



Cycle 2 2016 Funding Cycle

PCORI Application Guidelines for Pragmatic Clinical Studies To Evaluate Patient-Centered Outcomes

Published April 4, 2016
Updated June 23, 2016

These guidelines apply to the Cycle 2 2016 Funding Cycle for Pragmatic Studies to Evaluate Patient-Centered Outcomes PCORI Funding Announcement (PFA). Funding announcements, templates, and other resources are available at <http://www.pcori.org/Cycle-2-2016-pragmatic-studies/>. The Cycle 2 2016 Funding Cycle closes August 8, 2016, at 5 p.m. (ET).



About PCORI

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

PCORI was authorized by Congress in 2010 as a nonprofit, nongovernmental organization. PCORI's purpose, as defined by our authorizing legislation, is to help patients, 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."

Patient-Centered Outcomes Research Institute
1828 L St., NW, Suite 900
Washington, DC 20036
Phone: 202-827-7700
Fax: 202-355-9558
Email: info@pcori.org

Follow us on Twitter: [@PCORI](https://twitter.com/PCORI)



What Has Changed for Cycle 2 2016 Funding Cycle:

- Resubmission Policy and Letter section updated
- New dual-PI plan policy created
- New Leadership Plan Template created
- Updated language in the Detailed Peer Review Budget for Peer-Review-Related Costs section

CLOSED



Table of Contents

I. About These Guidelines	1
Administrative Issues	1
Funding Mechanism.....	2
II. Who Can Apply	2
III. How To Apply	2
IV. When To Apply	5
V. What To Include	5
Application Checklist.....	6
Letter of Intent (LOI)	8
PI and Contact Information.....	8
Principal Investigator (PI)	8
Administrative Official (AO)	8
Financial Official (FO)	9
PFA-Specific LOI Template	9
Application Requirements	10
PI and Contact Information.....	11
Project Information.....	11
Technical Abstract.....	11
Project Narratives	11
Public Abstract	12
Key Personnel.....	12
Milestones.....	13
Resubmission Policy and Letter	15
Research Plan Template.....	15
Research Strategy	15
Adherence to PCORI Methodology Standards.....	16
Justification of Assumptions	18
Dissemination and Implementation Potential.....	18
Replication and Reproducibility of Research and Data Sharing.....	19
Protection of Human Subjects	20



Consortium Contractual Arrangements.....	21
References Cited	21
Appendix (Optional).....	21
People and Places Template	22
Professional Profile/Biosketch and Patient/Stakeholder Partner Biosketch.....	22
Project Performance Site(s) and Resources.....	22
Leadership Plan (required if proposing a dual-PI application).....	22
Budget Template.....	23
Detailed Research Project Budget for Each Year of the Research Project Period.....	23
Detailed Peer Review Budget for Peer-Review-Related Costs	27
Budget Summary for Entire Project	28
Budget Justification.....	28
Letters of Support	29
VI. Additional Requirements	30
Required Education of Key Personnel on the Protection of Human Subject Participants	30
PCORI Public Access Policy.....	30
Registering Clinical Trials	30
Standards for Privacy of Individually Identifiable Health Information	31
Award Funding Conditions.....	31
Co-funding.....	31
Dissemination and Data Sharing	31
Appendix 1: Example Milestones	32
Appendix 2: Allowable and Unallowable Costs	34
Appendix 3: Administrative Actions	37



I. About These Guidelines

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

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

- PCORI's [Applicant FAQs](#)¹ cover common questions about PCORI and the general application process. However, applicants to the Pragmatic Studies PFA should refer to the [Pragmatic Studies FAQs](#)² for information that is most relevant to their submission.
- Visit PCORI's [Help Center](#)³ for additional applicant resources.
 - **Programmatic Inquiries:** Please contact the PCORI Helpdesk via email (sciencequestions@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 within three business days before a Letter of Intent (LOI) or application deadline.
 - **For Administrative, Financial, or Technical Inquiries:** Please contact the PCORI Helpdesk at pfa@pcori.org. PCORI will provide a response within two business days. Please note that during the week of the application deadline, response times may exceed two business days. Applicants may also call the PCORI Helpdesk (202-627-1885).

It is the applicant's responsibility to submit the application on or before the deadline. Please refer to [PCORI's Policy on Submission of Research Contract Applications](#).⁴

Administrative Issues

To ensure a thorough and competitive review process, PCORI strictly enforces the formatting and administrative compliance guidelines outlined in the PFAs, FAQs, and Application Guidelines. Applicants who fail to submit the required documents or who exceed the stated page limits may be rejected from the merit review process.

All rejection decisions made by the Contracts Management and Administration department are final. Please email pfa@pcori.org with any formatting or administrative compliance questions to ensure that your LOI or application will not be deemed noncompliant once submitted to PCORI. See [Appendix 3: Administrative Actions](#).

¹ Available at <http://www.pcori.org/content/faqs-applicants/>.

² Available at <http://www.pcori.org/funding-opportunities/how-apply/have-question/pragmatic-studies-evaluate-patient-centered-outcomes/>.

³ Available at <http://help.pcori.org/hc/en-us/>.

⁴ Available at <http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/>.



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

Funding Mechanism

PCORI issues contracts, not grants, to fund and administer meritorious research. Under these contracts, PCORI funds projects that demonstrate the highest probability that they will finish on time, on budget, and 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 term period. To review PCORI's sample contract terms and conditions, see [PCORI Contract for Funded Research Projects](#).⁵

II. Who Can Apply

Applications may be submitted by any private-sector research organization, including any nonprofit or for-profit organization; any public-sector research organization, including any university or college hospital or healthcare system; a laboratory or manufacturer; or a unit of local, state, or federal government. The Internal Revenue Service must recognize all US applicant organizations. 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) can only submit one LOI per PFA. However, an individual listed as a PI on one LOI may be listed and serve in another role (e.g., co-investigator, consultant) on other LOIs within the same PFA during the same cycle. A PI may submit multiple LOIs to different program PFAs in a cycle, but they must ensure that the research topics/projects are not similar. If a PI submits an LOI to multiple program PFAs, LOIs that show scientific overlap or that appear to be duplicate submissions will be disqualified. PCORI will contact the PI and give them an opportunity to choose which PFA they would like to apply to. This applies to single and dual-PI submissions.

III. How To Apply

Follow the instructions provided in these guidelines and in [PCORI Online](#)⁶ to submit an LOI and application, including all required documents. All required documents must be submitted through PCORI Online; failure to do so may result in the removal of the application from the review process. Please

⁵ Available at pcori.org/assets/2013/09/PCORI-PFA-Contract-for-Funded-Research-Projects.pdf/.

⁶ Available at <https://pcori.fluxx.io/>.



refer to your specific PFA for more information regarding the review process of LOIs 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](#)⁷ or [an EIN](#).⁸ Individual consultants are not required to provide a DUNS number.



Step 1: Register

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



Step 2: Submit a Letter of Intent (LOI)

An LOI is required for new and resubmitted applications, and it must be submitted *before* completion of an application. Download the PFA-specific LOI template from the [Funding Center](#). Please note that LOIs that exceed the five-page limit, which includes all references, will not be reviewed. For formatting instructions, please reference [step 4](#).

To submit an LOI you must go into [PCORI Online](#), complete the required fields, and upload the completed PFA-specific LOI into PCORI Online. For detailed instructions on how to navigate the system, please see the [PCORI Online System User Manual: Start a Letter of Intent](#).⁹



Step 3: Initiate Application Process

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

Applicants will be notified by **June 10, 2016** as to whether or not they are invited to submit a full application.

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

You can return to complete your application as many times as needed. However, to save your work

⁷ Available at <https://www.dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number//>.

⁸ Available at [http://www.irs.gov/Businesses/Small-Businesses-&-Self-Employed/Apply-for-an-Employer-Identification-Number-\(EIN\)-Online/](http://www.irs.gov/Businesses/Small-Businesses-&-Self-Employed/Apply-for-an-Employer-Identification-Number-(EIN)-Online/).

⁹ Available at <http://www.pcori.org/sites/default/files/PCORI-Online-Start-LOI.pdf/>.



before exiting, you must go to the Save and Review button at the bottom of the page.



Step 4: Format and Complete Required Documents

Required templates are available in the [PCORI Funding Center](#).¹⁰ Be sure to download the correct PFA-specific templates because they may vary between PFA and cycle. Keep the following in mind:

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

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 a half-inch from the edge of the page.
- Font: Use Calibri size 11 for the main body of the text. Figures, tables, and captions may be in smaller type (size 8 font).
- Page Numbers: Each page must be numbered consecutively for each PDF upload. Each section of an upload should begin with page 1.
- Spacing: Use single spacing.
- References: Use American Medical Association (AMA) style citation.



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.¹¹ To upload, select the name of the required document from the dropdown list. For detailed instructions, refer to the Templates and Uploads section of the [PCORI Online User Manual: Submitting an Application](#).



Step 6: Submit for Authorization

Once all required information has been completed and uploaded, click "Submit to AO" to forward the

¹⁰ Available at <http://www.pcori.org/funding-opportunities/>.

¹¹ See adobe.com for more information on Adobe Acrobat Professional.



application to your Administrative Official (AO) to authorize and submit. The AO must approve and submit the final application for official submission to PCORI prior to the deadline. **The PI should notify the AO when the application is ready for review, AO approval, and submission. The PI and the AO may not be the same individual.** Both the AO and the PI will receive emails confirming that PCORI has received the application.

IV. When To Apply

Deadlines for each funding cycle are noted in the PCORI Funding Center and the PFA. System or technical issues with PCORI Online affecting on-time submission of an application must be reported to PCORI before the specified deadline. Problems with computer systems at the applicant's organization or failure to follow instructions in PCORI Online, PCORI Application Guidelines, or a specific PFA are not valid issues warranting consideration of a deadline extension. Please see PCORI's [Policy on Submission of Research Contract Applications](#)¹² for complete information.

V. What To Include



Note: Only applicants selected to submit an application should begin the application process. You will be notified by **June 10, 2016** as to whether or not you have been invited to submit an application.

Applicants are encouraged to review this entire section and to print and complete the provided Application Checklist to ensure that the LOI and application are submitted correctly and completely. All required templates can be downloaded from the [PCORI Funding Center](#).¹³

¹² Available at <http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/>.

¹³ Available at <http://www.pcori.org/funding-opportunities/>.



Application Checklist

Letter of Intent	Submission Method	Length/Limit
<input type="checkbox"/> Letter of Intent		
<ul style="list-style-type: none"> PI and Contact Information 	Enter into PCORI Online	N/A
<ul style="list-style-type: none"> LOI Template 	Save file as "PI LastName_(last five digits of Request ID)_LOI.pdf" and upload	5 pages
Application	Submission Method	Length/Limit
<input type="checkbox"/> PI and Contact Information	Entered previously as part of the LOI; review and modify if needed	N/A
<input type="checkbox"/> Project Information		
<ul style="list-style-type: none"> Technical Abstract 	Enter into PCORI Online	6,000 characters/spaces
<ul style="list-style-type: none"> Public Abstract 	Enter into PCORI Online	3,000 characters/spaces
<ul style="list-style-type: none"> Project Narratives 	Enter into PCORI Online	Refer to PCORI Online
<input type="checkbox"/> Key Personnel	Enter into PCORI Online	As needed
<input type="checkbox"/> Milestones/Deliverables Template	Save file as "Milestones_PI LastName.pdf" and upload	3 pages
<input type="checkbox"/> Resubmission Letter (if appropriate)	Save file as "Resubmission_PI LastName.pdf" and upload	2 pages
<input type="checkbox"/> Research Plan Template	Save file as "ResearchPlan_PI LastName.pdf" and upload as a single file	As noted below
<ul style="list-style-type: none"> Research Strategy 		20 pages
<ul style="list-style-type: none"> Dissemination and Implementation Potential 		2 pages
<ul style="list-style-type: none"> Replication and Reproducibility of Research and Data Sharing 		2 pages
<ul style="list-style-type: none"> Protection of Human Subjects 		5 pages
<ul style="list-style-type: none"> Consortium Contractual Arrangements 		10 pages
<ul style="list-style-type: none"> References Cited 		10 pages
<ul style="list-style-type: none"> Appendix (optional) 		10 pages
<input type="checkbox"/> People and Places Template	Save as "PeoplePlaces_PI LastName.pdf" and upload	As noted below
<ul style="list-style-type: none"> Leadership Plan Template (required if proposing dual-PI application) 		5 pages
<ul style="list-style-type: none"> Professional Profile/Biosketch 		5 pages per individual

	<ul style="list-style-type: none"> • Patient/Stakeholder Partner Biosketch 	5 pages per individual
	<ul style="list-style-type: none"> • Project/Performance Site(s) and Resources 	15 pages
<input type="checkbox"/>	Budget Template Combine and save as "Budget_PI LastName.pdf" and upload	As needed
	<ul style="list-style-type: none"> • Detailed Budget for Each Project Year (prime and subcontractors) • Budget Summary for Entire Project (prime and subcontractors) • Budget Justification (prime and subcontractors) • Federally Negotiated or Independently Audited Indirect Cost Rate Letter (prime contractor) • Fringe Benefit Rate Policy Verification Document (prime contractor) 	
<input type="checkbox"/>	Letters of Support Save as "Letters_PI LastName.pdf" and upload as a single file	As needed
	<ul style="list-style-type: none"> • Letters of Support Table • Letters of Support 	

CLOSED



Letter of Intent (LOI)

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

Upon receipt of LOIs, PCORI program staff will review them for programmatic fit and potential overlap with existing projects in the portfolio. An applicant whose LOI does not meet program areas of interest, or whose LOI 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 by June 10, 2016.

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

- If electing to submit an application with two PIs, one PI must be designated as the Contact PI. The Contact PI is responsible for submitting the application and will serve as PCORI's primary point of contact for all communication. **No more than two PIs can be named on an application.**
- The PI(s) is responsible for the project's engagement, scientific, or technical aspects, as well as the project's peer-review-related activities.
- The Contact PI's institution must be the primary institution for the award.
- PIs can participate in other applications (from the same or another organization) in the same or a different role, such as co-investigator (co-I) or consultant. Refer to the [Who Can Apply](#) section for specific instructions.

B. Activities

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

Administrative Official (AO)



A. Description

- The AO is responsible for matters related to the award and the administration of the contract.
- The AO cannot be the PI.
- The AO's signature certifies that the organization 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

- The FO is responsible for required financial reporting.

B. Activities

- Completes and certifies expenditure reports on behalf of the organization.
- Executes accounting of contract funds and submission of invoices and payment details.

PFA-Specific LOI Template

Download the [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 note the following in particular:

- All references should be included as footnotes within the five-page limit using the American Medical Association (AMA) citation style. **Do not** submit an additional page of references. LOIs that exceed the five-page limit will not be reviewed.
- Do not upload additional documents, such as letters of endorsement or support, as part of your LOI, 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 boldface 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 nonresponsive because it lacks justification.



LOIs are qualitatively evaluated on the following criteria:

- Importance and relevance of the topics to PCORI priorities, as evidenced by critical gaps in decision making identified by clinical guidelines developers and/or recent relevant systematic reviews
- A sufficient size and scope to create 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 the rationale for the estimated sample size, citing published estimates that include effect sizes and standard deviations and explaining 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 proposed study significantly overlaps with previously funded studies or concurrent applications or, conversely, whether the application fills a gap in the portfolio of proposals with certain characteristics, including disease category, topics, priority population, and methodologies

Note: LOIs 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.

To submit an LOI, save the completed PFA-specific LOI as a PDF. Label your LOI file using the following nomenclature: "PI Last Name_(last five digits of Request ID)_LOI.pdf." A request ID number will be automatically generated once the LOI has been saved. When you select the Save and Review button, the new request ID number will be visible at the top of the webpage in [PCORI Online](#).

Application Requirements



Note: The following sections are applicable only if you have been invited to submit an application. Applicants will be notified of this decision via email by December 18, 2015.

You are invited to submit an application based on the information provided in the LOI. Any changes to the following require PCORI's approval:

- Principal Investigator (Contact PI and PI #2)
- Institution
- Study design
- Research question(s)
- Specific aims



- Comparators

If you need to change any of this information or have any questions, email pfa@pcori.org.

PI and Contact Information

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

Project Information

Enter the following information directly into PCORI Online.

Technical Abstract

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:
 - Overall study design
 - Main components of the intervention and comparator(s)
 - Study population (source, inclusion criteria, demographic information, clinical status, target sample size by arm)
 - Primary/secondary outcomes
 - Analytic methods

Project Narratives

PCORI may use these responses for programmatic assessment, 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, you must fill in the following text boxes (*refer to PCORI Online for character limits, including spaces, for each of the bullets listed below*):

- Name the study comparators.
- State why this comparison is important.
- Briefly summarize your Patient Engagement Plan.
- Indicate number of arms in proposed trial, if applicable.
- Indicate length of follow-up after intervention, if applicable.



- Supply list of primary/secondary outcomes.
- Provide 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 before submission.

Public Abstract

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

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

This summary should be comprehensible to a variety of audiences and will be reviewed by scientists, patients, and stakeholders during the merit review process. Public abstracts from applications that are awarded a contract will be posted on PCORI's website. The names of the individuals and organizations who join the research team, including patient and stakeholder partners, will also be posted on PCORI's website, as described in the Key Personnel section below.

Key Personnel

PCORI identifies key personnel as any individual who is considered critical to the project's scientific development and execution in a measurable way and whose absence from the project would affect the likelihood of success.

Note the following:

- Applications can include up to two PIs.
- PIs can serve in other roles (e.g., dual-PI, co-I, or consultant) on other applications.
- If applicable, applicants must explain the rationale for including two PIs in the Leadership Plan Template.
- Consultants and personnel from collaborating organizations may be included as key personnel if they meet the definition. See the [Glossary](#) for "Consultant" and "Subcontractor" definitions.
- Project Directors, or equivalent, are considered key personnel.
- Applicants are required to identify the patient and stakeholder partners, whether individuals or organizations, that will assist in conducting the project. If your project is funded, these partners will be named on the PCORI website along with the PI and the recipient organization. They may



also be recognized in other PCORI communications, such as press releases, or mentioned in response to requests for information. By providing the names of the partnering individuals and organizations, you acknowledge that you have obtained any required permission or consent from the respective partners to disclose their names to PCORI and to permit PCORI to make their names publicly available. If a patient or stakeholder partner wishes to remain anonymous, please contact us at pfa@pcori.org for additional guidance on how to recognize such partners appropriately.

- If awarded, the addition or replacement of key personnel listed in the submitted application requires PCORI's approval during contract negotiation and post-contract execution.

Milestones

Complete all required sections in the [Milestones/Deliverables Template](#) and upload as a single PDF to PCORI Online. Explain the projected goals and outcomes that will 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 conducted under the contract. 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
- Formation of Study Advisory Committee (SAC)¹⁴ comprised of national or regional representation of organizations that represent, at a minimum, patients and families with lived experience, relevant clinicians, payers, and health plans (other representation may be recommended in collaboration with PCORI, including other relevant stakeholders, such as scientific and methodological experts)

¹⁴ The intent of the Study Advisory Committee (SAC) described in the PFA is to ensure that a broad spectrum of stakeholders and patients advise and assist the research team with further refinement of the study questions, outcomes, and protocols. These stakeholders and patients must include national or regional organizations that represent, at minimum, patients and/or families with lived experience, relevant clinicians, payers, and health plans. Other representation may be recommended in collaboration with PCORI including individual patients with lived experience and other relevant stakeholders, including scientific and methodological experts. However, PCORI understands that engagement structures and approaches vary widely. Other engagement approaches such as forming stakeholder groups, panels, task forces, working groups, and other bodies, and/or involving individual patient and stakeholder partners in various ways are also permissible to employ, either in addition to or instead of the formation of the SAC. The SAC provision is not meant to require that a separate governance and/or advisory entity must be established beyond the study governance and advisory structure the awardee has planned, if an applicant already has an approach for including the relevant, required stakeholders and patient partners. For clarification in your application materials and for purposes of merit review, please indicate which body or structure is filling the requirements of the SAC, including the requirements for in-person meetings at least two times per year, and appropriate budgeting



- Minutes of data safety monitoring board (DSMB) meetings
- Study registration at ClinicalTrials.gov
- Final study protocol
- Expected monthly enrollment for the entire duration of recruitment, taking into account expected variation in recruitment throughout a calendar year (i.e., each enrollment month should be listed as a line item in the milestones spreadsheet)
- Questionnaire/tool
- Interim analyses
- Final analyses
- De-identified data sets, analytic data sets, and codebook
- Interim progress reports
- Final report

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, you may submit the deliverables 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 application 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 include:

- Abstracts accepted or presentations made
- Copies of manuscripts accepted for publication
- Meeting minutes from patient/stakeholder advisory panels, committees, or work groups
- Copies of drafts of instruments, data dictionaries, educational materials, manuals, or other project deliverables
- Copies of newsletters 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: Milestones entered into the template should be specific deliverables associated with a timeline and should include project objectives that will be accomplished at specific times during the proposed project.

Resubmission Policy and Letter

An applicant may resubmit an application that was not funded, and that completed PCORI's Merit Review process (i.e., the applicant received a summary statement). PCORI does not limit the number of times an applicant may resubmit.

If a full application was deemed nonresponsive and did not progress through the full Merit Review process, it is considered a new submission and requires submission of an LOI. Submitting the same application to a different program's PFA is also considered a new submission. Each program's PFA has different requirements; therefore, applicants should carefully review the program's specific PFA to which they are applying.

Submission of an LOI is also a requirement of resubmissions, (unless the applicant has received an Invitation to Resubmit, outlined below). Resubmitted applications require completion and submission of a two-page [resubmission letter](#). The resubmission letter provides an opportunity for applicants to give a high-level overview of how the application has been strengthened in its scientific merit and responsiveness to the current PFA. Simply responding to previous reviewers' concerns is not sufficient; the application must be programmatically responsive and demonstrate methodological rigor and patient-centeredness. The resubmission letter will inform the merit reviewers' understanding of the ways in which the applicant has made efforts to strengthen the application, and reviewers will evaluate the application based on its responsiveness to the PFA and the merit review criteria.

Applicants who previously submitted a dual-PI application and are now proposing a single PI application, or there is a change in the previous PI team, must address the rationale for the change within the resubmission letter.

All applications are evaluated using the same Merit Review criteria found in the PFA.

Research Plan Template

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, References Cited, Consortium Contractual Agreements, 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, and (F) 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 refer to PCORI's Methodology Standards.

Adherence to PCORI Methodology Standards

Applicants are required to adhere to the [PCORI Methodology Standards](#)¹⁵ 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 Patient-Centered Outcomes Research (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

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 six 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
- Standards for Systematic Reviews

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

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 for adherence to relevant methods standards. Following [PCORI's Methodology Standards](#), cite each relevant standard and provide a brief statement indicating how your

¹⁵ Available at pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf.



proposed research demonstrates adherence to the standard. Do not address standards that are not applicable to your study. PCORI program staff will review relevant standards and plans for adherence with the research team during the contract negotiation phase for applications that are awarded funding.

Please refer to the [Methodology Standards Checklist](#), which program staff members use to evaluate applications, as guidance. The stand-alone PCORI Methodology Checklist in the Application Resources is for your own use, to assist you in making sure that all relevant standards have been addressed. This stand-alone list does not need to be uploaded with your application.

While completing the Research Team and Environment (Section F) 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
- If multiple sites are involved, prior experience that demonstrates the likelihood of working together successfully (e.g., past data sharing, IRB reciprocity, or other factors) to facilitate efficient conduct of the study
- 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 that 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](#),¹⁶ 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](#).¹⁷

PCORI strongly supports active engagement of patients and other stakeholders and is committed to their meaningful participation in PCORI-funded research. All PCORI funding applicants are expected to consult with patients and other stakeholders on their decisional dilemma and evidence needs or reference previously documented decisional dilemmas in preparation for the submission of LOIs and

¹⁶ Available at <http://www.pcori.org/sites/default/files/Engagement-Rubric.pdf>.

¹⁷ Available at pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf.



applications.

To describe the decisional dilemma, state the specific clinical decision(s) and/or treatment choice(s) confronted by the decision makers and explain how the findings from the proposed research will inform those decisions. State why this decision, such as choosing a specific medication, surgical approach, or care delivery strategy to treat a condition or manage a specific population, is important to patients. Document the uncertainty faced by patients, clinicians, and other decision makers in making this decision. Identify the stakeholders you consulted in determining that the proposed study addresses their evidentiary needs for decision making, and indicate your commitment to continuing to engage them actively in the conduct of the study.

Applicants should carefully describe the pertinent evidence gaps and why the project questions represent decisional dilemmas for patients, caregivers and families, and other stakeholders, including clinicians and policy makers. Similarly, applicants should document how the project outcomes should be especially relevant to patients and should be meaningful endpoints for patients and their families.

New this cycle, applicants are not required to demonstrate that patients, stakeholders, and patient or stakeholder organizations are already engaged as research team members at the time an application is submitted; however, the Engagement Plan should outline how patients and other stakeholders will participate as partners in various phases of the proposed research, once awarded. To assist applicants, PCORI provides [sample engagement plans](#)¹⁸ 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.

Justification of Assumptions

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

Dissemination and Implementation Potential

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

PCORI is interested in robust research findings that can be rapidly disseminated and implemented in clinical and community practice, thus facilitating improvements in patients' and other stakeholders'

¹⁸ Available at <http://www.pcori.org/sites/default/files/PCORI-Sample-Engagement-Plans.pdf>.



healthcare decision making. Applicants should include a section that describes the potential for the impact of disseminating project findings and facilitating their widespread use in practice. Applicants should describe possible barriers to dissemination and implementation of their work in other settings and any other limitations of the study that may have an impact on the usability of the findings. 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 and other mechanisms.

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](#)¹⁹ and the [Engagement Rubric](#) for guidance on how to include patient and stakeholder partners in the dissemination process, as relevant. In addition, applicants should describe how study participants will be informed of the study results.



Note: 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 PCORI's merit review. Please include this with the letters of support PDF document, as the last item.

Replication and Reproducibility of Research and Data Sharing

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

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

Applicants must describe a replication that does the following:

- Provision of a complete, final study protocol describing the study population, primary and secondary hypotheses to be tested, sources and methods of measuring exposures, outcomes, and all covariates used in analyses, including data definitions, coding instructions, discussion guides for qualitative research, and the analysis plan; the protocol will usually be expected to be delivered to PCORI with the 12-month progress report and always within three months of the

¹⁹ Available at pcori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf.



end of the funding period. PCORI will reserve the right to share these materials with appropriate researchers, in consultation with the study's PI

Proposed clinical trials or observational studies should be registered at www.ClinicalTrials.gov.

Proposed evidence synthesis studies should be registered at <http://www.crd.york.ac.uk/prospero/>.

Reproduction of research findings: This requirement refers to reproducing research findings in the same data set by another researcher(s) not affiliated with the applicant's research team. The ability to reproduce important findings from the original data is critical to establishing trust in PCORI findings. Therefore, PCORI requires a data-sharing plan (described below). Although the plan below is required of all 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 that awardees prepare documentation to accompany their final data sets that enables others in the research community to utilize the data for additional/secondary analysis and to make the data and documentation available upon request.

The data-sharing plan must:

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

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

Protection of Human Subjects

This component (up to five pages) is included in the Research Plan Template. Describe the protection of human subjects involved in your research. For additional guidance, refer to [Section 5.0 "Human Subjects Research Policy"](#)²⁰ 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 as you complete this section.

All PCORI applications that involve interventions with human subjects should include a data safety monitoring plan (DSMP). Depending on the anticipated level of risk associated with the proposed study intervention(s), different approaches and options, including a full external data safety and monitoring board (DSMB), may be required. The plan submitted by the applicants should provide justification of the

²⁰ Available at grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#5_4_IRB_Approval



proposed option in accordance with the expected risk to human subject research participants.

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:

- The prime applicant is responsible for the project and must adhere to the terms and conditions of the contract. The prime applicant should negotiate its subcontracts accordingly.
- Signed subcontract agreements are not required at the time of application submission to PCORI.
- The submission of an application to PCORI signifies that programmatic and administrative personnel from your organization and from all proposed subcontract organizations that will be involved in this project are aware of your organization's subcontract agreement policy and that all involved organizations are prepared to establish the necessary interorganizational agreement(s) consistent with that policy.
- If applicable, subcontract personnel should be included under Key Personnel.
- Budget information for subcontracted organizations should be included in the Detailed Budget, Budget Summary for Entire Project, and Budget Justification.

References Cited

This component (up to 10 pages) is included in the Research Plan Template. Throughout the entire Research Plan, applicants should use in-text citations to reference published materials. In this section, list the full bibliographical citation of each reference cited. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), article title, journal or book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied on in preparing any section of the application. Citations that are publicly available in a free, online format may include URLs or PubMed ID numbers along with the full reference. *References should be limited to relevant and current literature.* It is important to be concise and to select only those literature references pertinent to the proposed research, so that the 10-page limit is not exceeded. Reference websites 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 PCORI merit review.*



People and Places Template

Professional Profile/Biosketch and Patient/Stakeholder Partner Biosketch

These components are included in the [People and Places Template](#). Complete a profile/biosketch section (up to five pages per individual) for each person listed as Key Personnel (including PI, co-I, consultant, or other significant contributors), copying the tables provided in this section as needed. Please note that you may submit a National Institutes of Health (NIH)-formatted biosketch in lieu of a PCORI-formatted biosketch. Though not required at the time of application submission, if any patient or stakeholder partners who join the research team are Key Personnel, they should fill out a Patient/Stakeholder Partner Biosketch or a Professional Profile/Biosketch. At a minimum, each profile must include the person's name, title, and degrees; each profile or biosketch may be no more than five pages. PCORI is especially interested to learn how each individual's previous experience, past performance, and training in the field of PCOR has prepared him or her to conduct this research. The backgrounds, relevant experiences, and roles of patient and stakeholder partners should also be described.

Applicants should assemble a research team that is best positioned 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, on time and within budget.

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.

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

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

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



Applicants must include a [Leadership Plan](#) (up to five pages) as the first section of the People and Places Template. The Leadership Plan must (1) Describe the governance and organizational structure of the leadership team and the research project; (2) Delineate the administrative, technical, scientific, and engagement responsibilities for each PI and the rationale for submitting a dual-PI application; (3) Discuss communication plans and the process for making decisions on scientific and engagement direction; and (4) Describe the procedure for resolving conflicts.

Note: Only the Contact PI may submit the application to PCORI.

Budget Template

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

Detailed Research Project Budget for Each Year of the Research 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 Two as well as for Year One. The subcontractor should follow this model and complete a Detailed Budget for each year of the proposed study.

All personnel information should be entered in the Personnel tab corresponding to that year in the budget template. You may add additional rows for personnel as needed. Following the example of a two-year study, you may delete the unused Year Three–Five Detailed Budget tabs. However, you may not add additional years. Maximum project periods are stated in each PFA. Note the following:

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. Provide a clear distinction between individuals who are considered Key Personnel and those considered Other Personnel.
- **Allowable Costs:** PCORI will pay compensation for personnel as long as the costs are consistent with and do not exceed what the applicant would normally pay under its own policy. Such compensation may include salaries and fringe benefits. See Appendix 2: Allowable and Unallowable Costs for more information.
- **Salaries** include wages earned by an employee, and fringe benefits may include insurance and retirement plans. Provide documentation to support the fringe benefits with the budget justification.
- **Level of Effort:** Personnel contributing to a PCORI-funded research project are expected to

monitor their total percent effort across all their active funding, so it does not exceed 100 percent. Before the application is submitted to PCORI, the AO must certify that individual personnel will not exceed 100 percent effort, if funded. Effort must be reported by the percentage of time over the course of the project year. If salary support is not being requested, use \$0 for the base salary.

- All personnel dedicating effort to the project should be listed on the personnel budget with their level of effort, even if they are not requesting salary support. Please list the base salary for each person in the Budget Justification and Detailed Budget. Describe in the Budget Justification detail the specific functions of the individual. Provide an explanation of how the role supports the project aims and note any overlap in job functions.
- Personnel Level of Effort Attributed to Tasks: Indicate by each task that is relevant to the study (protocol development, meeting attendance, data collection, data cleaning, analysis, etc.) what level of effort each individual involved in that task is contributing. For instance, Task 1: Person 1 at 10 percent FTE, Person 2 at 25 percent FTE, Person 3 at 15 percent FTE.
- Salary Cap: The PCORI base salary cap for personnel is \$200,000 annualized per individual, per year, exclusive of fringe benefits. An individual who earns less than \$200,000 should use his or her actual base salary to calculate personnel costs. An individual with a full-time employee base salary of more than \$200,000 must use \$200,000 as the base salary rate in determining the amount of salary and time to charge to the project.
- Fringe Benefits: These costs are calculated based on the institution's own policy. In the budget upload, following the Budget Justification, applicants must provide a verification of the fringe benefit rate policy for the prime organization.



Note: Personnel costs must account for the level of effort required to initiate and complete the mandated Peer Review Process. See [Detailed Peer Review Budget for Peer Review Related Costs](#) section for additional instructions.

B. Consultant Costs

- Consultant costs apply to those individuals who are not employees of the applicant organization or under a subcontract agreement as members of the contracted staff.
- Payments to nonemployee patient and stakeholder representatives should be included as consultant costs in the budget.
- Provide the total cost of consultant(s), as well as names, expected number of hours, and hourly rate.
- Include the daily consultant fee, travel expenses, nature of the consulting effort, and reasons that consultants are required for the proposed project. Note any overlap in duties with personnel. Consultant costs must be reasonable and justified within the Budget Justification.
- Include a letter of support from all consultants, verifying the work to be performed and how the



negotiated rate was established. See the [Letters of Support](#) section for more detailed information.

C. Supply Costs

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



Note: PCORI considers computers, tablets, docking stations, mobile data and protection plans, and software to be general office supplies that are not allowable as direct cost charges. If these items are proposed as essential in the performance of the research project, the following must be in the Budget Justification:

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

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

D. Travel Costs

- Travel may include any domestic or international travel by 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 other reimbursements.
- Travel costs should be itemized per trip and described as either scientific travel or programmatic travel, as outlined below:
 - Scientific travel includes travel to present at conferences, symposia, and similar events. Scientific travel is capped at \$10,000 over the full project period, including costs for applicant organization and subcontractor personnel.

- 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.
- Airline costs cannot exceed the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare. PCORI will not compensate upgrades.
- For each category of travel (scientific and programmatic), include the number of trips and a brief description of the trips, to include the number of people traveling and the 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 and include general categories, such as printing, publication, illustration costs, and non-consulting service contracts, when applicable.
- Use this section to include direct costs that cannot be accounted for in other budget categories. For example, these costs may include 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 useful life greater than one year.
- Up to three quotes for each item of proposed equipment must be included with the Budget Justification.
- Costs must be reasonable and necessary for the project.



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

G. Subcontractor Costs

- This category includes all consortium and contractual costs. The prime awardee must issue a subcontract agreement to a collaborator if the criteria listed below are met:
 - The subcontractor personnel's effort on the project is calculated as part of his or her "professional time" for his or her employer organization.



- The subcontractor will be using significant resources (e.g., office space, supplies, computer, and personnel) at his or her own organization when working on the PCORI-funded project.
- State in the Budget Justification why each subcontractor was selected. Provide detail on their specific role and the aim/deliverable they will be supporting on this project.
- Subcontractors must adhere to all PCORI budget guidelines, including allowable and unallowable costs.

H. Engagement Costs

- The budget should account for engagement activities and patient and stakeholder partner (individual and organizational) compensation.
- Each awardee will be required to form a SAC (or other appropriate engagement body), which will meet regularly in-person at least two times per year and use virtual communications at other times. These are to be budgeted activities and represented in the project milestones.

I. Indirect Costs

- PCORI limits the total indirect costs to 40 percent of personnel, consultant costs, travel, supplies, other expenses; and \$25,000 of all combined subcontractor costs.
- Applicants who do not have a federally negotiated or independently audited indirect cost rate may assess up to 10 percent indirect costs, to be noted in the Budget Justification.
- Foreign applicants are eligible for no more than 10 percent indirect costs.
- A copy of the prime applicant's federally negotiated or independently audited indirect cost rate letter must be submitted with the application. Include these copies in a single file with the Budget Justification.
- In the event that an indirect cost rate agreement is more restrictive than that of PCORI's accepted indirect cost application, PCORI will allow the applicant to use the less-restrictive rule when calculating indirect costs on submitted budget categories.

Detailed Peer Review Budget for Peer-Review-Related Costs

The detailed Peer-Review Budget must include costs related to the Peer Review Process. Please complete a Detailed Budget for the Peer-Review Process. (Refer to the Peer-Review Budget tab in the Detailed Budget Template.) Please note that the Total Budget will include the Peer-Review Budget and the Research Project Budget when determining compliance with the Maximum Project Budget in the PFA.

- The Peer-Review Budget must comply with the Research Project Budget guidelines and applicable restrictions, including the Salary Cap.
- Costs associated with the Peer-Review Process are limited to personnel, consultants, and



subcontractors.

- A Budget Justification must be included for the Peer-Review Budget.
- The Budget Summary must include the Peer-Review Budget.
- The PI has full discretion in identifying peer-review support personnel.
- The PI must dedicate measurable effort in support of the Peer-Review Process.
- Applicants must identify the peer-review support staff role within the budget at the time of submission.

Budget Summary for Entire Project

Complete a Budget Summary for the entire project for the prime applicant and each subcontracted organization, and for the entire Research Project Budget and Peer Review Budget for all research and peer-review-related costs. See [Appendix 2](#) to review acceptable and unacceptable uses of PCORI funding.

Budget Justification

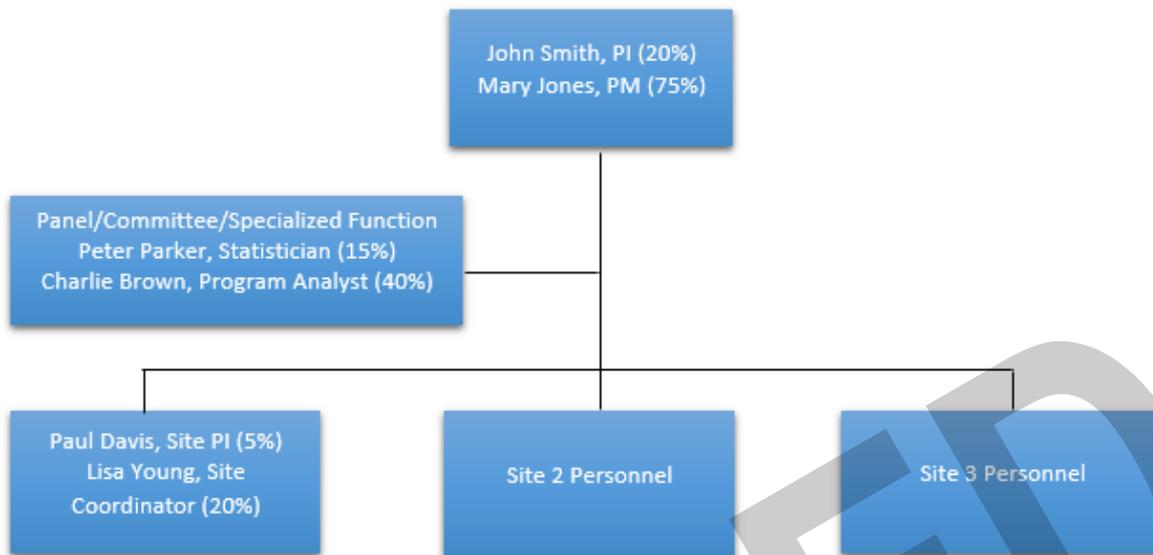
Complete a [Budget Justification](#) for the prime applicant and each subcontracted organization for the entire Research Project Budget and Peer Review Budget for all research and peer-review-related costs. Provide sufficient detail to explain the basis for costs and the reason that the costs are necessary to the project.

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.

Describe in detail the specific role and tasks each member of the research team will be performing and their impact on the project plan. PCORI will evaluate each member's contribution as listed in the Budget Justification to validate meaningful contribution and whether or not there is overlap in responsibilities. Provide a clear distinction between individuals who should be considered Key Personnel and those who should be considered Other Personnel.

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

Applicants should include an overall organizational chart (example below) indicating the roles and relationships of project personnel and including their titles/functions and percentages of effort. As determined by the needs of the study, this chart should include the project PI, individual site PIs, the Data Coordinating Center, statistical analysis team, advisory panels, DSMB, and personnel coordinating and managing data collection. Provide separate charts as needed for such components as individual sites, the data coordinating center, and so on, if these entail multiple personnel. If the percentages vary by contract year, provide separate charts for each version that is different. The budgetary information provided with the application should reference the organizational figures to facilitate PCORI's review.



Letters of Support

Save all letters of support as a **single PDF file** and upload it into the PCORI Online System, using the [Letters of Support Table](#) as the first page of the file. To enable easy reference for merit reviewers and PCORI staff, please be sure to follow the guidance below and in the table template. Reviewers are asked to consider the letters of support as outlined in the template and in this guidance. Failure to assemble the letters properly may result in key information being missed by the reviewers. If this occurs, PCORI will not send the application for re-review, as it will not be deemed an error in review but an error in application assembly.

All letters of support should be addressed to the PI, and they should demonstrate the commitment of key personnel and supporting organizations (e.g., dual-PIs, co-investigators, consultants, patient and stakeholder partners, stakeholder organizations) to your proposed project. 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. Letters of support should clearly reflect the substantive involvement and material contribution to be provided by the signatory parties, and are meant to substantiate the commitment of collaboration of all forms. The quality of the letters—and how they bolster the proposed research—is more important than the number of letters provided.

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

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

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the



department chair or appropriate organizational official, confirming the institutional support of the proposed project, space to conduct the research, equipment, and other resources available for the project to include staff. We also strongly encourage a letter from the leadership of your department or organization affirming support to disseminate and implement research findings that are appropriate and warranted for implementation.

- **Letters of Collaboration:** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. For all consultants, please also include a letter of support verifying the work to be performed and the negotiated rate.
- **Letters Confirming Access to Patient Populations, Data Sets, or Additional Resources:** If the proposed research plan involves access to patient populations, data sets, or additional resources, then include a letter of support, signed by the person with approval authority, confirming such access. If access cannot be confirmed at the time of contract negotiation, PCORI reserves the right to withhold funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.

List all letters in the [table](#) and include the page number on which each letter can be found in the single PDF file.

VI. Additional Requirements

Awardees are required to comply with the following requirements:

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

PCORI requires all applicants to adhere to the NIH policy on education in the protection of human subject participants in the conduct of research. This applies to all personnel listed in the application as Key Personnel. The policy and FAQs are available [from the NIH website](#).²¹

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" (i.e., PCORI-XXXX-XXXX). Clinical trials must be registered before enrollment of the first patient. All trials that meet the definition on the [NIH database](#)²² (see "[Data Element Definitions](#)") are required to register. Please

²¹ Available at grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

²² Available at prsinfo.clinicaltrials.gov.



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*, known as 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 or her institution. The [Office for Civil Rights](#)²³ 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](#).²⁴

Award Funding Conditions

At any time during the contract, PCORI reserves the right to discontinue funding for awardees who fail to meet the mutually-agreed-upon milestones. Applicants’ proposed milestones will be finalized in contract negotiations and prior to execution. For more information, please see PCORI’s [Standard Contract Template](#).

Co-funding

PCORI partners with various other research organizations to leverage additional funds for some of its programs. If you currently have a funded project and would like to seek PCORI funding to add a *new* aim to the study that advances PCORI funding objectives, you may submit an application. We recommend that you speak with a PCORI 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. Before receiving a PCORI contract, awardees must disclose all current and pending support.

Dissemination and Data Sharing

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

²³ Available at [hhs.gov/ocr](https://www.hhs.gov/ocr).

²⁴ Available at [grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html](https://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html).



Appendix 1: Example Milestones

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

- IRB approval
- Formation of SAC comprised of national or regional representation of organizations that represent, at a minimum, patients and/or families with lived experience, relevant clinicians, payers, and health plans; other representation may be recommended in collaboration with PCORI, including with other relevant stakeholders, such as scientific and methodological experts
- Adherence to methodology standards
- Minutes of data safety monitoring board 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)
- Start of follow-up data collection (if multiple follow-up time points are included in the study protocol, create a separate milestone for each data collection time point)
- Completion of 25 percent of follow-up data collection (if multiple follow-up time points are included in the study protocol, create a separate milestone for each data collection time point)
- Completion of 50 percent of follow-up data collection (if multiple follow-up time points are included in the study protocol, create a separate milestone for each data collection time point)
- Completion of 75 percent of follow-up data collection (if multiple follow-up time points are included in the study protocol, create a separate milestone for each data collection time point)
- Completion of follow-up data collection (if multiple follow-up time points are included in the study protocol, create a separate milestone for each data collection time point)
- Focus group results
- Intervention materials complete
- Final study protocol
- Primary Completion Date (if applicable; the primary completion date is the date that the final subject [or participant] was examined or received an intervention for the purposes of final



collection of data for the primary outcome; the primary completion date is defined in Section 801 of the Food and Drug Administration Amendments Act of 2007)

- Notification of posting final protocol on ClinicalTrials.gov
- Conducting of baseline assessments or measurements
- Start of follow-up assessments or measurements
- Completion of follow-up assessments or measurements
- Interim analyses
- Final analyses
- Interim progress reports, every six months
- Final report
- Manuscript submission or notification of publications
- Data sets, analytic data sets, 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 (e.g., 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 PCORI Program Officer, milestones listed above may not be relevant (e.g., recruitment milestones may not be relevant for observational studies).



Appendix 2: Allowable and Unallowable Costs

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

- Allowable costs (i.e., those costs that can be included in a proposed Detailed Budget in applying for a PCORI Funding Award and charged to the award) may include the following costs that derive from and directly support the research project:
 - Salaries and fringe benefits for study investigators and other research project staff (including engaged patient and stakeholder research study partners) related to their percentages of effort on conducting the research project (such costs should not include personnel who deliver patient care as a component of their participation in the research project)
 - Consultant fees
 - Travel for mandatory investigator meetings
 - Travel that is otherwise necessary for conducting the research project
 - Supplies
 - Equipment
 - Subcontracts
 - Expenses related to conducting engagement activities with patients and other stakeholders
 - Other direct research expenses
 - Indirect costs

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

- Typically, IRB fees are included in an organization's indirect cost pool. However, PCORI will allow this expense as a direct cost if the costs are not included as part of the indirect cost rate. By



submitting the application, the PI and AO certify that their institution treats IRB fees as direct costs, and the fee is allocable to the study. IRB fees are subject to audit.

- In general, costs for study interventions that constitute the procedures, treatments, interventions, or other standard clinical care (“patient care”) that are being proposed for comparison in the research project (“patient care costs”) will not be covered by PCORI. Patient care costs should be covered by the host healthcare delivery system, third-party payer, manufacturer of the product, developer of an intervention, or other interested party.
- The willingness of one or more stakeholder groups to cover patient care costs that will be incurred in the course of the research project, even when one of the comparators is not currently directly covered by insurance, will be taken as strong endorsement of the research project by the stakeholder group. Such commitments also provide an indication that the stakeholder groups will utilize the research study’s findings. (Such support for the study by a stakeholder group should be discussed in the application.)
- Absent specific permission in exceptional circumstances, PCORI will not cover patient care costs.
- PCORI may consider coverage of the co-payment or co-insurance costs of participating study subjects when that is necessary to preserve blinding in a study or to ensure access to the study for vulnerable populations.
- PCORI will generally cover costs for ancillary tasks directly related to the research project. Examples include costs for obtaining informed consent to participate in the research project, collecting data pursuant to the research protocol, or study-subject data collection and monitoring that would not normally be performed in the course of patients receiving the patient care being evaluated in the research project.

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

Allowable Costs			
 PERSONNEL SALARIES & BENEFITS	 TRAVEL COST	 SUBCONTRACTOR DIRECT & INDIRECT	 APPLICANT INDIRECT COSTS
 CONSULTANT FEES	 EQUIPMENT	 SUPPLIES	 OTHER

Commonly Disallowed Costs	Unallowable Costs		
 DATA PLANS (TABLETS AND OTHER MOBILE DEVICES)	 ADVERTISING	 DONATIONS	 INTEREST OF BAD DEBTS
 DOCKING STATIONS	 EXCESSIVE AIRFARE	 FUNDRAISING	 ENTERTAINMENT
 DOUBLE MONITORS	 ALCOHOLIC BEVERAGES	 PERSONAL EXPENSES	 LOSSES ON OTHER GRANTS
 ELECTRONICS PROTECTION PLANS	 ALUMNI ACTIVITIES	 STUDENT HOUSING AND STIPENDS	 MEMBERSHIPS
 OFFICE FURNITURE	 BAD DEBTS/LOSSES	 IDLE FACILITIES	 LOBBYING
 REPLACEMENT OF ITEMS PURCHASED ON AN EXISTING PCORI AWARD		 RENT	

PCORI considers computers, tablets, docking stations, mobile data and protection plans, laboratory and office furnishings, and software to be general office supplies that are not allowable as direct cost charges.



Appendix 3: Administrative Actions

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

Automatic Rejection	Modification by PCORI	Appended upon PCORI's Request*
An application or LOI will be automatically rejected if it: <ul style="list-style-type: none"> • Exceeds the specified page limit (LOI) • Exceeds the specified period of performance outlined in the PFA • Exceeds the maximum budget specified in the PFA • Has adjusted margins or font size (LOI) • Does not include or has an incomplete Research Strategy 	PCORI will modify an application by removing all pages that exceed stated limits for the following components: <ul style="list-style-type: none"> • Resubmission Letter • Research Strategy • Dissemination and Implementation Potential • Reproducibility and Transparency of Research • Protection of Human Subjects 	Unless automatically rejected or modified, PCORI may request that the applicant submit missing documents or correct non-compliant ones.

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