



Cycle 1 2019 Funding Cycle

PCORI Funding Announcement: Treatment Options for Age-Related Hearing Loss

Application Guidelines

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Updated February 1, 2019

These guidelines apply to the Cycle 1 2019 Funding Cycle for Treatment Options for Age-Related Hearing Loss. Funding announcements, templates, and other resources are available at pcori.org/apply. The Cycle 1 2019 Funding Cycle closes April 24, 2019, at 5 pm (ET).

About PCORI

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

PCORI was authorized by Congress in 2010 as a nonprofit, nongovernmental organization. PCORI's purpose, as defined by our authorizing legislation, is to help patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders make better-informed health decisions by "advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions."

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

I. About These Guidelines

This document provides key information to help researchers prepare for and respond to the Patient-Centered Outcomes Research Institute (PCORI) Funding Announcement (PFA) on [Treatment Options for Age-Related Hearing Loss](#).

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

- See PCORI's [Applicant FAQs](#)¹ for common questions about PCORI and the application process.
- Visit PCORI's [Help Center](#)² for additional applicant resources.
- **For Programmatic Inquiries:** Contact the PCORI Helpdesk via email (sciencequestions@pcori.org), phone (202-627-1884), or online (<http://www.pcori.org/PFA/inquiry>). PCORI will respond within two business days. However, we cannot guarantee that all questions will be addressed two business days prior to a Letter of Intent (LOI) or application deadline.
- **For Administrative, Financial, or Technical Inquiries:** Contact the PCORI Helpdesk at pfa@pcori.org. PCORI will respond within two business days. Note that during the week of the application deadline, response times may exceed two business days. Applicants may also call the PCORI Helpdesk at 202-627-1885.

It is the applicant's responsibility to submit the application on or before the deadline. Refer to [PCORI's Policy on Submission of Research Contract Applications](#).³

Administrative Considerations

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

All rejection decisions made by the Contracts Management department are final. Email pfa@pcori.org with any formatting or administrative compliance questions to ensure that your LOI or application will be compliant once submitted to PCORI. See [Appendix 3: Administrative Actions](#).

Unless otherwise stated in the Application Guidelines, all materials submitted on behalf of an applicant organization are the property of that organization. PCORI will not share or publicize the contents of an organization's application.

Funding Mechanism

PCORI utilizes a contract mechanism, not a grant mechanism, for its awards. PCORI funds projects that demonstrate the highest probability of being completed on time and within budget, and meeting all

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

² Available at <http://help.pcori.org/hc/en-us/>.

³ Available at <http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/>.

milestones and deliverables. *Applicants must submit representative budgets and Research Plans that allow the project to conclude within the approved contract term.*

As part of its active portfolio management, PCORI provides contractual and programmatic monitoring throughout the contract term period. Applicant institutions and the Administrative Officials are advised to carefully review PCORI's standard contract templates provided on the [Awardee Resources](#) page on the PCORI website.⁴ Note that international awardees will be issued a contract in U.S. dollars. Fluctuations in currency exchange rates will have no bearing on the contract value, nor will adjustments be made to accommodate losses or gains associated with such currency fluctuations.

II. 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; any laboratory or manufacturer; or any unit of local, state, or federal government. The Internal Revenue Service must recognize all U.S. applicant organizations. Organizations may submit multiple funding applications. Individuals are not permitted to apply. If you have questions about eligibility, contact pfa@pcori.org.

Nondomestic components of organizations based in the United States and foreign organizations may apply, as long as there is demonstrable benefit to the U.S. healthcare system and U.S. efforts in the area of patient-centered research can be shown clearly. However, PCORI's general preference is that prime awards be made to a U.S.-based organization.

A prime award contract to a non-U.S.-based organization should be carefully justified and preferably include a key U.S.-based organization and co-Principal Investigator as a subcontractor. In assessing whether a research award can be made to a non-U.S. organization as a prime contractor or subcontractor, and/or whether the research can be conducted outside the United States, PCORI will carefully review and consider the following factors:

- The research funded by PCORI must result in findings that are relevant and useful to U.S. patients and healthcare decision makers.
- The proposed project must demonstrate that essential scientific needs will be met by conducting the study outside the United States or having the study conducted by non-U.S. research organizations.
- The proposed study must demonstrate meaningful effort and involvement of U.S. organizations and investigators with pertinent expertise and experience to contribute to the project. The engagement plan for the proposed study should also adequately and sufficiently include U.S. patients and stakeholders and have clear relevance to the U.S. healthcare system.



Note: In general, a Principal Investigator (PI) can submit only one LOI per PFA. However, because PCORI's Broad PFA included funding opportunities across the four distinct PCORI

⁴Available at <http://www.pcori.org/sites/default/files/PCORI-PFA-Standard-Contract-for-Funded-Research-Projects.pdf/>.

National Research Priorities, it is permissible for a PI to submit multiple LOIs under different national research priority areas. The research topics and projects must be distinct and responsive to the specific respective national research priority areas, as outlined in the PFA. Moreover, an individual listed as a PI on one LOI may be listed as and serve in another role (e.g., co-PI, co-investigator, or 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 the PI must ensure that the research topics and projects are not similar. If a PI submits an LOI to multiple program PFAs, LOIs that exhibit scientific overlap or that appear to be duplicate submissions will be disqualified. PCORI will contact the PI and provide him or her with an opportunity to choose which PFA he or she would like to apply to. This applies to single- and dual-PI submissions.

III. How To Apply

To submit an LOI and application (if invited), including all required documents, follow the instructions provided in these guidelines and in [PCORI Online](#).⁵ All documents must be submitted through PCORI Online. Refer to the specific PFA for more information regarding the review process for LOIs and applications.

To submit an application or to register your organization in PCORI Online, you need a Data Universal Numbering System (DUNS) number and an Employer Identification Number (EIN). You can [apply for a DUNS number](#)⁶ and [an EIN](#),⁷ if applicable.



Step 1: Register

To apply for PCORI funding, an applicant (PI or PI designee) must register in [PCORI Online](#). To register, you must provide a name, an email address, a password, and a security question and answer. Once signed in, you will be directed to the home screen. Click on the Research Awards tile to apply for funding. PCORI strongly recommends that only the PI create the LOI/application record, because whoever creates the record will have permanent access to it in PCORI Online.



Step 2: Submit a Letter of Intent

An LOI is required for all applications. To submit an LOI, log in to [PCORI Online](#), complete the required LOI fields, and upload the completed PFA-specific LOI Template into the system.

PIs can download the LOI Template from the PFA page in the [PCORI Funding Opportunities](#) web page. For formatting instructions, reference Step 4. Each PFA cycle has one LOI Template.

⁵ Available at <https://pcori.force.com/engagement>.

⁶ Available at <https://www.test.grants.gov/applicants/organization-registration/step-1-obtain-duns-number.html>.

⁷ Available at <https://www.irs.gov/businesses/small-businesses-self-employed/apply-for-an-employer-identification-number-ein-online>.

For detailed instructions on how to navigate the system, reference the [PCORI Online: Pre-Award User Guide for Research Awards](#).⁸



Step 3: Begin Application Process

PCORI will notify applicants by the date specified within the PFA as to whether or not they have been invited to submit an application.

The application consists of multiple sections in [PCORI Online](#), all of which you must complete before submission. Log in to PCORI Online to view the full list of questions.



Step 4: Format and Complete Required Templates

Required templates are on the [PCORI Funding Opportunities](#)⁹ web page. Find the PFA to which you are applying to and download the correct PFA-specific templates, because they vary among PFAs and cycles. Keep the following in mind:

- Do not reorganize sections within the templates.
- Do not alter the templates' main header questions within your submission.
- You may delete instructional text.

You must format all required documents as follows:

- **Header:** Include the PI's full name in the top-left corner of every page.
- **Font:** Use Calibri size 11 font. Figures, tables, and captions may have size 8 font.
- **Spacing:** Use single spacing.
- **Margins:** Use at least half-inch margins. The header may fall within the top margin, but the body text may not begin closer than a half-inch from the edge of the page.
- **Page Numbers:** Number each page consecutively for each PDF upload. Begin each section of an uploaded document with page 1.
- **Page Limit:** This varies based on the document.
- **File Name Format:** This varies based on the document. Refer to the [Application Checklist](#).
- **References:** PCORI suggests including all references as in-text citations using American Medical Association (AMA) citation style, but other citation styles are acceptable.

⁸ Available at <http://www.pcori.org/sites/default/files/PCORI-Online-Pre-Award-User-Guide.pdf>.

⁹ Available at <http://www.pcori.org/funding-opportunities/>.



Step 5: Upload Required Documents

Follow the [Application Checklist](#) included in these guidelines to enter required information. Upload required documents to PCORI Online in the correct order. When instructed, use Adobe Acrobat Professional¹⁰ to combine documents into a single PDF file for upload. Within the Templates & Uploads tab, click “Choose file” to select a file from your computer, and click “Upload.” For detailed instructions, refer to the Templates & Uploads section of the [PCORI Online: Pre-Award User Guide for Research Award](#).



Step 6: Submit for Authorization

Once you have completed and uploaded all required information, select “Review & Submit,” and then select “Submit” to forward the application to your Administrative Official (AO) to authorize and submit. The AO must approve and submit the final application for official submission to PCORI before the deadline. **PCORI Online will email the AO, but the PI should notify the AO when the application is ready for review, AO approval, and submission.** The PI and the AO may not be the same individual. Both the AO and the PI will receive an email confirming that PCORI has received the application.

IV. When To Apply

Deadlines for each funding cycle are noted in the [PCORI Funding Opportunities](#) web page and in the PFA. System or technical issues with PCORI Online that affect the on-time submission of an application must be reported to PCORI before the specified deadline. Problems with computer systems at the applicant’s organization or failure to follow instructions in PCORI Online, in the PCORI Application Guidelines, or in PFAs are not valid issues warranting consideration of a deadline extension. See PCORI’s [Policy on Submission of Research Contract Applications](#)¹¹ for complete information.

V. What To Include



Note: Only applicants selected to submit an application may begin the application process.

You will be notified by February 26, 2019, regarding whether PCORI has invited you to submit an application.

Applicants are encouraged to review this entire section. Print and complete the provided Application Checklist to ensure that the LOI and application are submitted correctly. Download all required templates from the [PCORI Funding Opportunities](#)¹² web page.

¹⁰ See adobe.com for more information on Adobe Acrobat Professional.

¹¹ Available at <http://www.pcori.org/funding-opportunities/how-apply/policy-submission-research-contract-applications/>.

¹² Available at <http://www.pcori.org/funding-opportunities/>.

Application Checklist

Letter of Intent	Submission Method	Length/Limit
<input type="checkbox"/> Letter of Intent (LOI)		
<ul style="list-style-type: none"> Contact Information 	Enter into PCORI Online	N/A
<ul style="list-style-type: none"> Pre-Screen Questionnaire 	Enter into PCORI Online	N/A
<ul style="list-style-type: none"> Principal Investigator (PI) Information 	Enter into PCORI Online	N/A
<ul style="list-style-type: none"> Project Information 	Enter into PCORI Online	N/A
<ul style="list-style-type: none"> Project Personnel 	Enter into PCORI Online	N/A
<input type="checkbox"/> Templates & Uploads: LOI Template	Save file as "PI LastName_(five-digit LOI number)_LOI.pdf" and upload	2-pages
Application	Submission Method	Length/Limit
<input type="checkbox"/> Project Information		
<ul style="list-style-type: none"> Technical Abstract 	Enter into PCORI Online	500 words
<ul style="list-style-type: none"> Public Abstract 	Enter into PCORI Online	500 words
<input type="checkbox"/> Budget	Enter into PCORI Online	As needed
<ul style="list-style-type: none"> Detailed Budget for Each Project Year (prime) Peer Review Period (prime and subcontractors) 		
<input type="checkbox"/> Milestones Template	Save file as "Milestones_PI LastName.xls" and upload	As needed
<input type="checkbox"/> People and Places Template	Save file 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 Profile/Biosketch 		5 pages per individual
<ul style="list-style-type: none"> Project/Performance Site(s) and Resources 		15 pages
<input type="checkbox"/> Research Plan	Save file as "ResearchPlan_PI LastName.pdf" and upload as a single file	As noted below
<ul style="list-style-type: none"> Research Strategy 		12 pages
<ul style="list-style-type: none"> Research Team and Environment 		2 pages
<ul style="list-style-type: none"> Dissemination and Implementation Potential 		1 page
<ul style="list-style-type: none"> Protection of Human Subjects 		5 pages

	<ul style="list-style-type: none"> • Consortium Contractual Arrangements 	5 pages	
	<ul style="list-style-type: none"> • References Cited 	10 pages	
	<ul style="list-style-type: none"> • Appendix (optional) 	10 pages	
<input type="checkbox"/>	Methodology Standards Checklist	Save file as "MethodologyStandardsChecklist_PILastName.xls" and upload	As needed
<input type="checkbox"/>	Subcontractor Detailed Budget (for each project year) Template	Save file as "SubcontractorDetailedBudget_PILastName.pdf" and upload as a single file	As needed
<input type="checkbox"/>	Budget Justification (prime and subcontractors)	Save file as "BudgetJustification_PILastName.pdf" and upload as a single file	As needed
	<ul style="list-style-type: none"> • Budget Justification (prime and subcontractors) Template 	As needed	
	<ul style="list-style-type: none"> • Federally Negotiated or Independently Audited Indirect Cost Rate Letter (prime) 	As needed	
	<ul style="list-style-type: none"> • Fringe Benefit Rate Policy Verification Document (prime) 	As needed	
<input type="checkbox"/>	Letters of Support	Save file as "Letters_PILastName.pdf" and upload as a single file	As needed
	<ul style="list-style-type: none"> • Letters of Support Table 		
	<ul style="list-style-type: none"> • Letters of Support 		

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

PI and Contact Information

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



Principal Investigator (PI)

A. Description

- If electing to submit an application with two PIs, you must designate one as the Contact PI. The Contact PI is responsible for submitting the application and will serve as PCORI's primary point of contact for all communication. **No more than two PIs can be named on an application.**
- The PI is responsible for the project's engagement, scientific technical aspects, and 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 or consultant. Refer to the [Who Can Apply](#) section for specific instructions.

B. Activities

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

Administrative Official (AO)

A. Description

- The AO is responsible for matters related to the award and administration of the contract.
- The AO cannot be the PI.
- The AO's signature certifies that the organization will be accountable for appropriately using the funds awarded and for performing the PCORI-supported project.

B. Activities

- The AO manages contract activation, modifications, and additional required administrative matters.
- The AO certifies contract compliance of all applicable assurances and certifications referenced in the application.

Financial Official (FO)

A. Description

- The FO is responsible for all required financial reporting.

B. Activities

- The FO completes and certifies expenditure reports on behalf of the organization.
- The FO accounts for contract funds and submits invoices and payment details.

Key Personnel

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

Note the following:

- Applications can include up to two PIs.
- PIs can serve in other roles (e.g., dual-PI, co-PI, co-investigator, 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 [PCORI's Glossary](#) for “Consultant” and “Subcontractor” definitions.
- Applicants are required to identify the patient and other 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 other stakeholder partner wishes to remain anonymous, contact pfa@pcori.org for additional guidance on how to recognize such partners appropriately.
- After merit review, PCORI may request current, pending, and other support documentation from all key personnel. This material must be submitted prior to award.

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

Letter of Intent

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

Upon receipt of the LOIs, PCORI program staff will review them for programmatic fit and potential overlap with existing projects in the portfolio. If program staff determine that the LOI is a better fit for another program, they may transfer the LOI to that program. If that program is interested in inviting the applicant to submit an application, PCORI will notify the applicant and obtain his or her approval to switch programs. PCORI will not invite an applicant to submit an application if the applicant’s LOI does not meet program areas of interest or if it substantially overlaps with existing projects in the portfolio. Applicants will receive an email notification accepting or declining their LOI, as specified in the PFA.

PFA–Specific LOI Template

Download and complete the PFA–specific LOI Template from the [PCORI Funding Opportunities](#) web page. Do not include supplemental materials (e.g., supporting journal articles, Letters of Support) or additional information not requested in the template. Statements in gray italics denote how each response will be evaluated. Replace the gray italics and any instructional text with your responses, but retain the bold headings and question numbers. **Note that any additional template modifications will result in the disqualification of your LOI.**

LOIs are competitive and will be screened by PCORI staff. The information included in this template will be used as the primary source of information for the screening process. Focus on including only critical information, because space is limited. Provide a description that allows the scientific community to understand the project, including the aims and study design, without reviewing the full application. The page limit does not include references. PCORI suggests including all references as in-text citations using AMA style, but other citation styles are accepted. (**Note:** All LOI Templates must follow the formatting guidelines provided in [Step 4](#).)

Be sure to delete the template cover page before submitting an LOI. To submit an LOI, save the completed PFA–specific LOI as a PDF. Label your LOI file using the following nomenclature: “PI LastName_(five-digit LOI number)_LOI.pdf.” [PCORI Online](#) will automatically generate an LOI number, which will be visible at the top of the web page once you save the LOI. Click “Review & Submit” to review your submission, and then click “Submit.” Navigate back to the LOI and Application dashboard in PCORI Online, where you can see your LOI number and track your status. Once your LOI is submitted, you cannot edit it.

VI. Application Requirements



The following sections are applicable only if PCORI invites you to submit an application. You are invited to submit an application based on the information provided in the LOI. Any changes to the following require PCORI's approval:

- PI (Contact PI and PI #2)
- Institution
- 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 the information transferred from your LOI, and update as needed.

Project Information

Enter the following information directly into PCORI Online.

Technical Abstract

Provide a Technical Abstract within PCORI Online that summarizes your Research Strategy. The abstract must 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 questions and long-term objectives.
- **Study Description:** Describe in detail the study design. Include, as applicable, the following:
 - Overall study design
 - Main components of the intervention and comparator(s)
 - Study population (source, inclusion criteria, demographic information, clinical status, and target sample size by arm)
 - Primary and secondary outcomes
 - Analytic methods

Public Abstract

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

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 that compose the research team, including patient and stakeholder partners, will also be posted on PCORI's website, as described in the Project Personnel section.

Milestones Template

Applicants must complete the [Milestones Template](#) and upload it as an Excel file, not as a PDF, in PCORI Online, in the designated upload field. Follow the instructions in the Milestone Template and complete all required sections. Based on Milestone—Deliverable Name (Column B) and Description (Column C), applicants must provide the Due Date (Column D). Consider the guidance information in Column E as you determine the Due Date.

Milestones are concrete, specific events or accomplishments that are documented by deliverables. They include only the activities that the PCORI contract supports. Some examples of milestones include reaching specific patient accrual targets, developing a survey, commencing the intervention, and establishing project-specific databases. See [Appendix 1: Example Milestones](#) for a more complete list. If applicable, milestones may also include activities dedicated specifically to engagement, such as the recruitment of all patient/stakeholder research partners or results of annual surveys of patient/stakeholder partners. As part of Merit Review Criterion 3, Scientific Merit (research design, analysis, and outcomes), reviewers evaluate the submitted milestone schedule to assess the feasibility of the study plan.

Interim and final deliverables will be included in your research contract if your application is funded. 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, but are not limited to, the following:

- PCORI Progress Reports
- Study Protocol
- Copies of Institutional Review Board (IRB) approval
- Registration of the trial on [ClinicalTrials.gov](https://clinicaltrials.gov)
- Data Safety and Monitoring Plan
- Recruitment Plan

- Engagement Plan
- Scientific abstracts accepted or presentations made
- Scientific manuscripts accepted for publication
- Copies of drafts of instruments, data dictionaries, educational materials, manuals, or other project deliverables
- Reports of plans to adopt research findings in practice
- Charts, tables, graphs, or other summaries of preliminary data
- Other documents or materials, as appropriate



Note: Milestones must include specific deliverables associated with a timeline and must include project objectives that will be accomplished at specific times during the proposed project. PCORI encourages applicants to provide three to six milestones per six-month reporting period.

Budget

Complete all required sections in PCORI Online, including the Peer Review Budget section, and upload the [Subcontractor Detailed Budget Template](#) for each subcontractor and the [Budget Justification Template](#) to PCORI Online in their designated fields.

Detailed Research Project Budget for Each Year of the Research Project Period

For each program year, complete a Detailed Budget entered in PCORI Online for the prime applicant proposed in your application. For example, if your study lasts two years, the prime applicant must complete a Detailed Budget for Year One and for Year Two. You must enter all personnel information in the Project Personnel tab that corresponds to that year in the Budget tab. The applicant may add additional rows for personnel as needed. Following the example of a two-year study, applicants may delete the unused Years Three through Five Detailed Budget tabs. However, applicants may not add additional years. Each PFA states the maximum project periods. Note the following:

A. Personnel Costs

- Personnel Costs: These include the base salary for each scientific and technical staff member, employee patient or stakeholder partner, or other personnel on your project who are or are not accounted for in Section B: Consultant Costs. Provide a clear distinction between individuals who are key personnel and those considered “other” personnel.
- PCORI will reimburse personnel costs that are consistent with and do not exceed what the applicant would normally pay under its own policy. PCORI may request salary verification during the contract activation process. Such compensation may include salaries and fringe benefits. See [Appendix 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 within the Budget Justification.

- **Level of Effort:** Personnel who contribute to a PCORI-funded research project must monitor their total percentage of effort across all of their active funding, so that it does not exceed 100 percent. Before submitting the application to PCORI, the AO must certify that individual personnel will not exceed 100 percent effort if funded. You must report effort by the percentage of time over the course of the project year. If you are not requesting salary support, use \$0 for the base salary.
- All personnel who dedicate effort to the project must be listed on the Personnel Budget with their level of effort, even if they are not requesting salary support. List the base salary for each person in the Budget Justification and the Detailed Budget. Describe the individual's specific functions in the Budget Justification. Provide an explanation of how the role supports the project aims and note any overlap in job functions.
- **Salary Cap:** The PCORI base salary cap for personnel is \$200,000 annualized per individual, per year, excluding fringe benefits. An individual who earns less than \$200,000 must use his or her actual base salary to calculate personnel costs. An individual with a full-time employee base salary of more than \$200,000 must use \$200,000 as the base salary rate in determining the amount of salary and time to charge to the project.
- **Fringe Benefits:** These costs are calculated based on the institution's own policy. In the Budget Justification upload, 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 the [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 must be included in the budget as consultant costs.
- Provide the total cost of the consultant(s), as well as name(s), expected number of hours, and hourly rate.
- Include the daily consultant fee, travel expenses, nature of the consulting effort, and the reasons that the proposed project requires consultants. Note any overlap in duties with personnel.
- Consultant costs must be reasonable and justified within the Budget Justification.
- Include Letters of Support from each consultant, verifying the work to be performed and 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 be part of general or administrative use. Supplies are consumable items that are used on a regular basis or other tangible items that do not meet the definition of “equipment.” Include the category of supplies needed and the cost for each.
- Tangible items with per-unit costs of \$5,000 or more are considered equipment and cannot be accounted for under this category.
- Indicate general categories such as mailings, printing, lab, and equipment with less than \$5,000 per-unit costs. Provide detailed explanations in the Budget Justification for all costs exceeding \$1,000.
- For all supply costs, provide computations for the way that applicants arrived at the specific number.



Note: PCORI considers computers, tablets, docking stations, mobile data and protection plans, laboratory and office furnishings, and software to be general office supplies that are not allowable as direct-cost charges. If these items are proposed as essential for performing the research project, the following must be provided 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 project personnel or consultants directly related to, and necessary for, the project and within the limits explained below. PCORI uses the Federal Travel Regulations guidelines for per diem and other reimbursements.
- Travel should be devoted to programmatic activities necessary to conduct the project, such as focus groups, project team meetings, or data collection. Requests for travel to present at conferences or symposiums that are related to the topical areas of the project may also be included, but should be limited in number, and strongly justified. PCORI closely reviews all travel costs to ensure they are reasonable.
- Travel costs must be itemized per trip and must include the number of trips and a brief description of each one, including the number of people traveling and dates or duration of the stays.
- Airline or rail costs cannot exceed the customary standard commercial fare (coach or

equivalent), or the lowest commercial discount fare. PCORI will not compensate upgrades.

- In the Budget Justification Template, applicants must provide additional detail to explain the basis for the costs listed and describe how the travel is directly related to the proposed research project and necessary for achieving programmatic objectives.

E. Other Expenses

- Indicate and include general categories such as printing, publication, illustration costs, and non-consulting service contracts (when applicable).
- Use this section to include direct costs that cannot be accounted for in other budget categories. For example, these costs may include computer core services, data warehousing, or participant incentives.
- In the space provided, include a detailed explanation in the Budget Justification for items that exceed \$1,000. Applicants must provide additional detail for each of these costs.

F. Equipment Costs

- Equipment costs include those for tangible items that have a per-unit cost of \$5,000 or more and a useful life greater than one year.
- You must include with the Budget Justification up to three quotes for each item of proposed equipment.
- Costs must be reasonable and necessary for the project.



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

G. Subcontractor Costs

- This category includes all consortium and contractual costs. The prime awardee must issue a subcontract agreement to a collaborator if the criteria listed below are met:
 - The subcontractor personnel's effort on the project is calculated as part of his or her "professional time" for his or her employer organization.
 - The subcontractor will be using significant resources (e.g., office space, supplies, computer, and personnel) at his or her own organization when working on the PCORI-funded project.
- State in the Budget Justification why each subcontractor was selected. Provide detail on their specific role and the aim or deliverable they will be supporting on the project.
- Subcontractors must adhere to all PCORI budget guidelines, including allowable and unallowable costs.

H. Indirect Costs

- PCORI limits the total indirect costs to 40 percent of personnel, consultant costs, travel, supplies, and other expenses and on the first \$25,000 of each subcontract.
- Applicants that do not have a federally negotiated or independently audited indirect cost rate may assess up to 10 percent indirect costs, to be noted in the Budget Justification.
- Foreign applicants are eligible for no more than 10 percent indirect costs.
- A copy of the prime applicant's federally negotiated, or independently audited, indirect cost rate letter must be submitted with the application. Include these copies in a single file with the Budget Justification.
- While consortium indirect costs must be noted in the prime applicant's direct cost budget, consortium indirect costs are not included in the applicant's direct cost budget cap.

I. Engagement Costs

- The budget should account for patient and other stakeholder partner (individual and organizational) compensation. For additional guidance, review PCORI's Compensation Framework.
- Awardees should also consider costs of patient and other stakeholder expenses, project staff, engagement event and/or meeting costs, and incorporating partner feedback. For additional guidance, review PCORI's Budgeting for Engagement Activities document.

Detailed Peer Review Budget for Peer-Review-Related Costs

The detailed Peer-Review Budget must include costs related to the Peer-Review Process. 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.

- 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

A Budget Summary for the entire project for the prime applicant is created within PCORI Online when the budget is entered into the system. Review this information prior to submission. See [Appendix 2: Allowable and Unallowable Costs](#) to review acceptable and unacceptable uses of PCORI funding.

Subcontractor Detailed Budget Template

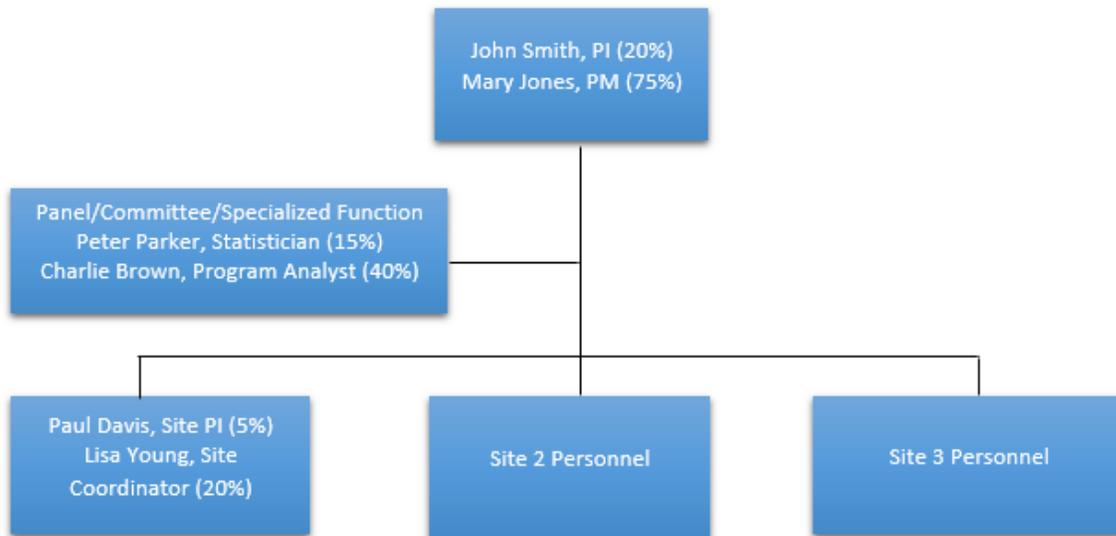
Complete the [Subcontractor Detailed Budget Template](#) for each subcontractor organization, then combine the files into a single PDF file and upload it to PCORI Online in the designated field. For each project year, complete a Detailed Budget for each subcontractor organization proposed in your application. All personnel information must be entered in the Personnel tab corresponding to that year in this template. Add additional rows for personnel as needed.

Budget Justification Template

Complete a [Budget Justification Template](#) for the prime applicant and each subcontracted organization for the entire Research Project Budget and Peer-Review Budget for all research- and peer-review-related costs. Provide sufficient detail to explain the basis for costs, the reason the costs are necessary to the project, and the reason for major cost variances. Include information about budgeting for engagement, including financial compensation of patient and other stakeholder partners, costs of patient and other stakeholder expenses, project staff, engagement event and/or meeting costs, and incorporating partner feedback. Note that some projects employ or assign an individual responsible for coordinating or managing all project-related patient and other stakeholder engagement. This person should be listed as full-time equivalent under personnel, consultant, or subcontractor costs. Explain the basis for travel costs, and describe how the travel is related to the proposed research and necessary for achieving programmatic objectives.

Describe the specific role and tasks each research team member will perform, along with the impact on the Project Plan. PCORI will evaluate each member's contribution as listed in the Budget Justification, to validate meaningful contributions and assess whether overlap in responsibilities occurs. Provide a clear distinction between individuals who should be key personnel and those who should be classified as "other" personnel.

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



Research Plan Template

Complete all required sections in the [Research Plan Template](#) and upload as a single PDF to PCORI Online. The Research Plan includes the Research Strategy, Research Team and Environment, Dissemination and Implementation Potential, Protection of Human Subjects, Consortium Contractual Arrangements, References Cited, and an optional Appendix.

Research Strategy

In this component of the Research Plan (up to 12 pages), applicants must describe their Research Strategy and work plan, in detail, and demonstrate how the proposed study responds to this PFA. This component also shows where merit reviewers may expect to find information to evaluate each of the merit review criteria delineated in the PFA. The Research Strategy addresses the following sections: (A) Specific Aims, (B) Background, (C) Significance, and (D) Study Design or Approach.

Per the PFA, applicants proposing use of an existing research network infrastructure (e.g., the National Patient-Centered Clinical Research Network [PCORnet]), research consortia, or related data resources (e.g., electronic medical records data from healthcare delivery systems or administrative claims data from public or commercial insurers) should address this with sufficient specificity in the Research Plan, as appropriate. Applicants should also refer to the PCORI Methodology Standards for Data Networks as Research-Facilitating Structures.

All applicants must 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.

As instructed in the Research Plan Template, complete the PCORI Methodology Standards Checklist to summarize adherence to the relevant PCORI Methodology Standards. Do not address standards that are not applicable to your study.

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

Provide all key personnel, professional and partner profiles/biosketches, and detailed site descriptions within the People and Places Template as a separate PDF upload.

Within the Study Design or Approach (Section D), applicants must outline how patients and other stakeholders will participate as partners in various phases of the proposed research. Applicants are encouraged to review [PCORI's Engagement Rubric](#),¹³ which can be found in the PCORI Funding Opportunities, before completing this section of the Research Strategy. Additionally, the [Engagement in Health Research Literature Explorer](#),¹⁴ a searchable, catalogued resource for peer-reviewed literature, can help applicants identify publications about engagement that are specifically relevant to their work. The Rubric and Sample Engagement Plans are not comprehensive or prescriptive; instead, they provide a variety of options to incorporate engagement, where relevant, into the research process. Applicants should also review the PCORI Methodology Standards Associated with Patient-Centeredness and PCORI's Sample Engagement Plans.

Applicants are expected to consult with patients and other stakeholders on their decisional dilemma and evidence needs, or to reference previously documented decisional dilemmas in preparation for the submission of LOIs and applications. To describe the decisional dilemma, state the specific clinical decision(s) 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 that patients and other stakeholders face in making this decision. Identify the patients and other stakeholders you consulted in determining that the proposed study addresses their evidentiary needs for decision making and indicate your commitment to continue engaging them actively in the conduct of the study. Similarly, applicants should document how the project outcomes are especially relevant and meaningful endpoints to patients and other stakeholders.

Justification of Assumptions

PCORI specifically seeks studies that are powered to detect meaningful effects. Applicants must justify the proposed sample sizes by explaining the assumptions used in all study power calculations. For example, the application must state all the necessary assumptions, such as 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.

Research Team and Environment

Within the Research Team and Environment component (up to two pages), applicants must describe the research team's capabilities to accomplish the goals of the proposed research project and the

¹³ Available at <http://www.pcori.org/sites/default/files/Engagement-Rubric.pdf>.

¹⁴ Available at <http://www.pcori.org/literature/engagement-literature>.

appropriateness of the research environment to conduct the study. Applicants must also describe the following:

- 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 the research environment's unique features or from community involvement
- 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

Provide all key personnel, professional and partner profiles/biosketches, and detailed site descriptions within the People and Places Template as a separate PDF upload.

Dissemination and Implementation Potential

In this component (up to one page), applicants should describe (A) their plans for making results available to study participants (as applicable), and (B) possible barriers to disseminating and implementing their work in other settings and any other study limitations that could have an impact on the usability of findings (e.g., propriety issues, applicability, scalability, and appropriate settings of care).

Beyond making results available to study participants (as applicable), PCORI does not expect awardees to budget for dissemination and implementation work at this juncture. However, be sure your proposed budget is consistent with supporting these plans. For projects that produce important findings, PCORI will consider subsequent applications for funding to support dissemination and implementation efforts through separate PFAs and other mechanisms.



Note: PCORI encourages researchers to submit documentation of any implementation agreement with the sponsoring organization, confirming that the organization will implement successful interventions on a large scale. PCORI will view this agreement as a positive factor during merit review. Include this with the Letters of Support PDF document as the last item.

Protection of Human Subjects

In this component (up to five pages), describe the protection of human subjects involved in your research. PCORI follows the Federal Policy for the Protection of Human Subjects ([45 CFR part 46](#)), including the Common Rule. For more detailed information, see Section 5, “Human Subjects Research Policy,” from the [Supplemental Grant Application Instructions for All Competing Applications and Progress Reports](#),¹⁵ which was issued by the U.S. Department of Health and Human Services (Department of HHS). Refer to the [Required Education of Key Personnel on the Protection of Human Subject Participants](#) requirement as you complete this section.

Consortium Contractual Arrangements

In this component (up to five pages), describe the proposed research projects that subcontracted organizations will perform. Explain the strengths that these partners bring to the overall project to ensure successful submission of contract deliverables in accordance with the milestone schedule.

Keep the following in mind as you complete this section:

- The prime applicant is responsible for the project and must adhere to the contract’s terms and conditions. The prime applicant must negotiate his or her subcontracts accordingly.
- Signed subcontract agreements are not required at the time of application submission to PCORI.
- Submitting an application to PCORI signifies that programmatic and administrative personnel from your organization and from all proposed subcontract organizations involved in the project are aware of your organization’s subcontract agreement policy and are prepared to establish the necessary interorganizational agreement(s) consistent with that policy.
- If applicable, include subcontract personnel under key personnel.
- Include budget information for subcontracted organizations 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 Research Plan, applicants should use in-text citations to reference published materials. In this section, list the full bibliographical citation for each reference. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article title and journal or book title, the volume number, the page numbers, and the year of publication. Include only bibliographic citations. PCORI suggests following AMA style when providing citations for source materials used to prepare any section of the application, but other citation styles are acceptable. Citations that are publicly available in a free online format may include URLs or PubMed ID numbers along with the full reference. *Limit references to relevant and current literature.* Be concise and select only those literature references pertinent to the proposed research, so that you do not exceed the 10-page limit. Reference websites in the standard URL format (i.e., <http://www.pcori.org>) along with the date on which the link was last accessed.

¹⁵ See <http://grants.nih.gov/sites/default/files/supplementalinstructions.docx>.

Appendix (Optional)

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

Methodology Standards Checklist

Applicants must complete the [PCORI Methodology Standards Checklist](#) and upload it as an Excel file to PCORI Online in the designated upload field. Applicants must complete Column D of the checklist, using the drop-down menu options to indicate whether each PCORI Methodology Standard applies to their proposed research. Applicants must complete the subsequent columns, as appropriate, following the instructions in the checklist. If the standard applies, in Column E provide the page number and section of your Research Plan where the text illustrates how you addressed the standard. Last, in Column F, indicate whether your study may deviate from the standard and provide a rationale. Refer to the [PCORI Methodology Report](#) for explanations of the standards.

Adherence to PCORI Methodology Standards

Applicants are required to adhere to [PCORI Methodology Standards](#)¹⁶ and accepted best practices. PCORI Methodology Standards include 54 individual standards that fall into 13 categories. The first five categories are cross-cutting and relevant to most patient-centered outcomes research (PCOR) studies. Researchers must refer to all of these standards when planning and conducting their research projects. These five categories are:

1. Standards for Formulating Research Questions
2. Standards Associated with Patient-Centeredness
3. Standards on Data Integrity and Rigorous Analyses
4. Standards for Preventing and Handling Missing Data
5. Standards for Heterogeneity of Treatment Effect

In addition to these five sets of standards, the first standard listed under “Standards for Causal Inference Methods”—(CI-1)—is cross-cutting and applicable to all PCOR studies.

The eight other standards categories will be applicable to certain study designs and methods. The standards in each of these categories must be used for guidance when they are relevant to a study.

These eight categories are:

6. Standards for Data Registries
7. Standards for Data Networks as Research-Facilitating Structures
8. Standards for Causal Inference Methods

¹⁶ See pori.org/assets/2013/11/PCORI-Methodology-Report-Appendix-A.pdf/.

9. Standards for Adaptive and Bayesian Trial Designs
10. Standards for Studies of Medical Tests
11. Standards for Systematic Reviews
12. Standards on Research Designs Using Clusters
13. Standards for Studies of Complex Interventions

These standards should be considered minimal. Additional best practices, including guidelines for conducting clinical trials developed by other organizations, must be addressed in the application.

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-PI, dual-PI, co-investigator, consultant, or other significant contributors), copying the tables provided in this section as needed. Note that you may submit the most recently posted National Institutes of Health (NIH)-formatted biosketch in lieu of a PCORI-formatted biosketch. Patient and stakeholder partners serving as key personnel may choose to complete the Patient and Stakeholder Partner Profile/Biosketch form in lieu of the Professional Profile/Biosketch. At a minimum, each profile must include the person's name, title, and degree(s). PCORI is especially interested to learn how each individual's previous experience, past performance, and training in the field of PCOR has prepared him or her to conduct this research. You must also describe the backgrounds, relevant experiences, and roles of patient and stakeholder partners.

Applicants must assemble a research team that is suited to complete the work. Applications must demonstrate that the study team's experience, leadership approach, governance, and organizational structure are appropriate for the project and will aid in achieving the project goals.

Project/Performance Site(s) and Resources

This component (up to 15 pages) is in the [People and Places Template](#). Demonstrate in detail that the proposed facilities have the appropriate resources required to conduct the project as planned, within budget, and on time.

Applicants must provide a description of the facilities they will use during the project, including capacity, capability, characteristics, proximity, and extent of availability to the project.

Leadership Plan (Required if Proposing a Dual-PI Application)

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

If proposing a dual-PI application, you must designate one as the Contact PI. The Contact PI must be employed by the applicant institution and listed first within the application. Although PCORI will recognize both PIs, the Contact PI is responsible for submitting the application and for communications between the PIs and PCORI, including coordinating meetings with PCORI staff.

Applicants proposing a dual-PI application, 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.

Letters of Support

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

All Letters of Support must be addressed to the PI and demonstrate the commitment of key personnel and supporting organizations (e.g., dual-PI, co-PI, co-investigators, consultants, patient and stakeholder partners, and stakeholder organizations) to the proposed project. Letters of Support are not required for personnel who are not contributing in a substantive, measurable way to the project's scientific development or execution. Letters of Support must reflect clearly the involvement and material contribution to be provided by the signatory parties and are meant to confirm the commitment of collaboration.

PCORI may contact any individuals or organizations included in the Letters of Support with questions or to confirm support as described in the letters.

Letters of Support must be organized as follows:

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organizational official, that confirms the institutional support of the proposed project; space to conduct the research; equipment; and other resources available for the project, including staff. PCORI also strongly encourages you to provide a letter from the department or organization leadership affirming support to disseminate 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. Letters of Support from patient and stakeholder partners must describe clearly the origin of the study topic and the role of the partners in defining the question, comparators,

goals and outcomes, and so on. PCORI also strongly encourages letters from patient or stakeholder partners or partnering organizations affirming support to disseminate and implement research findings that are germane and warranted for implementation. Include a Letter of Support for each consultant verifying the work to be performed and the negotiated rate.

- **Letters Confirming Access to Patient Populations, Data Sets, or Additional Resources:** If the proposed Research Plan involves access to patient populations, data sets, or additional resources, include a Letter of Support that confirm such access, signed by the person with approval authority. 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](#) (adding rows as needed), and include the page number on which each letter can be found in the single PDF file.

VII. Additional Requirements

Awardees are required to comply with the following requirements:

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

PCORI requires all applicants to adhere to the NIH policy on education in the protection of human subject participants in the conduct of research. This applies to all individuals listed as key personnel in the application. The policy and FAQs are available on the [NIH website](#).¹⁷

PCORI Public Access Policy

PCORI requires all awardees to adhere strictly to PCORI’s publication policies, which will be shared with awardees within the research contract.

Registering Research Projects

PIs are required to use the naming convention “PCORI-PCORI application number” (i.e., PCORI-XXXX-XXXXX). Clinical trials must be registered before enrollment of the first patient. All trials that meet the definition on the [NIH database](#)¹⁸ (see [Data Element Definitions](#)) are required to register, if funded.

Funded clinical trials or observational outcomes studies must be registered at [ClinicalTrials.gov](#).

Funded evidence-synthesis studies must be registered at [PROSPERO](#).¹⁹ Funded patient registries must be registered at <https://patientregistry.ahrq.gov/>.

¹⁷ Available at <http://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

¹⁸ Available at <https://prsinfo.clinicaltrials.gov/>.

¹⁹ Available at <http://www.crd.york.ac.uk/prospéro/>.

Standards for Privacy of Individually Identifiable Health Information

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

Decisions about the applicability and implementation of the Privacy Rule reside with the researcher and his or her institution. The [Office for Civil Rights](#)²⁰ provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools related to “Am I a covered entity?” Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding and progress monitoring of grants, cooperative agreements, and research contracts is available from [NIH](#).²¹

Award Funding Conditions

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

Co-Funding

PCORI partners with various other research organizations to leverage additional funds for some of its programs. If you currently have a funded project and would like to seek PCORI funding to add a new aim to the study that advances PCORI funding objectives, you may submit an application. We recommend that you speak with a Program Officer in advance.

Note: PCORI will not fund a project that is already funded through another funding entity. By submitting the application to PCORI, the AO is certifying that no overlap in funding exists at the time of submission. Prior to receiving a PCORI contract, awardees must disclose all current and pending support.

Dissemination and Data Sharing

PCORI encourages openness in research and making research data available for purposes of replication and reproducibility. As such, if an award is made through this targeted Funding Announcement, the Awardee will be required to adhere to [PCORI’s Policy for Data Management and Data Sharing](#).

The Policy articulates PCORI’s requirement that certain Awardees—specifically those funded through the Pragmatic Clinical Studies (PCS) and all targeted Funding Announcements—make the underlying data and data documentation (e.g., study protocol, metadata, and analytic code) from their PCORI-funded research projects available to third-party requestors. The Policy includes details about what data certain Awardees will be expected to deposit into a PCORI-designated data repository and when that data would be available for third-party requests.

A full data management and data sharing plan is not required at the time of application. If an award is

²⁰ Available at <http://www.hhs.gov/ocr/>.

²¹ Available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

made, the Awardee will be required to develop and maintain such a plan, which is described in detail in the [PCORI Methodology Standards for Data Integrity and Rigorous Analyses](#), specifically Standard IR-7. This plan must be appropriate for the nature of the research project and the types of research project data, and consistent with applicable privacy, confidentiality, and other legal requirements. Awardees are also strongly encouraged to include, as appropriate, language in the research project's informed consent forms that allows for the de-identification and sharing of study data for secondary research purposes.

As part of the Policy, PCORI intends to cover reasonable costs associated with the time and effort needed for preparing, depositing, and maintaining the Full Data Package in the repository for a period of at least seven (7) years following acceptance by PCORI of the Final Research Report. PCORI will negotiate with Awardees on the specific budget needs associated with this Policy requirement at the time of Award, in addition to the requested research project budget.

The information here is meant for informational purposes only and does not attempt to be an exhaustive representation of the Policy for Data Management and Data Sharing. Please refer to the Policy in its entirety for additional information.

Appendix 1: Example Milestones

Milestones are significant events, deliverables, tasks, or outcomes that occur over the course of each project and signify study progress. The completion of each milestone is intended to mark progress toward the project goals and to ensure that the project is on schedule and likely to be completed within the contract period. As part of Merit Review Criterion 3, reviewers evaluate the submitted milestone schedule to assess the feasibility of the study plan.

In general, and at the discretion of your PCORI project team if awarded, the following are examples of milestones and deliverables to be submitted to PCORI. You may reference this list as you complete this section of your application.

Required:

- Awardees must submit a PCORI Progress Report in PCORI Online at least every six months.

Within first six to nine months of an executed contract:

- Develop, finalize, and submit copy of study protocol in accordance with the PCORI Methodology Standards.
- Submit IRB approval in PCORI Online (continuing approval submitted annually).
- Select and register project at appropriate site for the study design (ClinicalTrials.gov, RoPR, or other as approved by PCORI before study start date).
- Submit updated Data Safety and Monitoring Plan. Refer to the PCORI Policy on Data Safety and Monitoring Plans for PCORI-Funded Research here: <http://www.pcori.org/sites/default/files/PCORI-Policy-Data-Safety-Monitoring-Plans.pdf>.
- Submit updated Recruitment Plan.
 - Elements in the recruitment plan should, at a minimum, include the following: timeline; total target sample size for primary analysis; name and # study sites; historical patient volume and estimated eligible N across study sites; estimated yield/consent; estimated loss to follow-up/attrition; and estimated monthly enrollment.
- Submit updated Engagement Plan.
 - Elements of the updated Engagement Plan should include the following: updated roster of committee/panel members with short bios; patient and/or stakeholder advisory panel(s) or committee(s) governance schematic; planned training for patient and other stakeholder partners on the research process; proposed meeting schedule; tasks or opportunities wherein patients and/or stakeholders will have input via consultation, collaboration, or leadership; and efforts to evaluate/assess engagement.
- Begin recruitment: Site(s) activated and screening for study enrollment.
- Enroll first patient. From this point forward, submit monthly enrollment update to PCORI including cumulative and interval recruitment, accrual, and retention for the overall study (e.g., number eligible, approached, consented, enrolled, retained).
 - Monthly enrollment updates are not required in the milestones schedules, but awardee must include milestones to enroll and retain 25, 50, 75 and 100 percent of targeted sample size (include target N of patients per reporting period) throughout the duration of the project.

Within the first 12 to 15 months of an executed contract:

- Submit 100 percent of the IRB approvals across sites to PCORI.
- Submit status report detailing executed subcontract agreements across sites.
- Seventy-five percent of the sites must have started recruiting patients.
- The 25 percent cumulative enrollment target has been met.
- Programmatic Evaluation Materials are due to PCORI. For projects with a duration of four or more years, awardee must submit document that demonstrates study progress and feasibility based on metrics provided by PCORI at the time that contract is executed. In general, the Programmatic Evaluation will encompass the first 12 to 15 months of the contract, with materials due to PCORI ~15 months.

Remainder of Contract:

- Primary Completion Date
 - An estimated Primary Completion Date must be provided when registering the study in ClinicalTrials.gov. For studies that are not clinical trials or non-prospective observational studies registered on [ClinicalTrials.gov](http://www.clinicaltrials.gov), the Awardee and PCORI shall agree on a Primary Completion Date as a milestone that precedes the agreed-upon date to submit a Draft Final Research Report.
- Results submitted to ClinicalTrials.gov or applicable database
 - Awardee ensures results are submitted to ClinicalTrials.gov or another database. For ClinicalTrials.gov, the generated tables are a required section in the Draft Final Research Report. Results must be submitted to ClinicalTrials.gov no later than submission of the Draft Final Research Report.
- Draft Final Research Report Submission
 - Submit Draft Final Research Report according to instructions found at: <http://www.pcori.org/sites/default/files/PCORI-Draft-Final-Research-Report-Instructions.pdf>
- Draft Final Research Report Revisions
 - Upon receipt of written summary, and as applicable, PI will make revisions and submit revised Draft Final Research Report and disposition of comments table for acceptance in accordance to PCORI policy and process.
- Submit Final Progress Report.
- Approval/sign off of the Lay Abstract
 - No later than 90 days beyond the date PCORI accepts the final report.

If awarded, a contractual milestone schedule will be negotiated and finalized with the PCORI project team. Additional reporting, such as monthly enrollment updates, may be required.

Appendix 2: Allowable and Unallowable Costs

Acceptable uses of PCORI research contract funds are those that directly support the proposed research project, including collecting and analyzing data and obtaining relevant data sets. Because PCORI primarily funds comparative clinical effectiveness research, the research projects generally involve the comparison of clinical interventions or strategies that are considered to be accepted standard of care and are not experimental or investigational. As a result, when 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 that can be included in a proposed Detailed Budget when applying for a PCORI Funding Award and charged to the award) may include the following costs that derive from and directly support the research project:

- Salaries and fringe benefits for study investigators and other research project staff (including engaged patient and other stakeholder research study partners) related to their percentage of effort on conducting the research project (Such costs may not include personnel who deliver patient care as a component of their participation in the research project.)
- Consultant fees
- Travel for mandatory investigator meetings
- Travel that is necessary for conducting the research project
- Supplies
- Equipment
- Subcontracts
- Expenses related to conducting engagement activities with patients and other stakeholders
- Other direct research expenses
- Indirect costs

A funding applicant must specifically request costs related to conducting the research project through itemization on the Detailed Budget. PCORI will consider this request 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, PCORI will not cover 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”). The host healthcare delivery system, third-party payer, product manufacturer, developer of the intervention, or other interested party must cover the patient care costs.

- The willingness of one or more stakeholder groups to cover patient care costs incurred during the research project, even when one of the comparators is not currently directly covered by insurance, will be taken as a strong endorsement of the research project by the stakeholder group. Such commitments also indicate that the stakeholder groups will use the research study’s findings. (Such support by a stakeholder group must be discussed in the application.)
- Except for specific permission in exceptional circumstances, PCORI will not cover patient care costs.
- PCORI may consider coverage of the co-payment or co-insurance costs of participating study subjects when necessary to preserve blinding in a study or to ensure access to the study for vulnerable populations.
- PCORI will generally cover costs for ancillary tasks necessary to implement or monitor patient care as part of conducting the research project. Examples include costs for obtaining informed consent to participate in the research project; collecting data pursuant to the research protocol; or collecting and monitoring study subject data that would not normally be performed in the course of patients receiving the patient care evaluated in the research project.

PCORI will review all proposed costs. Costs must be deemed allowable, allocable, and directly necessary for 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. For more information, see [PCORI Cost Principles](#).

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

Automatic Rejection	Modification by PCORI	Appended upon PCORI's Request*
<p>An application or LOI will be automatically rejected if any of the following apply:</p> <ul style="list-style-type: none"> • 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 	<p>PCORI will modify an application by removing all pages that exceed stated limits.</p>	<p>Unless automatically rejected or modified, PCORI may request that the applicant submit missing documents or correct noncompliant ones.</p>

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