comparison of interest to a patient or other decision maker?
4. What are the specific aims of the study?
5. Describe
   i. Study design
   ii. Population to be studied (including inclusion/exclusion criteria)
iii. Comparators (the two or more options being compared); if one of the options is “usual care,” please provide details of “usual care”
iv. Study outcomes including measures important to patients and families
6. Are the options being compared options that have either been shown to be efficacious or effective, or alternatively, are they commonly used in clinical practice?
7. What are the pre-specified subgroup analyses?
8. What is the estimated sample size? Explain the rationale for this sample size, citing references that support the assumptions underlying the estimate.
9. How has the research team engaged appropriate patient, clinician, and delivery-system organizations in helping to design the study? How will these stakeholders participate in conducting and reporting the study and in disseminating and implementing study findings? Name the organizations that will participate.
10. What is your previous experience with recruiting and retaining study participants in trials of similar size and type and in the target population(s)? Describe potential barriers to achieving targeted sample size and potential methods to overcome the barriers.
11. If the proposed intervention is found to be effective, what factors will facilitate or impede its sustainability and scalability in real-world settings?
12. What are the estimated duration and total direct costs of the proposed study?
13. If your proposed budget exceeds a total direct cost of $10 million, please provide justification. (Note: Although subcontractor direct and indirect costs are considered to be direct costs to the prime, subcontractor indirect costs should not be included when determining if the budget exceeds the total direct cost limit.)

Project Information

Technical Abstract

Enter into the PCORI Online System. Please copy and paste the Technical Abstract that you submitted as part of your LOI. Applicants can revise the abstract if needed.

Project Narratives

Enter into the PCORI Online System. In this section, applicants are asked to describe the specific aims of the research, how the research plan is responsive to the PFA, and how this research is comparative, in addition to other questions and prompts. Responses may be used by PCORI for programmatic triage, to assign applications to the appropriate review panel, and to provide a high-level overview to Merit Review panel members.

Public Abstract

Enter information in the PCORI Online System. Provide a description, written in lay language that allows the general public to understand your project. Please include the following:
• **Background**—State the problem or question your research is designed to address.
• **Objectives**—Briefly describe the specific aims of the study, specific research question(s), and long-term objectives.
• **Methods**—Give a concise description of the study population, sample size, engagement plan, and analytic methods that will be employed. Your proposed research is **required** to adhere to all relevant [PCORI Methodology Standards](#).  
• **Patient Outcomes**—Specify the study outcomes and state briefly why these are important to patients.
• **Patient and Stakeholder Engagement**—If applicable, describe how patients and/or other stakeholders will be engaged in the planning and conduct of the research project.
• **Anticipated Impact**—Describe how your study findings will be used in health decision making and the anticipated impact of your research findings. Pay particular attention to how this anticipated impact will help to advance PCORI’s mission.

Public abstracts for proposals that are awarded a contract will be posted on PCORI’s website.

**Key Personnel**

Enter information in the PCORI Online System. Keep the following guidelines in mind as you complete this section:

• Applications can include multiple co-PIs.
• PIs can serve in other applications as other roles (co-investigator or consultant).
• Individuals cannot serve as PIs for multiple PCORI Funding Awards in the same cycle.
• Investigators may serve as PI on only one application per cycle for any individual PCORI 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-investigator or consultant.
• 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 application.
• PCORI identifies key personnel as any individual that is considered critical to the project’s scientific development and execution in a measurable way whether or not salary is requested and whose absence from the project would have a significant impact on the approved scope of the project.
• Consultants and subcontractor personnel may be included as key personnel if they meet the same definition.

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10 Available at [pcori.org/research-we-support/research-methodology-standards/](https://pcori.org/research-we-support/research-methodology-standards/)
• The program director/principal investigator (PD/PI) is always considered senior/key personnel.
• Anyone who could be replaced without significantly affecting the direction or conduct of the project should not be listed as key personnel.
• 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.
• Post-award, any change to key personnel listed in your application will require prior approval by PCORI as detailed in the contract terms and conditions. To review PCORI’s contract terms and conditions, see PCORI Contract for Funded Research Projects.11

Milestones

Enter information in the PCORI Online System. Describe milestones and explain your 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, results of annual surveys of patient/stakeholder research partners, and establishment of databases. Exclude any PCORI reporting requirements, such as semi-annual progress or financial reports.

You must include at least one deliverable or interim deliverable to be submitted to PCORI during each three-month period of the project, at least for the first two years. After the first two years, subject to PCORI’s discretion, the deliverables may be submitted to PCORI during each six-month period. The proposed milestones will be used to determine whether project progress is appropriate to the timeline. The required deliverables will be included in your final agreement if your application is awarded a contract.

The following milestones should be included, as appropriate:

1. Institutional Review Board (IRB) approval
2. Minutes of the Data Safety Monitoring Board (DSMB) meetings
3. Study registration at ClinicalTrials.gov
4. Final study protocol
5. Start of recruitment (Indicate target total)
6. Completion of 25 percent of recruitment
7. Completion of 50 percent of recruitment
8. Completion of 75 percent of recruitment

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11 Available at pcori.org/assets/2014/02/PCORI-PFA-Contract-for-Funded-Research-Projects.pdf
9. Completion of recruitment
10. Focus group results
11. Questionnaire/tool
12. Interim analyses
13. Final analyses
14. Datasets, analytic datasets, and codebook
15. Interim Progress Reports
16. Final Report
17. Copies of manuscripts accepted for publication

In addition to tracking these milestones, we are interested in learning how your work is having an impact. Therefore, should you be selected for a PCORI contract, the following additional deliverables may be required following contract execution:

- Abstracts from presentations made to professional groups or associations;
- Copies of drafts of instruments, data dictionaries, educational materials, manuals, or other project deliverables;
- 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; and
- 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.

Research Plan Template

Please complete all required sections and upload as a single PDF into the PCORI Online System. The Research Plan Template includes: Research Strategy; Dissemination and Implementation Potential; Reproducibility and Transparence of Research; Protection of Human Subjects; References Cited; Consortium Contractual Agreements; and an optional Appendix.

Research Strategy

This component is included in the Research Plan Template. Please answer all questions.

Dissemination and Implementation Potential

This component 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, facilitating improvements in patients’ and other stakeholders’ decision making about health care. Therefore, applications should include a section that describes the potential for disseminating your findings and facilitating their widespread use in practice. We also request that you describe possible barriers to dissemination and implementation of your work in other settings. Please note, we are asking you to describe the potential for dissemination and implementation. PCORI does not expect you to undertake this 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 PCORIs Methodology Standards and Patient and Family Engagement Rubric for guidance on how to include patient and stakeholder partners in the dissemination process, as relevant.

Researchers are encouraged to submit documentation of an implementation agreement with the sponsoring organization confirming that any 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 with other Letters of Support.

**Reproducibility and Transparency of Research**

This component is included in the Research Plan Template. Describe the ability to replicate potentially important findings from PCORI-funded studies in other data sets and populations. This is essential to building confidence in the accuracy of these findings. PCORI will 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.

**Protection of Human Subjects**

This component is included in the Research Plan Template. Describe the protection of human subjects involved in your research. For additional guidance, refer to [Section 5.0 “Hum an Subjec ts Rese arch Policy”](http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#5_4_IRB_Approval) from the *Supplemental Grant Application Instructions for All Competing Applications and Progress Reports*, issued by the US Department of Health and Human Services (HHS).

**References Cited**

This component is included in the Research Plan Template. Provide a list of references cited in the Research Plan. Each reference must include 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 (PMID) numbers along with the full reference. *The 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](http://www.pcori.org)) with the date the link was last accessed.

**Consortium Contractual Arrangements**

This component 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.

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 all proposed subcontract organizations who 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 inter-organizational agreement(s) consistent with that policy.
- Personnel information for 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 Templates.

**Appendix (Optional)**

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

**Engagement Template**

Upload into the PCORI Online System. The template is based on PCORI’s Patient and Family Engagement Rubric (included as an appendix to the Engagement Template). Before completing this
template, applicants are encouraged to review the rubric, PCORI’s PCOR Engagement Principles as noted in the rubric, and PCORI’s Methodology Standards Associated with Patient-Centeredness.

Applicants must complete the template as well as provide an Engagement Plan (included in the Research Plan Template) that outlines how patients and other stakeholders will participate as partners in various phases of the proposed research. To assist applicants, PCORI provides examples of engagement plans from previously funded projects.

The rubric and sample engagement plans are not intended to be comprehensive or prescriptive. Instead, they provide a variety of options to incorporate engagement, where relevant, into the research process. Applicants may choose to include some, but not all activities, and also may include additional innovative approaches.

**People and Places Template**

*Professional Profile/Biosketch*

This component is included in the People and Places template. Complete a Professional Profile/Biosketch section for each person listed as a principal investigator, co-principal investigator, co-investigator, or other significant contributor, copying the tables provided in this section as needed. Please note that information from the National Institutes of Health (NIH) biographical sketches can be incorporated. At a minimum, each profile must include the person’s name, title, and degrees; however, PCORI is especially interested to know each individual’s previous experience, past performance, and training in the field of PCOR that has prepared them to conduct this research.

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.

*Note: PCORI recognizes that not all sections of the Professional Profile may apply to patient or stakeholder members of the research team.*

*Project Performance Site(s) and Resources*

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

Applicants should provide a description of the facilities that will be used during the project, including capacity, capability, relative proximity, and availability to the project, and describe how the research environment will contribute to the probability of success and discuss ways in which the project will
benefit from unique features of the research environment or community involvement or will employ useful collaborative arrangements.

Applicants should also describe 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; and access to and support of patient groups.

**Budget Templates**

Please complete all required documents and save as a single PDF before you upload into the PCORI Online System.

*Detailed Budget and Budget Summary for the Entire Project*

Complete a Detailed Budget for each program year and a Budget Summary for the Entire Project for the prime applicant and each subcontracted organization. See [Appendix 2: Allowable and Unallowable Costs](#) to review acceptable and unacceptable uses of PCORI funding.

Please keep the following in mind:

**A. Personnel 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 eligible costs also include fringe benefits, including 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 such persons in the budget justification template 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 per individual, per year, exclusive of fringe benefits. An individual who earns less than $200,000 should use his/her actual base salary to calculate personnel costs. An individual with a base salary 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. Applicants must provide verification of the fringe benefit rate policy for the prime organization and all subcontractors with the budget upload. If funded, PCORI will verify these costs with the applicant and any subcontractors.

• **Personnel Costs:** In addition to noting the base salary for each scientific/technical staff, you must note the base salary for each employee patient or stakeholder partner of your research team, if these members are not accounted in Section B: Consultant Costs.

**B. Consultant Costs**

• Consultant costs apply to those individuals who will dedicate time to the project neither as an employee of the applicant organization nor under a subcontract agreement as a member of contracted staff. Payments to non-employee patient and stakeholder representatives should be included.

• Consultant costs must be expressed in an hourly rate.

• Consultant costs must be reasonable and justified within the budget justification.

• Provide 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 for 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, including an amount for each category.

• Include details for each cost that exceeds $1,000 in the space provided. You will be asked to provide further detail for each of these costs in the Budget Justification Template.

• For all supply costs, provide computations for how you arrived at the specific number.

**D. Travel Costs**

• Travel may include any domestic and/or international travel by an employee or other personnel 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 (FTR) as the guidelines for per diem and reimbursement.
• Travel costs should be itemized per trip and described as either scientific travel or programmatic travel, as outlined below:
  o **Scientific Travel**—including travel to present at conferences, symposiums, and so forth. Scientific travel is capped at $10,000 over the full project period, including costs for applicant organization and subcontractor personnel.
  o **Programmatic Travel**—including travel needed for the conduct of the project (i.e., focus groups, consultants, and others). Although 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.
  o PCORI reviews all travel costs for reasonableness.

• 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 Template, you are asked to provide added 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. Inpatient and Outpatient Care Costs

• List the total for inpatient care costs and outpatient care costs in the appropriate row.

• PCORI will cover project-related inpatient/outpatient costs that insurance does not cover.

• In the Budget Justification Template, you are asked to justify the costs associated with inpatient and outpatient care cost.

F. Other Expenses

• Indicate general categories such as printing costs, publication costs, and non-consulting service contracts, including an amount for each category.

• Use this section to include direct costs that cannot be accounted for in other budget categories. These costs may include travel costs or participation incentives for study subjects, or coverage of copayments/coinsurance.

• Include details for each cost that exceeds $1,000 in the space provided. You will be asked to provide further detail for each of these costs in the Budget Justification template.

G. Equipment Costs

• List each item of proposed equipment and its anticipated cost. Equipment costs include tangible items that cost $5,000 or more.

• Up to three quotes for each item of proposed equipment can be included with the Budget Justification Template.
• Costs must be reasonable and necessary for the project. Equipment must not be easily available or accessible at a lower cost.

• Equipment costs will be analyzed and must be approved by PCORI during the award negotiation phase for projects that are funded.

H. Subcontractor Costs

• This category includes all consortium and contractual costs. A Subcontractor Arrangement is required if the criteria listed below are met.
  o The subcontractor PI’s effort on the project is calculated as part of his/her “professional time” for his/her employer organization.
  o The subcontractor will be using significant resources (e.g., office space, supplies, computer, and personnel) at his/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. Please refer to the guidelines in Sections A–I.

I. Indirect Costs

• Indirect costs for the project may be calculated according to the applicant’s federally negotiated or independently audited indirect cost rate; however, the total indirect costs charged to the project cannot exceed the PCORI indirect cost cap.

• Include a copy of the applicant’s and each subcontractor’s federally negotiated or independently audited indirect cost rate letter with the budget justification and upload into PCORI Online (this will become one single file).

• Foreign applicants will use the same calculation to determine their own indirect cost cap, but are eligible for no more than 10 percent.

• Applicants and subcontractors may assess only their indirect costs, not to exceed 40 percent, on the first $25,000 of all subcontractor costs combined (direct and indirect). Subcontractors with third tier subcontractor must follow this budget guideline.
Budget Justification

Complete a Budget Justification for the prime applicant and each subcontracted organization for the entire project. Please provide sufficient detail to understand the basis for costs; the reason why the costs are necessary to the project; and an explanation for major cost variances. Use continuation pages as needed.

You are also asked to specify any other sources of funding that are currently available or anticipated to support the proposed research project, including amounts and the time period for these other sources of funding.

Letters of Support

Save as one PDF file and upload into the PCORI Online System. Provide Letters of Support, addressed to the PI, to demonstrate the commitment of key personnel (e.g., principal investigators, co-investigators, consultants, patient and stakeholder partners, stakeholder organizations). A letter from the leadership of your department or organization affirming support to disseminate and implement research findings that are germane and warranted for implementation is also highly encouraged. Letters of Support are not required for personnel such as research assistants who are not contributing in a substantive, measurable way to the scientific development or execution of the project.

6.1 Additional Requirements

Awardees are required to comply with the following requirements:
**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 are 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 Effect (HTE)

Five 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

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

All applicants should specifically discuss their capacity to measure factors such as differential adherence to chosen treatments (or participation in intervention programs) that could create or explain apparent differences in the effectiveness of the alternative interventions being compared in clinical populations.

Research plans will be reviewed at merit review for adherence to relevant methods standards. We ask that you indicate whether each standard is relevant to your research plan. Please provide a brief statement after each relevant standard indicating how your proposed research demonstrates adherence to the standard. Please indicate “not applicable” next to each standard that does not apply to your research. If you choose to deviate from a standard please briefly indicate why. Reviewers will be instructed to evaluate adherence to methods standards.

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

**Required Education of Key Personnel on the Protection of Human Subject Participants**
PCORI requires all applicants to adhere to NIH policy on education in the protection of human subject participants in the conduct of research. This applies to all personnel listed in the application as key personnel. The policy is available on the NIH website.\(^3\)

**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**

Proposed clinical trials or observational outcomes studies should be registered at ClinicalTrials.gov. Proposed evidence synthesis studies should be registered at PROSPERO.\(^4\) PIs are required to use the following naming convention: “PCORI-PCORI application number” (e.g., PCORI-XXXX-XXXX). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the NIH database\(^5\) (see “Data Element Definitions”) are required to register.

**Standards for Privacy of Individually Identifiable Health Information**

The Department of Health and Human Services (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 applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The Office for Civil Rights\(^6\) 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 can be found on the NIH\(^7\) website.

**Award Funding Conditions**

PCORI reserves the right to discontinue funding for awardees who fail to meet the mutually agreed upon milestones at any time during the contract. Proposed milestones should be presented in the

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\(^3\) Available at grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html
\(^4\) Available at crd.york.ac.uk/prospero
\(^5\) Available at prsinfo.clinicaltrials.gov
\(^6\) Available at hhs.gov/ocr
\(^7\) Available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html
application, but final milestones will be negotiated in the post-award period prior to the beginning/activation of the funding period.

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.

Dissemination and Data Sharing

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

7.0 How Does PCORI Review and Score Applications?

PCORI conducts rigorous merit review of the applications it receives. Note that applications may be eliminated from the review process for administrative or programmatic reasons. An application may be administratively triaged if it is incomplete or submitted past the stated due date and time, or it does not meet the administrative or formatting criteria outlined in this document, in the PCORI templates, and in the PCORI Online System. An application may be programmatically triaged if it is not responsive to the guidelines as described in the PCORI PFA, if it describes research that is non-comparative, or if it otherwise does not meet PCORI programmatic requirements. Per our enabling legislation, in cases when two proposed research plans overlap, funding preference must be given to proposals submitted on behalf of NIH and AHRO.

Review Process

Merit Review Panel: Applications are evaluated by members of a PCORI Merit Review Panel. Each panel is composed of domain experts, researchers, patients, and other stakeholders, with the size of the panel contingent upon a number of factors such as the total number of applications received. In plenary, reviewers discuss and report on each application’s strengths, weaknesses, and preliminary scores. Each panelist then assigns a final overall score to each application.

Applications are reviewed against PCORI’s review criteria:

- Criterion 1: Impact of the condition on the health of individuals and populations
- Criterion 2: Potential for the study to improve health care and outcomes
- Criterion 3: Technical merit, including adherence to PCORI’s Methodology Standards
- Criterion 4: Patient-centeredness
Criterion 5: Patient and stakeholder engagement

**Post-Panel Review:** Following the in-person panel review, meritorious applications are reviewed by a Selection Committee that includes members of PCORI’s Board of Governors. The Selection Committee works with staff to identify a slate of applications for possible funding based on merit review scores, programmatic balance, and PCORI’s strategic priorities. This slate is proposed to PCORI’s Board of Governors for its consideration and approval.

**Funding Recommendations:** Factoring in the total available funds allotted for this announcement, high-scoring applications that fit the programmatic needs, satisfactorily address reviewers’ critiques, and adhere to PCORI’s Methodology Standards will be considered for funding by the PCORI Board of Governors.

**Scoring**

During the preliminary and in-person panel reviews, reviewers use a nine-point scale to assign criterion scores, initial overall scores, and final overall scores. Letters of Intent are not scored.

<table>
<thead>
<tr>
<th>Range</th>
<th>Score</th>
<th>Descriptor</th>
<th>Characteristics</th>
</tr>
</thead>
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<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
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<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
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<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
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<td></td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
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<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
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<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weakness</td>
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<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
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Appendix 1: Key Terms

Allowable Costs—A cost that is approved within the budget and is not otherwise unallowable under the PCORI Funded Research Policies. A direct cost is allocable to the project if the goods or services involved are chargeable or assignable to the project in accordance with relative benefits received or other equitable relationship. As a result, a cost is allocable to the funded project if (1) it is incurred solely to advance the work under the project, or (2) it benefits both the funded project and other work of the recipient organization, in proportions that can be approximated through use of reasonable methods.

Biosketch—A profile of the experience and accomplishments of the key personnel in an application. A biosketch also satisfies the requirements of the PCORI Professional Profile.

Burden—A term that refers to the frequency of the condition, the expected mortality and morbidity, and/or the burden of suffering associated with symptoms, complications, or other consequences of the condition. Additionally, it may include the costs to the US population of healthcare services used, the individual patient’s out-of-pocket expenses, as well as intangible costs to the patient, such as time away from paid or unpaid occupations.

Clinical Practice Guidelines—Systematically developed statements or recommendations to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. They present indications for performing a test, procedure, or intervention, or the proper management for specific clinical problems. Guidelines may be developed by government agencies, institutions, organizations such as professional societies or governing boards, or convening expert panels.

Closeout—The process by which PCORI determines that all applicable administrative actions and all required work of the contract have been completed and officially closes the contract.

Comparative Effectiveness Research (CER)—The direct comparison of existing healthcare interventions to determine which interventions work best for which patients and which interventions pose the greatest benefits and harms. The core question of comparative effectiveness research is which treatment works best, for whom, and under what circumstances.

Conflict of Interest—As defined by PCORI’s authorizing legislation, a Conflict of Interest is any “association, including a financial or personal association, that has the potential to bias or has the appearance of biasing an individual’s decisions in matters related to the Institute or the conduct of activities” [Patient Protection and Affordable Care Act, Pub L No. 111-148, 124 Stat 727, §6301(a)(3)]. Conflicts of Interest will be considered and managed throughout every step of the review and selection process, including, but not limited to, the technical and programmatic reviews, the selection and assignment of scientific and stakeholder reviewers, Board of Governors deliberations, and post-award negotiations and monitoring.

Consultant—An individual hired to provide professional advice or services for a fee.

Contract—The legally binding document that PCORI uses to make awards for research projects.
Data Universal Numbering System (DUNS)—A unique identifier assigned to a single business entity. You may apply for a DUNS number online. Available at [dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number](dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number).

Employer Identification Number (EIN)—The Federal Tax Identification Number used to identify a business entity. You may apply for an EIN in various ways, including online. Available at [iirs.gov/businesses/small/article/0,,id=102767,00.html](iirs.gov/businesses/small/article/0,,id=102767,00.html).

Financial Official (FO)—The individual designated by the recipient organization who is responsible for the proper accounting of contract funds and the submission of payment details. The FO is responsible for completing and certifying the required yearly expenditure reports.

Fringe Benefits—A form of pay for the performance of services. Fringe benefits commonly include health insurance, group term life coverage, and non-wage compensation.

Indirect Costs—Costs not directly accountable to the project. Indirect costs include taxes, administration, personnel, and security costs.

Institutional Review Board (IRB)—A group that follows federal regulations, state laws, and institutional policy to review, monitor, and approve research in order to protect the ethical rights and privacy of the subjects involved.

Letter of Intent (LOI)—A notification to PCORI that an organization intends to apply. Submission of an LOI is a prerequisite to submitting an application.

Merit Review—A review of applications by qualified reviewers who read, score, and provide feedback on the applications.

Merit Review Officer (MRO)—A scientist who presides over a merit review panel and is responsible for coordinating and reporting the discussion of each application assigned to it. The MRO serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications reviewed.

Methodology Committee—Per PCORI’s authorizing legislation, the 17-member group working to develop and advance scientific methods in patient-centered outcomes research. The Methodology Committee is a subsetting committee that supports the PCORI Board of Governors.

Patients—Individuals who have or have had the condition under study; it may include patient surrogates or caregivers as well. It does not necessarily mean, but does not exclude, patient advocates or patient navigators.

Patient-Centered Outcomes Research (PCOR)—Research that helps people and their caregivers communicate and make informed healthcare decisions, while allowing their voices to be heard in assessing the value of healthcare options. This research answers patient-centered questions. A full definition can be found at [pcori.org/what-we-do/pcor](pcori.org/what-we-do/pcor).
PCORI Funding Center—The central location on PCORI’s website where applicants can access all templates, guidelines, information, and training needed to prepare and submit an application. Available at pcori.org/apply.

PCORI Online System—PCORI’s online application and management system, designed to facilitate the applicant’s submission of materials, and the activation of a contract through completion and closeout. Available at https://pcori.fluxx.io.

Principal Investigator (PI)—Lead scientist(s) for a research project. The primary Principal Investigator on a contract or application for funding who serves as PCORI’s primary point of contact for that contract or application.

Professional Profile—A profile of the experience and accomplishments of a person who will play a significant role on a PCORI-funded research project. Also see Biosketch.

Programmatic Review—A review of the scientific portion(s) of the application to ensure that it meets PCORI’s programmatic requirements.

Public Abstract—A summary of the research plan that is written for, and will be accessible to, a general, lay audience.

Randomized Controlled Trial (RCT)—An experiment in which participants are randomly allocated to receive one of two (or more) diagnostic, preventive, therapeutic, or palliative interventions and are then followed to determine the effects of the intervention.

Reasonable Costs—A cost may be considered reasonable if the nature of the goods or services acquired or applied is appropriate and justifiable. The amount involved reflects the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made.

Renewed Support—Approval of an additional funding period for the same project within the approved project period. The original agreement will remain in place and additional funds obligated near the end of each funding period. Any funds remaining on the contract prior to the new obligation will remain available for the recipient’s use.

Research Team—A group of people organized to function cooperatively to design and conduct research. For PCORI, teams should include patients and other stakeholders as key contributors to the research process.

Senior/Key Personnel—Individuals who contribute to the scientific development or execution of the project in a substantive and measurable way. The contribution is independent of financial compensation.

Stakeholders—Includes clinicians (e.g., physicians, nurses, pharmacists, counselors, and other providers of care and support services); patient-advocacy groups; community groups; researchers;
health-related associations; policy makers; and organizational providers, purchasers, payers, and industries for whom the results of the research will be relevant.

**Technical Abstract**—A summary of the research plan that is written for scientists and researchers.
Appendix 2: Allowable and Unallowable Costs

Acceptable uses of PCORI contract funds are those that directly support the proposed research project, including collection and analysis of data and obtaining relevant data sets. Overall, costs include salaries and fringe benefits for study investigators and other project staff (including patient and stakeholder partners), consultant fees, travel for investigator meetings (both in person and via teleconference), travel that is clearly project-related, supplies, equipment, subcontract agreements, and other direct research expenses, and indirect costs. Unallowable costs should not be included either as direct costs or through an indirect cost pool. The examples listed below are not considered allowable under PCORI contracts. These examples are not all-inclusive.

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