Eugene Washington PCORI Engagement Award Program
Submission Instructions for October 2020 Funding Opportunities

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About PCORI

The Patient-Centered Outcomes Research Institute (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” and by promoting the dissemination and uptake of this evidence.

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.

Key Information for the Engagement Awards October 2020 Funding Cycle:

- Applicants should consider alternative plans for convening should an in-person meeting not be feasible. Please consult PCORI’s Applicant and Awardee FAQs Related to COVID-19 to ensure your proposed project adheres to PCORI’s guidance related to applicant pre-award concerns.

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I. About These Instructions

This document provides key information to help applicants prepare for and respond to the following Eugene Washington Patient-Centered Outcomes Research Institute (PCORI) Engagement Awards Funding Announcements (PFAs):

- Capacity Building PFA
- Dissemination Initiative PFA
- Stakeholder Convening Support PFA

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

- See PCORI’s Engagement Award FAQs for common questions about PCORI and the Engagement Awards application process.

For programmatic, administrative, and technical questions, or to schedule a call with program staff: Contact us by email (ea@pcori.org) or phone (202-370-9312). PCORI will respond within three business days.

Administrative Considerations

Applicants that fail to submit the required documents may be rejected from the review process. All rejection decisions made are final.

Unless otherwise stated within the Submission Instructions, 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

The Eugene Washington PCORI Engagement Awards are issued as firm-fixed-price “service-based” or “mission-based” contracts. They are not research awards, nor should they be treated as such. Applicants are expected to discuss the announcement and the potential resulting contractual mechanism with their contracts and grants management office to ensure they are able to accept it.

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. 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.
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 upon milestones and deliverables. Applicants’ proposed milestones will be finalized in contract negotiations and prior to execution. See PCORI’s Standard Contract Template for Funded Engagement Award Projects for more information.

Key Roles

PCORI refers to two specific roles with particular responsibilities. Keep the following in mind as you review the Submission Instructions and complete your LOI and application:

Project Lead (PL)

- **Description:**
  - The PL is the lead representative of the applicant organization for the project.
  - The PL serves as PCORI’s lead point of contact.
  - The PL’s organization/institution must be the primary organization/institution for the award.
  - PLs can participate in other applications (from the same or other organizations/institutions) in a different role, such as project lead designee or consultant.
  - If electing to submit an application with a co-PL, you must designate one individual as the primary PL. The primary PL is responsible for submitting the application and will serve as PCORI’s primary point of contact for all communication.

- **Activities:**
  - The PL assumes responsibility and accountability for project execution, compliance, and organizational conduct.
  - The PL manages day-to-day project operations.
  - The PL acts as the applicant organization’s lead representative.

Administrative Official (AO)

- **Description:**
  - The AO is responsible for matters related to the award and administration of the contract.
  - The AO cannot be the Project Lead.
  - The AO’s signature certifies that the applicant organization will be accountable for appropriately using the funds awarded and for performing the PCORI-supported project.

- **Activities:**
  - The AO manages contract activation, modifications, and additional require administrative matters.
  - The AO certifies contract compliance of all applicable assurances and certifications referenced in the application.
II. Who Can Apply

Applications may be submitted by any private-sector organization, including any nonprofit or for-profit organization; any public-sector organization, including any university or college hospital or healthcare system; 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 ea@pcori.org.

Non-domestic 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-Project Lead as a subcontractor. In assessing whether an Engagement Award can be made to a non-U.S. organization as a prime contractor or subcontractor, and/or whether the project can be conducted outside the United States, PCORI will carefully review and consider the following factors:

- The proposed project must result in findings that are relevant and useful to U.S. patients and healthcare decision makers.
- The proposed project must demonstrate meaningful effort and involvement of U.S. organizations and key personnel with pertinent expertise and experience to contribute to the project. The proposed project should also adequately and sufficiently engage U.S. patients and stakeholders and have clear relevance to the U.S. healthcare system.

Organizations may submit applications for Engagement Awards funding regardless of whether they have either applied for or received previous awards from PCORI. In their application, organizations should note any other applications concurrently submitted to PCORI or projects currently funded by PCORI so our staff can confirm that there is no overlap between projects.
III. How to Apply

Applying for PCORI funding is a two-stage process. To submit an LOI and application (if invited), including all required documents, follow the instructions provided in this document and in the PCORI Engagement Awards Online Application System. All required documents must be submitted through PCORI Online. Failure to follow these submission instructions or to submit all required documents through this system may result in removal of the application from the review process.

Step 1: Register

To apply for PCORI funding, an applicant (Project Lead or PL designee) must register in the PCORI Engagement Awards Online Application System. 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. Select the “Engagement Awards” button to begin applying. PCORI strongly recommends that only the Project Lead create the LOI/application record, because whoever creates the record will have permanent access to it in PCORI Online. Please contact us at ea@pcori.org with questions regarding the registration process.

To submit a Letter of Intent or 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 and an EIN, if applicable. Applicants should enter their EIN number formatted as “XX-XXXXXXXX”. International organizations should enter “99-9999999” in the EIN field in the Letter of Inquiry (LOI).

Step 2: Submit a Letter of Inquiry (LOI)

An LOI is required before completing a full application. To submit an LOI, log in to the PCORI Engagement Awards Online Application System, select the “Engagement Awards” button, then select the “Create an LOI” button and complete the required fields.

Applicants should refer to the LOI Question Guides for the Engagement Award PFA you are applying to when developing your responses. The LOI Question Guides are to guide your response and will not be accepted as an LOI submission – all LOIs must be submitted through PCORI Online.

- [Capacity Building LOI Question Guide](#)
- [Dissemination Initiative LOI Question Guide](#)
- [Stakeholder Convening Support LOI Question Guide](#)
Note: The Project Lead (PL) will be prompted to certify that they are authorized by their organization to submit the LOI to PCORI. By the PL selecting ‘Yes’ it is presumed this authorization has been received from the AO. It is not required for the Administrative Official (AO) to log in to PCORI online and formally authorize the LOI prior to submission.

The PL must formally submit the LOI to PCORI before the 5:00pm (ET) deadline. The PL will receive an email confirming that PCORI has received the LOI.

For detailed instructions on how to navigate the system, reference PCORI Online: Pre-Award User Guides for Engagement Awards.

Step 3: Begin Application Process

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

PCORI will notify applicants as to whether they have been invited to submit an application. The application consists of multiple sections in the PCORI Engagement Awards Online Application System, all of which you must complete before submission. Log in to PCORI Online to view the full list of questions. Information entered as part of the LOI submission will be saved and can be edited as needed.

Step 4: Format and Complete Required Application Templates

Required application templates are on the PCORI Funding Opportunities web page. Find the PFA to which you are applying 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.
- Adherence to font size, type density, line spacing, and text color requirements is necessary to ensure readability and fairness.
You must format all required documents as follows:

- **Document Format:** All uploaded documents must be in PDF, Microsoft Word, or Microsoft Excel format. Some documents must be uploaded as a specific format, including:
  - The Workplan document must be uploaded in Microsoft Word format.
  - The Budget document must be uploaded in Microsoft Excel format.
  - The Milestones/Deliverables table must be uploaded in Microsoft Excel format.

- **Header:** Each page should include the name of the organization, the project title, and the full name of the PI in the header’s left corner.

- **Font:** Use Calibri size 11 font for body text and size 8 font for figures, tables, and captions.

- **Type Density:** Must be no more than 15 characters per linear inch (including characters and spaces).

- **Line Spacing:** Use single spacing. Must be no more than six lines per vertical inch.

- **Text Color:** No restriction. Though not required, black or other high-contrast colors are recommended since they print well and are legible to the largest audience.

- **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 or Microsoft Word document upload. Begin each uploaded document with page 1.

- **Page Limit:** This varies based on the document.

- **File Name Format:** We recommend naming the file LOI Number-Organization Name/Acronym-Template Name (i.e., 12345-PCORI-Workplan.doc or 12345-PCORI-Budget_Justification.xls).

- **References:** PCORI suggests including all references as in-text citations using American Medical Association (AMA) citation style, but other citation styles are acceptable.

- **Appendices:** Not permitted as part of the Workplan proposal attachment. All graphs, charts, or graphics must be included in the body of the Workplan and all apply towards the maximum page count.

Legibility is of paramount importance. Applications that include attachments that do not conform to the minimum requirements listed above may be withdrawn from consideration.
Step 5: Upload Required Application Documents

Follow the Submission Checklist included in the Appendix to enter required information. Within the Attachments tab, click “Choose file” to select the appropriate file from your computer, and click “Upload.” When instructed, use Adobe Acrobat Professional¹ to combine documents into a single PDF file for upload. For detailed instructions, refer to the Attachments section of the PCORI Online: Pre-Award User Guides for Engagement Awards.

Step 6: Submit Application for Authorization

Once you have completed and uploaded all required information, select “Review/Submit” in the upper right corner, verify the information in your application, and then select “Submit” to forward the application to your Administrative Official (AO) to authorize and officially submit the application to PCORI. The AO must approve and submit the final application for official submission to PCORI before the 5:00pm (ET) deadline. PCORI Online will email the AO, but the PL should notify the AO when the application is ready for review, AO approval, and submission. The PL and the AO may not be the same individual. After official submission, both the AO and the PL will receive an email confirming that PCORI has received the application.

IV. When to Apply

Deadlines for each funding cycle are noted on 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 Online before the specified deadline. Problems with computer systems at the applicant’s organization or failure to follow instructions in PCORI Online, in the Engagement Award Submission Instructions, or in PFAs are not valid issues warranting consideration of a deadline extension.

V. Letter of Inquiry (LOI) Requirements

An LOI must be submitted and evaluated for programmatic fit for PCORI to determine if you will be invited to submit a full application.

The content included in your LOI is the primary source of information for PCORI’s competitive screening process. PCORI will not invite an applicant to submit an application if the applicant’s LOI does not meet program goals 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.

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¹ See adobe.com for more information on Adobe Acrobat Professional.
Refer to the Pre-Award User Guides for Engagement Awards for step-by-step instructions on navigating the PCORI Engagement Awards Online Application System to submit your LOI. The information below is intended to give programmatic guidance on the type and format of information that applicants should submit.

LOI Form

The LOI form includes the eight main sections of the LOI, as listed below.

General Information Tab

Provide basic information about the PL and the primary institution or organization applying for the award.

See Section ‘I. About These Instructions’ above and PCORI’s Glossary for definition of the PL role.

Note: When searching for and selecting the individuals to serve as PL, please ensure the user account selected matches the current email address of that individual. If the individual’s account shows an old email address, they will need to update their profile information in PCORI Online prior to submission of the LOI. Multiple users in the system may have the same name and care should be taken to ensure the correct individual is selected.

Additional Key Roles

Provide basic information about the AO and any PL Designees (up to two).

See Section ‘I. About These Instructions’ above and PCORI’s Glossary for definition of the AO role.

Note: When searching for and selecting the individuals to serve as AO or PL Designee, please ensure the user account selected matches the current email address of that individual. If the individual’s account shows an old email address, they will need to update their profile information in PCORI Online prior to submission of the LOI. Multiple users in the system may have the same name and care should be taken to ensure the correct individual is selected.

Pre-Screen Questionnaire Tab

Review the list of activities that are considered out of scope for an Engagement Award. Select “yes” or “no.” Please note that if you answer “yes,” your LOI may be considered out of scope. A full list of activities considered out of scope is in the PFA for the Engagement Award you are applying to.

Organization & Project Lead Details

Provide responses to the questions about the organization and the Project Lead.
**Project Summary**

Provide detailed, but brief descriptions that allow PCORI to understand the project without having to review a full application. Applicants invited to submit a full application will have an opportunity to add additional details in response to these questions.

Note: Focus on including only critical information as space is limited. All character counts include spaces and other formatting. Please adhere to the character counts listed in each individual question prompt. Disregard the automated counter's maximum when instructed.

**Additional Project Information**

Provide information about the budget, requested contract period, and the stakeholder communities your project seeks to engage.

If applying for the Engagement Award: Capacity Building or Engagement Award: Stakeholder Convening Support, identify if your proposal focuses on either of PCORI’s updated research priority areas – intellectual and developmental disabilities or maternal mortality. While PCORI will accept applications for research support projects—not research—on any topic, this funding cycle welcomes projects highlighting either of the two special areas of interest around intellectual and developmental disabilities and maternal mortality.

**Note:** The amount requested from PCORI includes both direct costs and any requested indirect costs. This total cost – direct costs and indirect costs combined – may not exceed the maximum allowable amount as specified in the funding announcement you are responding to.

**Note:** For the October 2020 Engagement Awards Funding Cycle, the contract start date should be planned for no earlier than May 1, 2021.

**Using PCORI-funded Evidence & Tools**

Identify if your proposed Engagement Award project will disseminate eligible PCORI-funded evidence. Applicants must identify each completed PCORI-funded research study proposed for dissemination in the LOI. All evidence that is the focus of an Engagement Award must have been published (comparative clinical effectiveness research results) or posted on PCORI’s website (Systematic Reviews, Systematic Review Updates, and Evidence Updates) by the LOI submission deadline. Eligibility criteria is available in the PFA to which you are applying.

Additionally, identify if your proposed Engagement Award project will use or adopt a PCORI-funded engagement tool or resource, and if so, describe the engagement tool(s) or resource(s) selected and justification for its continued and expanded use. Information about prior use/implementation of the tool(s) or resource(s), including any data on its effectiveness to build capacity for patient and stakeholder engagement in PCOR/CER should be provided.
Authorizations

The Project Lead should select “Yes” to certify that they are authorized by their organization to submit the LOI. Click “Save.”

- By the PL selecting ‘Yes’ it is presumed this authorization has been received from the AO. It is not required for the Administrative Official (AO) to log in to PCORI online and formally authorize the LOI prior to submission.

Review/Submit

When you have completed the LOI and are ready to submit, click “Review/Submit” at the top of the page. You will be taken to a read-only version of the LOI. To continue editing, click “Back to Record.” To print the LOI, click “Print.” When you have fully reviewed the LOI and are ready to submit, click “Submit.” Click “OK” in the pop-up window to verify your submission.

Note: The LOI does not need to be submitted by the AO in PCORI Online. PCORI encourages the PL to inform the AO when the application is ready for submission, so it can be reviewed before final approval and submission. The AO and the PL may not be the same person. The AO acknowledges PCORI’s contractual mechanism as a contract and not a grant, and that the applicant institution is able to accept the contract terms and conditions without alteration.

VI. Application Requirements

Applicants may submit a full proposal by invitation only. These invitations will be sent via email, along with instructions on how to access the application.

Information entered into the LOI will be carried over to the full application. The application is divided into several tabs:

- General Information
- Additional Key Roles
- Pre-Screen Questionnaire
- Organization & Project Lead Details
- Project Summary
- Additional Project Information
- Using PCORI-funded Evidence & Tools
- Key Personnel
- Attachments
- Budget
- Authorizations

Additional guidance is provided for specific sections of the application, as listed below.
Project Summary Tab

In addition to reviewing and revising the information provided in the LOI, as needed, provide additional information, as follows:

- A project summary that may be made public on the PCORI website or in other PCORI-related publications (up to 3,500 characters including spaces):
  - **Background**—Briefly state the problem or question that the project is designed to address.
  - **Proposed Solution to the Problem**—Briefly describe the manner in which the problem or question will be resolved, including your project’s location (i.e., city, town, district) and setting (i.e., clinic, community center, school).
  - **Objectives**—Briefly describe the project aims, including the long-term objectives.
  - **Activities**—Provide a concise description of project activities that will occur throughout the project’s duration.
  - **Outcomes and Outputs** (projected)—Specify the projected outcomes and state their significance. What tangible outputs will this project produce (i.e., training curricula, research agenda, etc.)?
  - **Patient and Stakeholder Engagement Plan**—Who are the patients and stakeholders involved in or impacted by the project, how will they be engaged, and how often will they be engaged in the planning and execution of the proposed project?
  - **Project Collaborators**—Which organizations or institutions are helping to lead, subcontract, or support this project in any way?

Additional Project Information Tab

**Patient and Stakeholder Compensation**

Indicate whether patient or stakeholder partners engaged in the project will receive financial compensation for their role(s) and, if yes, describe this compensation. See PCORI’s Financial Compensation Framework for guidance.

**Collaboration and Partnerships**

Provide the name of organizational collaborators or partners, and describe the organization’s role in meeting the project’s goals and objectives. Collaborator/partner organizations are project contributors that are not subcontractors (i.e., have no fiscal relationship to the applying organization). PCORI encourages applications that will include novel collaboration with accreditation organizations, credentialing bodies, educational enterprises, patient advocacy groups, industry, professional societies, and subspecialty societies.
Using PCORI-funded Evidence & Tools

Identify if your proposed Engagement Award project will disseminate eligible PCORI-funded evidence. Applicants must identify each completed PCORI-funded research study proposed for dissemination. All evidence that is the focus of an Engagement Award must have been published (comparative clinical effectiveness research results) or posted on PCORI’s website (Systematic Reviews, Systematic Review Updates, and Evidence Updates) by the LOI submission deadline. Eligibility criteria is available in the PFA to which you are applying.

Additionally, identify if your proposed Engagement Award project will use or adopt a PCORI-funded engagement tool or resource, and if so, describe the engagement tool(s) or resource(s) selected and justification for its continued and expanded use. Information about prior use/implementation of the tool(s) or resource(s), including any data on its effectiveness to build capacity for patient and stakeholder engagement in PCOR/CER should be provided.

Key Personnel Tab

PCORI identifies key personnel as any individual who contributes to the development or execution of the project in a substantive and measurable way. The contribution is independent of financial compensation.

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.

Select “New” to enter new key personnel in the online system. Limit your application to five key personnel. The PL should not be included under this tab. When finished entering your key personnel, select “Next” to be taken to the next tab of the application.

Attachments Tab

Required templates vary by Engagement Award PFA and are listed as Applicant Resources on the webpage of the PFA you are applying to:

- Capacity Building Applicant Templates
- Dissemination Initiative Applicant Templates
- Stakeholder Convening Support Applicant Templates

Upload required documents by selecting “Choose File” and following the system prompts for each document type. We recommend naming the file LOI Number-Organization Name/Acronym-Template Name (i.e., 12345-PCORI-Workplan.doc or 12345-PCORI-Budget_Justification.xls). Maximum file size for all documents is 10 MB. Documents should be PDFs, Microsoft Word files, or Microsoft Excel files only.
Please note the following files that must be uploaded in specific formats:

- The **Budget** and **Milestones/Deliverables Table** documents must be uploaded in Microsoft Excel format.
- The **Workplan** document must be uploaded in Microsoft Word format.

When finished uploading all required files, select “Continue” to be taken to the next tab of the application.

*Required attachments are described below:*

**Workplan**

Upload the required template in a Microsoft Word file format, following required page limits. Complete all sections of the template.

**Note:** Applicants should consider alternative plans for convening should an in-person meeting not be feasible. Please consult [PCORI’s Applicant and Awardee FAQs Related to COVID-19](#) to ensure your proposed project adheres to PCORI’s guidance related to applicant pre-award concerns.

**A. Workplan (Limit 15 pages)**

Describe in detail the project and its strategy or approach. Include the following sections:

- **Background**—State the problem or question the project is designed to address.
- **Proposed Solution**—If a solution to the problem is proposed, explain it. Explain why it is believed that this solution will work and be better than previous solutions. Describe how the solution will be achieved (designed and implemented) or is at least achievable.
- **Objectives**—Briefly describe the project’s aims, including the long-term objectives.
- **Methods**—Provide a concise description of project methods that will be employed.
- **Expected Project Outcomes and Impact**—Specify the key projected outcomes and their significance, along with the metrics you will use to measure them.
- **Evaluation Plan**—Briefly outline the plans for evaluation of project outcomes. Consider the Evaluation Reporting Tool (end-of-project required deliverable) in the development of the evaluation plan.
- **Sustainability**—Briefly outline the project team’s plans for sustainability after the project period has ended. Future funding from PCORI should not be assumed. If the project does not lend itself to sustained activities after the project period concludes, provide justification.

In addition, describe past performance, including any similar projects you or your organization has conducted, any past experience with PCORI, or any additional relevant experience.
**Note:** Appendices are not permitted as part of the Workplan proposal attachment. All graphs, charts, or graphics apply towards the 15-page limit and must be included in the body of the Workplan and all apply towards the 15-page limit.

**B. Project Timeline (Limit 2 pages)**

Describe the project’s major activities and expected milestones, by month.

**C. Patient and Stakeholder Engagement Plan (Limit 2 pages)**

In this component (up to 2 pages), describe the plan to engage patients and stakeholders meaningfully throughout the proposed project. The application should integrate patients and stakeholders in the development of the project plan and in the project’s key elements. The Patient and Stakeholder Engagement Plan should address the following questions:

- Does the application describe how patients and stakeholders were or will be identified and engaged in the project?
- Are the roles of patients and key stakeholders significant in formulating the project’s questions and design, and in the project’s conduct and dissemination of results?
- Are the roles proposed for patients and stakeholders in any dissemination or implementation plans meaningful and likely to be effective?

**Protection of Human Subjects**

If applicable, in this component (up to five pages), describe the protection of human subjects involved in your project. 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, titled “Human Subjects Research Policy” from the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, which was issued by the U.S. Department of Health and Human Services.

**Subcontractual Arrangements**

Describe the project components that subcontracted organizations will perform. Explain the strengths that these partners bring to the overall project. Describe subcontract personnel, including names, degrees (if applicable), role(s) on the project, and contact information. Note the following:

- Signed subcontract agreements are not required at the time of application submission to PCORI.
- The submission of an application to PCORI signifies that programmatic and administrative personnel from your organization and all proposed subcontract organizations 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.
- Budget information for all subcontracted organizations must be included in the Budget template and Budget Justification template.
References Cited

In this component (up to 10 pages) in the Project Workplan and Timeline, if applicable, provide a list of references cited. Each reference must include the names of all authors (in the same sequence in which they appear in the publication); article title; and journal or book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials used 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. The references should be limited to relevant and current literature. It is important to be concise; select only those literature references pertinent to the proposed project so that the 10-page limit is not exceeded. Websites should be referenced in the standard URL format (i.e., http://www.pcori.org) with the date the link was last accessed.

Milestones/Deliverables Table

Upload the required template in Microsoft Excel format. PCORI encourages applicants to provide three to six milestones each project year, though there is no minimum or maximum, in addition to the required interim progress reports every six months. There should be at least one milestone or deliverable in the period between each of the required reports. Applicants should insert rows for additional milestones or deliverables, when and where appropriate as they would correspond to the timing of the milestone or deliverable.

Include a brief narrative summary of each project milestone or deliverable. For due dates, please use numerical dates formatted as XX/XX/YYYY, rather than generic months, date ranges, or written dates.

In general, deliverables are measurable and verifiable outputs or objects, and resources that can be shared broadly with the PCOR community, inclusive of project findings and adaptable tools for others to build on. These could be things such as data collection tools, meeting materials, narrative summaries, outreach materials, reference materials and training materials.

A draft final progress report is a required deliverable, to be submitted to PCORI one month prior to the end of the project period. The PCORI template must be used for this submission. PCORI will review and copy edit the submitted draft final progress report to prepare the document to be shared publicly on the awardee’s PCORI project page at the conclusion of the project period. PCORI will return the copy edited final progress report to the Project Lead during the last month of the project period.

The final progress report is a required deliverable to be submitted to PCORI at the end of the project period (on the Agreement Term Date).

All Engagement Award applicants must include a completed Evaluation Reporting Tool as a deliverable at the end of the project period on the Agreement Term Date. The Evaluation Reporting Tool is available as an Applicant Resource in the Engagement Award PFAs.
The **Engagement Award: Stakeholder Convening Support** PFA has additional requirements for completing and uploading the Milestones/Deliverables Table. The following milestones/deliverables are required:

- **Convening Date**
  - This milestone should be entered with the date of the planned convening. Enter multiple milestones if the proposed project has multiple convenings planned.

- **Draft Meeting Materials**
  - This deliverable should be submitted 1-3 months prior to the convening. Draft meeting materials may include agendas, participant lists, presentations, etc.

- **Final Meeting Materials**
  - This deliverable should be submitted at the time of the convening or during the month after the convening. Final meeting materials may include agendas, participant lists, presentations, etc.

- **Lay Conference Summary**
  - This deliverable is required to be submitted within 90 days after the convening. The applicant is required to provide a two- to three-page meeting summary report, written in lay terms, for posting on the PCORI website.

- **All convenings must also produce at least one deliverable that seeks to move collaborators closer to participation in and/or dissemination of PCOR/CER.**

### Budget

Upload the required template in Microsoft Excel format. Enter a detailed budget for each year of the project period. Each Engagement Award PFA states the maximum project period. Include all costs for your organization in the applicant worksheets. If applicable, include all costs for each subcontracted organization in the subcontractor worksheets.

See Appendix 2: Allowable and Unallowable Costs and [PCORI Cost Principles: Description of Allowable Direct Costs under a PCORI Award](#) to review acceptable and unacceptable uses of PCORI contract funds.

- **Note:** The award total costs includes all direct costs plus all indirect costs. Your requested funding amount may not exceed the award total costs (direct + indirect) as specified in the funding announcement you are responding to.

- **Note:** Applicants should consider alternative plans for convening should an in-person meeting not be feasible. Please consult [PCORI’s Applicant and Awardee FAQs Related to COVID-19](#) to ensure your proposed project adheres to PCORI’s guidance related to applicant pre-award concerns.
Keep the following guidelines in mind as you complete each section of the worksheet:

A. Personnel Costs

- Personnel costs 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 considered key personnel and those considered “other” personnel. Add additional rows for personnel as needed.

- 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 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 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.

- Inflation/Cost of Living Adjustments may only be assessed on base salaries less than the $200,000 salary cap.

- 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.
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 consultant(s), as well as name(s), expected number of hours, and hourly rate.

- Include the daily consultant fee, 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. Include the category of supplies needed and the cost for each.

- Indicate general categories such as mailings and printing 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, 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 project, the following must be provided in the Budget Justification:

- Detailed explanation of why purchasing these items is necessary to complete the proposed project

- Statement verifying that the requested items are not currently available for the PL’s use

- Statement ensuring 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**

• Applicants should consider alternative plans for convening should an in-person meeting not be feasible. Please consult [PCORI’s Applicant and Awardee FAQs Related to COVID-19](https://www.pcori.org/awardees/awardees-faqs) to ensure your proposed project adheres to PCORI’s guidance related to applicant pre-award concerns.

• 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 project and necessary for achieving programmatic objectives.

**E. Other Expenses**

• 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, publication, illustration costs, and non-consulting service contracts (when applicable).

• In the space provided, include a detailed explanation for items that exceed $1,000. Applicants must provide additional detail for each of these costs in the Budget Justification.
**F. 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:
  
  o The subcontractor personnel’s effort on the project is calculated as part of his or her “professional time” for his or her employer organization.
  
  o 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.

**G. 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 all subcontractor costs combined (direct and indirect).

- 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.

- If funded, the indirect cost rate submitted at the time of application is what PCORI will utilize during contract negotiations. If there is a change in the indirect cost rate once a project is executed, and the awardee wishes to charge a different rate, they must contact their PCORI Contract Administrator and provide a copy of the new federally negotiated rate or independently audited rate. PCORI may allow a change in the rate charged, but the awardee will need to reallocate within their existing, approved budget. PCORI will not allow additional funds to offset any increases in indirect costs and the rate increase cannot result in a reduction in scope of the approved project.
Budget Justification

Upload the required template. 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 proposed in the budget for the applicant organization and for each subcontracted organization (if applicable) for each year of the project period.

- Describe the specific role and tasks each project 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 project. Include funding amounts and the period during which the funding will be available. Use continuation pages as needed.

- **Federally Negotiated Cost Agreement**: If requesting greater than 10 percent indirect costs, add this document to the end of the Budget Justification and combine as one file.

**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.

Biosketch

Complete a Profile/Biosketch, for the PL and each person listed in the Key Personnel. Combine them into one PDF or Microsoft Word document for uploading.

At a minimum, each profile must include the person’s name, title, and degree(s). PCORI is especially interested to know each individual’s previous experience, past performance, and training in the field of PCOR (if applicable) has prepared him or her for their role in this project. Applicants must assemble a project team that is suited to complete the work. If the PL does not have PCOR experience, please outline appropriate collaborative arrangements with PCOR experts.

Information from National Institutes of Health (NIH) biographical sketches can be incorporated. Applicants may use an NIH biographical sketch in lieu of the PCORI-provided template (up to five pages in length per individual); however, they must clearly demonstrate their PCOR/CER experience within the NIH template.

**Note**: PCORI recognizes that not all sections of the Professional Profile/Biosketch may apply to patient or other stakeholder members of the project team. There is no educational degree requirement for the Project Lead or Key Personnel; however, they should have prior experience applicable to their role on the project.
Letters of Support

Provide no more than five Letters of Support and save all Letters of Support as a single PDF file for uploading. All Letters of Support must be addressed to the PL and demonstrate the commitment of key personnel and supporting organizations (e.g., co-PL, consultants, subcontractors, 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 development or execution. You may consider having like stakeholders co-sign a letter in order to adhere to the five-letter maximum.

You are also highly encouraged to include a letter from the leadership of your organization, indicating that the organization will implement the project findings if they prove to be germane and warranted for implementation.

Please include Letters of Support from each consultant, verifying the work to be performed and how the negotiated rate was established. These Letters of Support are permitted in excess of the five-letter maximum.

Some Engagement Award PFAs have additional requirements for completing and uploading the Letters of Support document and are permitted in excess of the five-letter maximum:

- If applying for **Engagement Award: Capacity Building**, and using or adopting a PCORI-funded engagement tool or resource, the applicant must provide a Letter of Support from the relevant copyright owner of the tool or resource. This will typically be from the awardee institution of the original PCORI Award project team. The relevant owner must grant the applicant rights to the engagement tool(s)/resource(s) sufficient to carry out the project. This additional Letter of Support does not count towards the five-letter maximum.

- If applying for **Engagement Award: Dissemination Initiative**, all applicants must include a Letter of Support from the Principal Investigator (PI) – or another member of the original research team who played a significant role – of each PCORI-funded study whose **published findings** are being disseminated in the project that demonstrates their acknowledgement and/or support (applicable for the dissemination of CER study results only). This additional Letter of Support does not count towards the five-letter maximum.

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

*Other (nonrequisite) attachments you may wish to submit:*

**Recent Articles/Evaluations (optional)**

Up to three articles by or evaluations of your organization (published or conducted within the past five years) may be included. Please combine them into one document and upload as a PDF or Microsoft Word document in the PCORI Engagement Awards Online Application System.
**Board of Directors Template (optional)**

Upload the appropriate template. List your organization’s current Board of Directors, including board role and affiliations.

**Budget Tab**

Provide details related to the budget. To begin creating the budget, click “+New.” Enter the subtotal dollar amount for each of the following line items for each year of the budget. The amounts entered into the Engagement Awards Online Application System should match the information entered into the Budget attachment.

- Personnel Costs
- Consultant Costs
- Supply Costs
- Travel Costs
- Other Expenses
- Subcontractor Costs
- Indirect Costs

Click ‘Save’ to save the new budget record.

**Review and Submit**

When you have completed the application, and are ready to submit, click “Review/Submit.” This will show a read-only view of the application. Once you have reviewed and are ready to submit to the Administrative Official (AO) for approval, click “Submit.” Then click “OK” to verify the submission.

Once the application is submitted for internal approval, the AO will receive an email notification and can log in to PCORI Online to review, approve, and submit the application to PCORI.

The AO will navigate to the “Open Items” on the Dashboard and locate the application that is “Submitted - Pending AO Approval.” Review the read-only version of the submitted application by clicking on the magnifying glass. Then, click on the icon under AO Approve/Withdraw to approve, reject, or withdraw the submitted application.

On the AO Approve/Withdraw page, use the drop-down menu to “approve” or “reject” the submitted application. Once the review is complete and the decision has been made, click “Save” and then “Review/Submit.” This will show a read-only view of the AO decision. To submit to PCORI, click “Submit.” To change the decision, click “Back to Record.”
VII. Additional Requirements

Awardees are required to comply with the requirements listed below.

**PCORI Public Access Policy**

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

**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 applicability and implementation of the Privacy Rule reside with the PL and their institution. The [Office for Civil Rights](https://www.hhs.gov/ocr/) 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 awards, cooperative agreements, and research contracts is available from [NIH](https://www.nih.gov/).

**Contract Terms and Conditions of Award**

The administrative and funding instruments used for the Eugene Washington PCORI Engagement Awards are firm-fixed-price “service-based” or “mission-based” contracts. They are not research awards, nor should they be treated as such. Applicants are expected to discuss the announcement and the potential resulting contractual mechanism with their contracts and grants management office to ensure that they are able to accept it. As a funding organization, PCORI retains the right to administer programmatic and contractual oversight with awardees during the contract period.

**Cofunding**

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.

PCORI will not fund a project already sponsored or funded through another organization. By submitting the application to PCORI, the AO is certifying that there is no overlap in funding at the time of submission.
Dissemination and Data Sharing

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

Award Process

PCORI may request additional information from the applicant after the initial review of the full proposal. Applicants will be notified of the programmatic review decision in writing within 90 days of submission of the full application. If the full proposal is awarded, a PCORI staff member will coordinate arrangements to begin contract negotiations. Typically, contract negotiations take about eight weeks.

Awardee organizations agree to provide PCORI with opportunities to comment on the conference agenda, including session topics, agenda structure, and speaker suggestions. If you anticipate requesting a PCORI speaker for this meeting or conference, please fill out a speaker request form through the PCORI Speakers Bureau at least two months in advance of the meeting or conference. In addition, complimentary registrations for at least three PCORI staff or PCORI guests are required.

PCORI may be acknowledged in all publicity and in the program or agenda for the meeting/conference and any proceedings or publications resulting from the meeting/conference. Specifics of this recognition should be identified in the application. Sources and amounts of other funding for the meeting/conference must also be clearly identified in the Budget Justification.

Note: Detailed terms and other requirements will be provided to awardees to be agreed upon before the funding contract begins.

VIII. Engagement Award Review Process

PCORI rigorously reviews the LOIs and applications it receives. Note that PCORI may eliminate LOIs and applications from the review process for administrative or programmatic reasons. An LOI or application will be administratively triaged if it is incomplete or if it does not meet the administrative or formatting criteria outlined in this document, in the templates provided, and in the PCORI Engagement Awards Online Application System. An application will be programatically triaged if it is not responsive to these guidelines. See Eugene Washington PCORI Engagement Awards Review Process for additional details about the review process.
LOIs and applications will be considered nonresponsive for an Engagement Award if they propose:

- Projects solely intended to increase patient engagement in health care or healthcare systems rather than healthcare research
- Projects to design or test healthcare interventions
- Activities that involve the use of a drug or medical device
- Development of clinical practice guidelines, care protocols, or decision support tools
- Development of coverage, payment, or policy recommendations or guidelines
- Projects related to quality measures, or engagement around quality measures
- Projects to recruit and enroll patients for clinical trials
- Projects that only involve patients as subjects (individuals enrolled into a study as participants)
- Research studies including randomized controlled trials, observational studies, and pragmatic clinical studies
- Development or maintenance of a registry, or recruitment to participate in a registry
- Projects designed solely to validate tools or instruments not created through a PCORI-funded project
- Writing research proposals or completing grant applications, grantmaking
- Projects focused on social determinants of health, with no focus on patient-centered outcomes research or comparative clinical effectiveness research
- Planning for dissemination or dissemination initiatives without including PCORI-funded research or related products
- Implementation of PCORI findings in a clinical practice setting (PCORI will fund dedicated implementation efforts through the Limited PCORI Funding Announcement: Implementation of PCORI-Funded Patient-Centered Outcomes Research Results)
- Projects or meetings without a clear focus on patient-centered outcomes research or comparative clinical effectiveness research
Appendix 1: Key Terms

Allowable Costs—These are costs that are approved within the budget and are not otherwise disallowed under the PCORI Engagement Awards policies described in this document. A direct cost is allowable to the project if the goods or services involved are chargeable or assignable to the project in accordance with relative benefits received or another equitable relationship. As a result, a cost is allowable to the funded project if (a) it is incurred solely to advance the work under the project; or (b) it benefits both the funded project and other work of the recipient organization, in proportions that can be approximated through use of reasonable methods.

Biosketch—This is a profile of the experience and accomplishments of the key personnel in an application. Such a biosketch also satisfies the requirements of the Professional Profile/Biosketch described in the application requirements above.

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

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

Consultant—This is an individual hired to provide professional advice or services for a fee.

Contract—This is the legally binding document that PCORI uses to make awards for Engagement Award projects.

Employer Identification Number (EIN)—This is the federal tax identification number used to identify a business entity. You may apply for an EIN in various ways, including online. International applicants are not required to enter an EIN in the electronic LOI or application; they should enter “99-999999” in the EIN field in the Letter of Inquiry (LOI).

Fringe Benefits—This is a form of pay for the performance of services. Fringe benefits commonly include health insurance, group term life coverage, and nonwage forms of compensation.

Indirect Costs—These are costs not directly accountable to the project. Indirect costs include taxes, administration, personnel, and security costs.
Institutional Review Board (IRB)—This is a group that follows federal regulations, state laws, and institutional policy to review, monitor, and approve research in order to protect the ethical rights and privacy of the subjects involved.

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

Patient-Centered Outcomes Research (PCOR)—This is research that helps people and their caregivers communicate and make informed healthcare decisions while allowing their voices to be heard in assessing the value of healthcare options. This research answers patient-centered questions. A full definition can be found at http://www.pcori.org/content/patient-centered-outcomes-research.

Patients—These are individuals who have or have had the condition under study; they may include patient surrogates or caregivers as well. This does not necessarily mean, but does not exclude, patient advocates or patient navigators.

PCORI Engagement Awards Online Application System—PCORI Engagement Awards’ Online Application and Management System, designed to facilitate the applicant’s submission of materials. The PCORI Engagement Awards Online Application System can be found at https://pcori.force.com/engagement/CommunitiesCustomLogin.

Professional Profile—This is a profile of the experience and accomplishments of a person who will play a significant role on a PCORI-funded project. See also Biosketch.

Project Lead—This is the primary person on a contract or application for funding. He or she serves as PCORI’s primary point of contact for that contract or application.

Public Project Summary—This is a summary of the Project Plan written for a lay audience. This summary is made publicly available if the project is funded.

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

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

Stakeholders—These include clinicians (e.g., physicians, nurses, pharmacists, counselors, and other providers of care and support services); patient advocacy groups; community groups; researchers; health-related associations; policy makers; and organizational providers, purchasers, payers, and industries for whom the project results will be relevant.
Appendix 2: Allowable and Unallowable Costs

Allowable costs (i.e., costs 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 project:

- Salaries and fringe benefits for project lead(s) and other project staff (including engaged patient and other stakeholder partners) related to their percentage of effort on conducting the project
- Consultant fees
- Travel that is necessary for conducting the project
- Supplies
- Subcontracts
- Expenses related to conducting engagement activities with patients and other stakeholders
- Other direct project expenses
- Indirect costs

A funding applicant must specifically request costs related to conducting the 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 PL 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.

PCORI will review all proposed costs. Costs must be deemed allowable, allocable, and directly necessary for the successful execution of the proposed project. A notification of pending award is subject to budgetary review and successful contract negotiation. The actual award amount may vary. For more information, please see PCORI Cost Principles.
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: Submission Checklist

**Note:** All character count restrictions include spaces and other formatting. Follow the character count limit when specified in the question prompts.

### Step 1: Letter of Inquiry (LOI) Checklist

<table>
<thead>
<tr>
<th>LOI Form (Tabs)</th>
<th>Submission Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ General Information</td>
<td>Enter into <a href="#">online system</a></td>
</tr>
<tr>
<td>□ Additional Key Roles</td>
<td>Enter into <a href="#">online system</a></td>
</tr>
<tr>
<td>□ Pre-Screen Questionnaire</td>
<td>Enter into <a href="#">online system</a></td>
</tr>
<tr>
<td>□ Organization &amp; Project Lead Details</td>
<td>Enter into <a href="#">online system</a></td>
</tr>
<tr>
<td>□ Project Summary</td>
<td>Enter into <a href="#">online system</a></td>
</tr>
<tr>
<td>□ Additional Project Information</td>
<td>Enter into <a href="#">online system</a></td>
</tr>
<tr>
<td>□ Using PCORI-funded Evidence &amp; Tools</td>
<td>Enter into <a href="#">online system</a></td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>LOI Submission</th>
<th>Submission Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Authorizations</td>
<td>PL obtains authorization from Administrative Official (AO); PL enters authorization into <a href="#">online system</a> for official submission to PCORI</td>
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</tbody>
</table>

### Step 2: Application Checklist

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<tr>
<th>Proposal Form (Tabs)</th>
<th>Submission Method</th>
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</thead>
<tbody>
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<td>□ General Information</td>
<td>Enter into <a href="#">online system</a></td>
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<td>Enter into <a href="#">online system</a></td>
</tr>
<tr>
<td>□ Organization &amp; Project Lead Details</td>
<td>Modify LOI information; Enter into <a href="#">online system</a></td>
</tr>
<tr>
<td>□ Project Summary</td>
<td>Modify LOI information; Enter into <a href="#">online system</a></td>
</tr>
<tr>
<td>□ Additional Project Information</td>
<td>Modify LOI information; Enter into <a href="#">online system</a></td>
</tr>
<tr>
<td>□ Using PCORI-funded Evidence &amp; Tools</td>
<td>Modify LOI information; Enter into <a href="#">online system</a></td>
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<td>Key Personnel Tab</td>
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<tr>
<td>Key Personnel</td>
<td>Enter into online system</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Attachments Tab</th>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
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<tbody>
<tr>
<td>Workplan</td>
<td>Upload as Microsoft Word file</td>
<td>15 pages</td>
</tr>
<tr>
<td></td>
<td>• Workplan</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Project Timeline</td>
<td>2 pages</td>
</tr>
<tr>
<td></td>
<td>• Patient &amp; Stakeholder Engagement Plan</td>
<td>2 pages</td>
</tr>
<tr>
<td></td>
<td>• Protection of Human Subjects (if applicable)</td>
<td>As needed</td>
</tr>
<tr>
<td></td>
<td>• Subcontractor Agreements (if applicable)</td>
<td>As needed</td>
</tr>
<tr>
<td></td>
<td>• References Cited (if applicable)</td>
<td>10 pages</td>
</tr>
<tr>
<td>Milestones/Deliverables Table</td>
<td>Upload as Microsoft Excel file</td>
<td>As needed</td>
</tr>
<tr>
<td>Budget</td>
<td>Upload as Microsoft Excel file</td>
<td>Complete worksheets, as applicable</td>
</tr>
<tr>
<td></td>
<td>• Federally Negotiated Indirect Cost Rate (if available)</td>
<td>10 pages, plus Federally Negotiated Indirect Cost Rate (if available), combined in one document</td>
</tr>
<tr>
<td>Biosketch</td>
<td>Combine and upload</td>
<td>4 pages per individual, combined in one document</td>
</tr>
<tr>
<td>Letters of Support</td>
<td>Combine and upload</td>
<td>Maximum of 5 letters (unless otherwise directed in PFA/Instructions) combined in one document</td>
</tr>
<tr>
<td>Board of Directors List (optional)</td>
<td>Upload</td>
<td>2 pages</td>
</tr>
<tr>
<td>Recent Articles/Evaluations (optional)</td>
<td>Combine and upload</td>
<td>Up to 3 articles or evaluations</td>
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<table>
<thead>
<tr>
<th>Budget Tab</th>
<th>Submission Method</th>
<th>Length/Limit</th>
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<tbody>
<tr>
<td>Budget</td>
<td>Enter into online system</td>
<td>Enter totals into fields to match information in Budget proposal attachment</td>
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<table>
<thead>
<tr>
<th>Application Submission</th>
<th>Submission Method</th>
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</thead>
<tbody>
<tr>
<td>Authorizations</td>
<td>PL submits application to AO; AO enters authorization into online system for official submission to PCORI</td>
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