Winter 2015 Funding Cycle
PCORI Application Guidelines for Large Pragmatic Studies to Evaluate Patient-Centered Outcomes

Published August 18, 2014

These guidelines apply to the Winter 2015 Funding Cycle for Large Pragmatic Studies to Evaluate Patient-Centered Outcomes PCORI Funding Announcement (PFA). Funding announcements, templates, and other resources are available at pcori.org/PFA/large-pragmatic-studies-winter/. The Winter 2015 Funding Cycle closes February 3, 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 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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PCORI Funding Announcement Winter 2015 Cycle: Pragmatic Studies Application Guidelines
What Has Changed for the Winter 2015 Funding Cycle:

- New section on “Administrative Issues”
- 3.0 How to Apply: specified required EIN and DUNS number for registration; modified “Step 3: Begin Full Application Process”; added “Step 4: Complete Required Documents”
- Updated the Application Checklist to match the new requirements
- Added LOI Screening information; applicants must download the PFA-specific LOI and upload it into PCORI Online
- Updated the Technical Abstract, Public Abstract, and Project Narratives descriptions
  - There is no longer a Technical Abstract template.
- Updated Milestones language; deliverables must be every three months; updated deliverables examples
- Resubmission Letter is now a separate template/upload for the full application. Applicants must be invited to resubmit to this PFA. The Resubmission Letter has a two-page limit.
- Research Plan Template:
  - Research Strategy: increased to 20 pages, “Adherence to PCORI Methodology” has been moved to p. 13, under Research Plan Template; updated directions for Research Team and Environment (Section G); updated Engagement Plan (Section E)
    - Engagement Template (previously a standalone) has been consolidated with the Engagement Plan (Section E)
  - Updated “Dissemination and Implementation Potential”
    - In the template, added item C: “Describe how you will make study results available to study participants after you complete your analyses.”
  - “Reproducibility and Transparency of Research” renamed as “Replication and Reproducibility of Research and Data Sharing” with information; no change to the template
  - “Consortium Contractual Arrangements” increased the page limit to 10 pages (previously five pages)
- People and Places Template: updated Professional Profile/Biosketch; added a Patient/Stakeholder Partner Biosketch; added clarifying directions to the Project Performance Site(s) and Resources section
- Budget Template: all budget templates have been consolidated into one document; applicants must upload verification of fringe benefit rate policy; modified Indirect Costs (Section I)
- 6.0 Additional Requirements: added clarifying language to “Co-Funding”
- Added Appendix 1: Milestones Examples
- Added Appendix 2: Engagement Rubric (modified and moved into the Application Guidelines); renamed from “Patient and Family Engagement Rubric”
- Moved Allowable and Unallowable Costs to Appendix 3 (previously Appendix 1)
1.1 About These Guidelines

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

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 general application process. However, applicants to the Large Pragmatic Studies PFA should refer to the Pragmatic FAQs\(^2\) for information that is most relevant to their submission.
- Programmatic Inquiries: Please contact the PCORI Helpdesk via email (pfa@pcori.org), via 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. One week prior to an application deadline, 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/page 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 and/or administrative compliance questions.

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 and on budget, and that they will meet all milestones and deliverables. Therefore, applicants should submit realistic budgets and Research Plans without the expectation of receiving cost/no-cost extensions.

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\(^1\) Available at pcori.org/funding-opportunities/applicant-faqs
\(^2\) Available at http://www.pcori.org/funding-opportunities/funding-center/pragmatic-clinical-studies-faqs/
\(^3\) Available at pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications/
As part of its active portfolio management, PCORI provides programmatic oversight throughout the contract period. To review PCORI’s sample contract terms and conditions, see [PCORI Contract for Funded Research Projects](#).

### 2.0 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. 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, 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. Letters of Intent with scientific overlap or those that appear to be duplicate submissions will be removed during the LOI screening process.

### 3.0 How to Apply

Follow the instructions provided in these guidelines and in the [PCORI Online System](#) to submit an LOI and 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. Please refer to your specific PFA for more information regarding the review process of Letters of Intent and applications.

To submit an application or to register your organization in our system, you will need a Data Universal Numbering System (DUNS) number and an Employer Identification Number (EIN). If necessary, you can [apply for a DUNS number](#) and/or [an EIN](#). Individual consultants are not required to provide a DUNS number.

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4 Available at pcori.org/assets/2013/09/PCORI-PFA-Contract-for-Funded-Research-Projects.pdf
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 prior to completion of an application. Download the PFA-specific LOI template from the Funding Center. Please note that Letters of Intent that exceed the five-page limit, which includes all references, 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 into 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.

Step 3: Begin Full Application Process

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

Applicants will be notified by October 31, 2014, 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 navigation pane 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 Arial, Calibri, 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 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 into 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. Please ensure that the AO approves and submits the application to PCORI prior to the submission deadline. It is the responsibility of 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
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.

Any system or technical issues with the PCORI Online System that hinder the on-time submission of an application must be reported to PCORI prior to 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 specific PFA; and/or failure to complete all required user profiles by the submission deadline are not considered system issues and may result in rejection of your LOI or application. Please see PCORI’s Policy on Submission of Research Contract Applications\(^\text{\textsuperscript{11}}\) for further information.

5.0 What to Include

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.\(^\text{\textsuperscript{12}}\)

\(^{11}\) Available at pcori.org/funding-opportunities/funding-center/pcori-policy-on-submission-of-research-contract-applications

\(^{12}\) Available at pcori.org/apply
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<td>• Project Narratives</td>
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<tr>
<td>• Public Abstract</td>
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| **Key Personnel** | | As needed |

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<td>• Dissemination and Implementation Potential</td>
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<td>• Replication and Reproducibility of Research and Data Sharing</td>
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<td>• Protection of Human Subjects</td>
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<td>• Consortium Contractual Arrangements</td>
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<td>• References Cited</td>
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<td>• Appendix (optional)</td>
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<td>• Professional Profile/Biosketch</td>
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- Patient/Stakeholder Partner Biosketch 4 pages per individual
- Project/Performance Site(s) and Resources 15 pages

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<th>Budget Template</th>
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<td>Detailed Budget for Each Project Year (prime and subcontractors)</td>
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<td>Budget Summary for Entire Project</td>
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<td>Budget Justification (prime and subcontractors)</td>
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<td>Federally Negotiated or Independently Audited Indirect Cost Rate Letter (prime and subcontractors)</td>
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<td>Fringe Benefit Rate Policy Verification Document (prime and subcontractors)</td>
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<td>Dissemination and Implementation Agreement(s)</td>
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Letter of Intent (LOI)

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

Upon receipt of Letters of Intent, 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 30 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.
   - 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 prior to 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, or consultant.

B. Activities
   - Assumes responsibility and accountability for research execution, organization conduct, and compliance
   - Manages day-to-day operation of the research and project
   - Acts as lead research representative of the organization/institution
   - Serves as PCORI lead point of contact

Administrative Official (AO)

A. Description
   - Responsible for matters related to the award and administration of the contract
   - 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
• Manages contract activation, renewals, milestones, and additional required materials
• Oversees submission of the contract activation, renewals, milestones, and additional required materials
• Certifies 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
• Completes and certifies the required yearly expenditure reports
• Executes accounting of contract funds and submission of invoices and payment details

PFA-Specific LOI Template

Download the Large Pragmatic Studies LOI Template from the Funding Center. Provide a thorough description that allows the scientific community to understand the project, including its aims and study design, without reviewing the full application. Refer to the PFA for specific instructions on how to complete the LOI. You must answer all questions listed in the LOI Template. Please also note the following:

• All references should be included as in-text citations or footnotes within the five-page limit. **Do not** submit an additional page of references. Letters of Intent that exceed the five-page limit will not be reviewed.
• Do not upload additional documents as part of your LOI, to include letters of endorsement or support, as they are not requested at this stage. Their inclusion will result in LOI rejection without review.
• If you are resubmitting your LOI, please highlight or bold the changes that you have made since your original submission. Do not include the Resubmission Letter Template or exceed the five-page limit.
• For the budget justification on total direct costs, an answer such as “will not exceed $10 million” will be deemed non-responsive because it lacks justification.

Letters of Intent are qualitatively evaluated on the following criteria:

• Importance and relevance of the topics to PCORI priorities, as evidenced by critical gaps identified by clinical guidelines developers and/or recent relevant systematic reviews
• A sufficient size and scope that it will have a significant impact on patient outcomes and/or healthcare practices
• Clarity and credibility of applicants’ responses to the LOI questions, as well as justification of the need for a large pragmatic study, including rationale for the estimated sample size, citing published estimates including effect sizes and standard deviations, and whether the sample size is sufficiently large to permit a valid and rigorous comparative analysis of important subgroups
• Prior relevant experience
• Programmatic fit and balance, taking into consideration whether the study proposed significantly overlaps with previously funded studies or concurrent proposals or, conversely, whether the proposal fills a gap in the portfolio of proposals with certain characteristics, including disease category, topics, priority population, and methodologies

Note: Letters of Intent are not assigned scores.

For those rare circumstances when the estimated total direct costs exceed $10 million, please provide in your LOI a detailed justification that ties the extra expense to the success of the project. Please note that any request for a project period longer than five years will be denied.

Please answer all of the questions in the LOI Template. To submit an LOI, save the completed PFA-specific LOI as a PDF, upload it into the PCORI Online System, and complete the required fields. The deadline for LOI submission is October 1, 2014, by 5:00 p.m. (ET).

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 on or before October 31, 2014.

Full Application Requirements

⚠️ The following sections are applicable only if you have been invited to submit a full application. Applicants will be notified of this decision via email by October 31, 2014.

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

Enter into the PCORI Online System. Provide a technical abstract that summarizes your research strategy. 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:
  o Overall study design
  o Main components of the intervention and comparator(s)
  o Study population (source, inclusion criteria, demographic information, clinical status, target sample size by arm)
  o Primary/secondary outcomes
  o Analytic methods

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
• How patients and other stakeholder partners will help to make the project successful

Keep in mind that this summary should be comprehensible to a variety of audiences and will be reviewed by patient and stakeholder reviewers during Merit Review. Public abstracts from proposals that are awarded a contract will be posted on PCORI’s website.

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):

• Name the study comparators
• State why this comparison is important
• Number of arms in proposed trial, if applicable
• Length of follow-up after intervention, if applicable
• Primary/secondary outcome
• 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.
Key Personnel

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-investigator or consultant).
- Investigators may serve as 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-investigator or consultant.
- PCORI identifies key personnel as any individual who 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.
- 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 are considered key personnel.
- Anyone who could be replaced without significantly affecting the direction or conduct of the project should not be listed as key personnel.
- In your application, you 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 awarded, PCORI will need to approve additional and/or replacement key personnel (listed in the submitted application) during contract negotiation and post-contract execution, as detailed in contract terms and conditions.

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. Exclude any PCORI reporting requirements, such as semiannual progress or financial reports.

The following milestones should be included, as appropriate:

- Institutional Review Board (IRB) approval
• Minutes of data and safety monitoring board (DSMB) meetings
• Study registration at ClinicalTrials.gov
• Final study protocol
• Start of recruitment (indicate target total)
• Completion of 25 percent of recruitment
• Completion of 50 percent of recruitment
• Completion of 75 percent of recruitment
• Completion of recruitment
• Questionnaire/tool
• Interim analyses
• Final analyses
• De-identified datasets, analytic datasets, and codebook
• Interim progress reports
• Final report
• Copies of manuscripts accepted for publication

You must include at least one deliverable 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. If your application is awarded a contract, the required deliverables will be included in your final agreement.

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:

• Abstracts accepted or presentations made
• Copies of papers 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 from patient/stakeholder partner organizations, highlighting the project
• 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
• 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 and attached to a timeline; whereas, the milestones described within the Research Strategy should include overall goals that will be accomplished during the proposed study.
Resubmission Letter

PCORI receives hundreds of applications for each PFA every funding cycle. Funding on the first attempt is difficult, but not impossible. If an application does not result in funding, a PI or organization may resubmit an application for a specific PFA. We do not limit the number of resubmissions; however, applicants wishing to reapply must submit a new LOI. Please note that your LOI or application is not considered a resubmission unless the full application proceeded through PCORI Merit Review.

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

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, 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) Patient Population, (D) Study Design or Approach, (E) Engagement Plan, (F) Project Milestones and Timeline, and (G) Research Team and Environment. Please provide all the information requested, as outlined in the template.

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

Adherence to PCORI Methodology Standards

Applicants are required to adhere to the PCORI Methodology Standards\(^\text{13}\) 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 five 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

\(^{13}\) Available at pcors.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf
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. These five categories are:

- 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. 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 such factors as differential adherence to chosen treatments (or participation in intervention programs) that could result in differences in the effectiveness of the alternative interventions being compared in clinical populations.

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. After each relevant standard, please provide a brief statement indicating how your proposed research demonstrates adherence to the standard. To help reviewers quickly identify the adherence to a particular standard, applicants must cite each Methodology Standard within the proposal as the standard is being addressed. For example, when applicants describe the need for their proposed study within the Background section, they should indicate the particular standard for Identify Gaps in Evidence in parenthesis such as (RQ-1).

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 G) component, applicants should describe:

- How and why those research sites were selected
- How they tie back to the research project
- The resources, facilities, support, and collaborations available to ensure the project’s success
- Ways in which the project will benefit from unique features of the research environment or community involvement, or will employ useful collaborative arrangements
- How 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

The Engagement Plan (Section E) follows PCORI’s Engagement Rubric, which should be used as a guide. Before completing this section of the Research Strategy, applicants are encouraged to review the rubric, PCORI’s PCOR Engagement Principles (noted in the rubric), and PCORI’s Methodology Standards Associated with Patient-Centeredness.  

Applicants must outline how patients and other stakeholders will participate as partners in various phases of the proposed research. To assist applicants, PCORI provides sample 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 may include additional innovative approaches.

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 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 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 and the 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 any implementation agreement with the sponsoring organization confirming that successful interventions will be implemented by

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14 Available at pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf
15 Available at pcori.org/assets/2013/11/PCORI-Sample-Engagement-Plans.pdf
16 Available at pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf
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.

PCORI is committed to maximizing the utility and usability of data collected in our funded projects. This is essential to building confidence in the accuracy of these findings. PCORI supports 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. Please propose a method for sharing data and appropriate documentation upon request.

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 datasets. It applies to all applicants, regardless of the size of the project.

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 along with the first 12-month progress report, and always within three 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.

**Reproduction of research findings:** This requirement refers to reproducing research findings in the same dataset 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 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 utilize the data for additional/secondary analysis and make the data and documentation available upon request.

The data-sharing plan must:
• State that a complete, cleaned, de-identified copy of the final dataset used in conducting the final analyses will be made available.
• Propose a method by which investigators will make this dataset 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. For additional guidance, refer to Section 5.0 “Human Subjects Research Policy”17 from the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, issued by the US 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 10 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 inter-organizational 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,

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17 Available at grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#5_4_IRB_Approval
list the full bibliographical citation of each reference cited. 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. 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 four pages per individual) for each person listed as key personnel (including PI, co-investigator, or other significant contributors), copying the tables provided in this section, as needed. Please note that you may submit an 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 four pages. PCORI is especially interested to learn how each individual’s previous experience, past performance, and training in the field of PCOR has prepared them 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 for all sites combined) 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

Please complete all required sections and upload the Budget Template into 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 is for two 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 only be used after all the personnel rows for each budget detail year have been completed. Following the example of a two-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 3: 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 levels of effort, even if they are not requesting salary support. Please list the base salary for such persons 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/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 an employee of the applicant organization or under a subcontract agreement as a member 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 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/or 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 and/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 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
necessary for achieving programmatic objectives.

E. 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.
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 five 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 projects that are funded.

G. 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.

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.
• 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 only 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.
• Submit a copy of the applicant’s and each subcontractor’s federally negotiated or independently audited indirect cost rate letter. Include these copies after the Budget Justification, in a single file of budget materials uploaded to PCORI Online.

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 3 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 justify the costs associated with inpatient and outpatient care. Also, 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 amounts of funding and the period during which it will be available. Use continuation pages as needed.
**Letters of Support**

Letters of Support are required with the full application. Combine and save all Letters of Support as one PDF file and upload into the PCORI Online System. Letters of Support are required from all key personnel, addressed to the PI or institution, to demonstrate the commitment of key personnel (e.g., PI, co-investigators, consultants, patient and stakeholder partners, stakeholder organizations, subcontractor sites). A letter from the leadership of your department or organization affirming support to disseminate and implement research findings, if appropriate, is also highly recommended. Consultants should also write Letters of Support, verifying the work to be performed and the negotiated rate. There is no limit on the number of Letters of Support submitted.

Letters of Support are not required from personnel, such as research assistants, who are not contributing in a substantive, measurable way to the scientific development or execution of the project.

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.
6.0 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 National Institutes of Health (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 and FAQs are available from the NIH website.  

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. PIs are required to use the following naming convention: “PCORI-PCORI application number” (e.g., PCORI-XXXX-XXXXX). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the NIH database (see “Data Element Definitions”) are required to register. Please also list your registration as a milestone in your application.

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 applicability and implementation of the Privacy Rule reside with the researcher and his/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 upon milestones at any time during the contract. Proposed milestones should be presented in the application,

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18 Available at grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html
19 Available at prsinfo.clinicaltrials.gov
20 Available at hhs.gov/ocr
21 Available at grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html
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.

Of 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 contact, 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 in order to facilitate availability of data and samples.
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 assure 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:

- Institutional Review Board (IRB) approval
- Adherence to Methodology Standards
- Minutes of data and safety monitoring board (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 analyses
- Final analyses
- Interim Progress Reports, every six months
- Final Report
- Manuscript submission or notification of publications
- Datasets, analytic datasets, and codebook
- Copies of published manuscripts
- Engagement updates, every six months, noting specific engagement activities that patients/stakeholders participated in during the reporting time period. Examples of engagement activities include describing how patient and stakeholders were involved in the development of interventions 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 not be relevant (e.g., recruitment milestones may not be relevant for observational studies).
Appendix 2: Engagement Rubric

General Guidance

- The term “patient partners” is intended to include patients (those with lived experience), family members, caregivers, and the organizations that represent them that are representative of the population of interest in a particular study.

- Stakeholder partners may include members of constituencies based on professional, rather than personal, experience. For example, these constituencies can include: clinicians, purchasers, payers, industry, hospitals/health systems, policy makers, training institutions, and researchers. Some individuals may fit into several categories.

- The Engagement Plan is intended to provide guidance to applicants, merit reviewers, awardees, and Engagement/Program Officers (for creating milestones and monitoring projects) regarding engagement in the conduct of research. It is not intended to be comprehensive or prescriptive. Instead, it provides a variety of options to incorporate engagement, where relevant, into the research process. Applicants can choose to include some, but not all, activities and can include additional innovative approaches not listed here. This guidance is based on the promising practices identified in the first four rounds of PCORI awards. It is also consistent with PCORI’s Methodology Standards for patient-centeredness and PCOR Engagement Principles.

- The Engagement Plan includes four sections: Planning the Study, Conducting the Study, Disseminating the Study Results, and PCOR Engagement Principles.

- The Engagement Plan is designed to help applicants “show their work” when describing how input from patient and stakeholder partners will be incorporated throughout the entire research process.

- Include patient and stakeholder partners in all relevant sections of the application, such as the biosketches, the budget, and the dissemination and implementation assessment.

- Avoid relying entirely on patient partners who have dual roles on the project (e.g., relying on stakeholders or researchers who also happen to be patients). Including at least one patient partner who has no other role on the project is important.
Engagement Rubric: Guidance for Completing Each Section of the Engagement Plan

Each numbered section below corresponds to a numbered section in the Engagement Plan.

1. **PLANNING THE STUDY:** Describe how patient and stakeholder partners will participate in study planning and design.

   As you fill out Section 1 of your Engagement Plan, refer to the information below.

   **Potential activities include:**
   - Identifying the topic and developing the research question to be studied
   - Creating the intervention
   - Identifying the comparators
   - Defining the characteristics of study participants

   **Examples of how to demonstrate this in your proposal:**
   - Provide Letters of Support from patient and stakeholder partners that clearly describe the origin of the study topic and the role of the patient partners in defining the question, outcomes, comparators, and goals/outcomes, etc.
   - Describe meetings, focus groups, and other events convened to engage patient and stakeholder partners in the planning of your study, and include key guidance on study design offered by your patient and stakeholder partners.
   - Discuss how the engagement of patients and other stakeholders helped to refine your study’s research question, outcomes, and comparators.

   **Real-World Examples:**
   - *Epilepsy study:* The patients and parents of patients with epilepsy pose the question: Which anti-epileptic drugs best preserve sufficient cognition to go to work or school and to function normally, while still preventing seizures adequately?
   - *Diabetes study:* Clinicians who reviewed the initial study design indicated that clinical practice is quite variable and suggested that a three-arm approach would be more appropriate for the study. The study design was revised accordingly.
   - *Cancer study:* Patient partners determine that all women with breast cancer would be eligible versus only women who had completed active treatment.

2. **CONDUCTING THE STUDY:** Describe how patient and stakeholder partners will participate in the study conduct.

   As you fill out Section 2 of your Engagement Plan, refer to the information below.

   **Potential activities include:**
   - Participating in and monitoring the conduct of the project
   - Assisting with the recruitment of study participants
• Assisting with data collection and data analysis
• Participating in the evaluation of patient and stakeholder engagement

Examples of how to demonstrate this in your proposal:
• Provide Letters of Support from patient and stakeholder partners that clearly describe the role of these partners in conducting and monitoring the study.
• Clearly articulate in the application the roles of the patient and stakeholders partners in each component of study conduct (e.g., helping to draft survey tools and focus group questions, reviewing participant materials for readability), including the dissemination and implementation assessment.
• Include a plan for “check-ins” with patient and stakeholder partners to monitor their perceptions of the extent to which (a) they are meaningfully involved in the study and (b) their participation is contributing to the study. Plan similar “check-ins” with other research team members to monitor and evaluate their engagement.

Real-World Examples:
  o Chronic pain study: The informed consent document is developed with patient partners to make it understandable to study participants.
  o Depression study: Patient advocacy groups assist with recruitment through their patient networks—the “book club” model.
  o Preeclampsia study: The study team will recruit via a national network of local health departments and community health centers, as well as a preeclampsia advocacy group’s website and Facebook page.

3. DISSEMINATING THE STUDY RESULTS: Describe how patient and stakeholder partners will be involved in plans to disseminate study findings, and ensure that findings are communicated in understandable, usable ways.

As you fill out Section 3 of your Engagement Plan, refer to the information below.

Potential activities include:
• Identifying partner organizations for dissemination
• Planning dissemination efforts
• Participating in dissemination efforts, such as the authoring of manuscripts and the presentation of study findings

Examples of how to demonstrate this in your proposal:
• Clearly identify the role of patient and stakeholder partners in planning the dissemination of the study’s findings.
• Include patient and stakeholder partners on a project committee that will oversee dissemination.
• Include patient and stakeholder partners in dissemination and implementation assessment.

**Real-World Examples:**

- **Trauma study:** The research team will convene a policy summit with relevant professional societies during the third year of the study to focus on identifying ways to speed the implementation of findings into practice.
- **Cardiac study:** A Patient Dissemination Board is helping to craft the dissemination plan and advise the research team on how to best share study findings.
- **Chronic pain study:** Patient partners co-author manuscripts, present at scientific and lay conferences, and share study findings through their networks.

4. **PCOR ENGAGEMENT PRINCIPLES:**

As you fill out Section 4 of your Engagement Plan, refer to the information under each principle or set of principles below.

• **Reciprocal Relationships:** *Describe the roles and decision-making authority of all research partners, including patient and stakeholder partners.*

**Examples of how to demonstrate this in your proposal:**

- Explain how decisions are made within your research team, including the decision-making authority that patient and stakeholder partners have and in what circumstances.
- Include patient and stakeholder partners as key personnel, with biosketches illustrating how the skills and experiences of the patient partners prepare them to function effectively in this role.

• **Co-learning:** *Describe plans to ensure that patient and stakeholder partners will understand the research process and researchers will understand patient engagement and patient-centeredness.*

**Examples of how to demonstrate this in your proposal:**

- Training and educational opportunities are provided, such as patient and stakeholder partner training in human subjects protection.
- Training is provided by patient advocacy organizations, patients/survivors, and clinicians/caregivers for the researchers providing the intervention (e.g., training in better communication with patients, led by patient instructors).

• **Partnership:** *Describe how the time and contributions of patient partners are valued and demonstrated in fair financial compensation, as well as reasonable and thoughtful time commitment requests.*

**Examples of how to demonstrate this in your proposal:**
• Compensation for patient partners is included in the budget at an appropriate level.
• Meetings are held at a time and in a location that accommodates patient and stakeholder partners. Compensation is provided for transportation and related expenses.
• Accommodations are made to encourage the full engagement of a diversity of patient and stakeholder partners, and the research team includes a diversity of members. For example, a project that focuses on Latino health should consider including Spanish-speaking individuals on the research team and may wish to conduct patient and stakeholder meetings in both Spanish and English.

**Trust, Transparency, Honesty:** Describe how major decisions are made inclusively and information is shared readily with all research partners, including patient and stakeholder partners; patient and stakeholder partners and research partners express commitment to open and honest communication with one another; and the study team commits to communicate study findings to the community studied in a meaningful and usable way.

**Examples of how to demonstrate this in your proposal:**
• Commitments to trust, transparency, and honesty are stated in many applications. These commitments can be demonstrated through describing how the research team—including patient and stakeholder partners—will communicate with each other, the frequency of this communication, the roles of each member of the research team, and the decision-making authority of each member of the research team.
Appendix 3: 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, travel that is clearly project-related, supplies, equipment, subcontracts, other direct research expenses, and indirect costs.

- PCORI will not cover costs for interventions that are being compared in the proposed study.
- PCORI will consider covering costs for ancillary tasks necessary in the implementation or monitoring of a clinical intervention or strategy as part of the research program. Examples include costs for obtaining consent, collecting data, or monitoring that would not normally be performed in routine care.
- Support for the study by the involved healthcare delivery systems must be documented.
- Costs for study interventions must be covered by delivery system, payer, manufacturer, or developer of the intervention.
- The willingness of one or more of the stakeholder groups to cover treatment costs, even when one of the proposed intervention arms is not currently covered by insurance, will be taken as strong endorsement of the study by the health system or payer, and evidence of increased likelihood that they will implement or use the study's findings if definitive.
- Such material support for the study by host delivery system, payer, or developer should be discussed in the application.
- In exceptional cases, PCORI may consider coverage of the co-payment or coinsurance costs of participating patients when that is necessary to preserve blinding in a study or to ensure access to the study for vulnerable populations.

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 subject to budgetary review and successful contract negotiation. The actual award amount may vary.

Unallowable costs should not be included as direct costs.