Eugene Washington PCORI Engagement Award Program
Submission Instructions for October 2021 Cycle Funding Opportunities

Published August 2, 2021
About PCORI

The Patient-Centered Outcomes Research Institute (PCORI) was authorized by federal law in 2010 and reauthorized for an additional ten years in 2019 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 2021 Funding Cycle:

- At this time, PCORI strongly discourages all in-person convening activities, and encourages applicants to consider alternative plans for any in-person convening activities within applications for future awards. More information on application requirements can be found in the Submitting a Successful Application section of each PFA. Additionally, 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.

- PCORI is aware that there is an evolving context around the COVID-19 pandemic. We are committed to working with awardees to adapt projects and processes to the evolving context during this time so that deliverables are implemented fully as per the executed contract.

- As in previous cycles, applicants should keep personnel costs below 50 percent of the total project budget. In this funding cycle, additional guidance for project budget development is included in the Submitting a Successful Application section of each PFA and the Budget section of the Engagement Awards Submission Instructions.
Table of Contents

I. About These Instructions .................................................................................................... 5
   Administrative Considerations.......................................................................................... 5
   Funding Mechanism.......................................................................................................... 6
   Award Funding Conditions............................................................................................... 6

II. Who Can Apply ............................................................................................................... 6

III. How to Apply ................................................................................................................ 7

IV. When to Apply ............................................................................................................... 10

V. Letter of Intent (LOI) Requirements ............................................................................. 10
   Key Roles............................................................................................................................ 11
   LOI Form............................................................................................................................. 12
      Contact Information Tab.................................................................................................. 12
      Pre-Screen Questionnaire Tab....................................................................................... 13
      Organization & Project Lead Details Tab........................................................................ 13
      Project Summary Tab...................................................................................................... 13
      Additional Project Information Tab.............................................................................. 13
      Using PCORI-funded Evidence & Tools Tab................................................................. 14
      Attachments Tab (for the Engagement Award: Dissemination Initiative PFA only)....... 14
      Authorizations Tab.......................................................................................................... 15
      Review/Submit................................................................................................................. 15

VI. Full Proposal Requirements ........................................................................................ 15
   Contact Information Tab.................................................................................................. 15
   Pre-Screen Questionnaire Tab......................................................................................... 16
   Organization & Project Lead Details Tab.......................................................................... 16
   Project Summary Tab....................................................................................................... 16
   Additional Project Information Tab.................................................................................. 17
   Using PCORI-funded Evidence & Tools Tab...................................................................... 17
   Key Personnel Tab.......................................................................................................... 17
   Attachments Tab.............................................................................................................. 18
      Workplan....................................................................................................................... 18
      Milestones/Deliverables Table..................................................................................... 20
      Budget............................................................................................................................ 21
      Budget Justification....................................................................................................... 27
      Biosketch....................................................................................................................... 28
      Letters of Support......................................................................................................... 28
      Recent Articles/Evaluations (optional)........................................................................ 30
      Board of Directors Template (optional)........................................................................ 30
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 Frequently Asked Questions (FAQs) for common questions about PCORI and the Engagement Awards application process.
- Visit PCORI’s Applicant Training resources for PCORI Online cheat sheets and user guides for 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

To ensure a thorough and competitive review process, PCORI strictly enforces the formatting and administrative compliance guidelines outlined in the PFAs, FAQs, and Engagement Award Submission Instructions. Applicants must complete all required applicant templates as specified by each PFA using the PCORI-provided files. If applicable, all Letters of Support must be submitted by the full proposal submission deadline. Applicants that fail to submit all required documents may be rejected from the review process. All rejection decisions are final.

Unless otherwise stated in the Submission Instructions, all materials submitted on behalf of an applicant organization are the property of that organization. PCORI may conduct analyses of data related to unfunded applications or funded awards for internal purposes. Such analyses may be done by PCORI staff or by third party contractors working on PCORI’s behalf. Any such analyses will be done to provide transparency and accountability for PCORI programs and expenditures using public funding. Submission of an application to PCORI constitutes permission for the above and to post information about any awarded projects, including project title, name of the primary investigator or program director, the name of the organization receiving the award, and the project description on PCORI.org.
Funding Mechanism

The Eugene Washington PCORI Engagement Awards are issued as firm-fixed-price “service-based” or “mission-based” agreements. 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 agreement term period. Applicant institutions and the Administrative Officials are advised to carefully review PCORI’s standard contract/agreement templates provided on the Awardee Resources page on the PCORI website. Note that international awardees will be issued an agreement in U.S. dollars. Fluctuations in currency exchange rates will have no bearing on the contract/agreement value, nor will adjustments be made to accommodate losses or gains associated with such currency fluctuations.

Award Funding Conditions

At any time during the agreement period, PCORI reserves the right to discontinue funding for awardees that fail to meet the mutually agreed upon milestones and deliverables. Applicants’ proposed milestones and deliverables will be finalized in negotiations and prior to execution. See PCORI’s Standard Agreement Template for Funded Engagement Award Projects for more information.

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. 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 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. Organizations may submit multiple applications in a funding cycle, but each application must have a unique project lead and be unique in scope (see Key Roles section for more information).

III. How to Apply

Applying for PCORI funding is a two-stage process. To submit an LOI and full proposal (if invited), including all required documents, follow the instructions provided in this document, the PFA you are applying to, and in PCORI Online. All required documents must be submitted through PCORI Online. Failure to follow these submission instructions or to submit all required documents through the PCORI Online 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 PCORI Online. To submit a Letter of Intent or full proposal, 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. 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 tile to apply for funding. PCORI strongly recommends that only the Project Lead create the LOI/full proposal 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.

Step 2: Submit a Letter of Intent (LOI)

An LOI is required before completing a full proposal. To submit an LOI, log in to PCORI Online, select the Engagement Awards tile, select the Funding Opportunities button, search for the Engagement Awards PFA, and complete the required LOI 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 the Engagement Awards User Guide and Cheat Sheets in the [PCORI Online Applicant Training](#).

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**Step 3: Begin Full Proposal Development Process**

**Note:** Only applicants invited to submit a full proposal may begin this step of the process.

PCORI will notify applicants by the date specified within the PFA as to whether they have been invited to submit a full proposal. The full proposal 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.

**Note:** Information entered as part of the LOI submission will automatically appear in the full proposal in PCORI Online and must be reviewed in full and edited as needed prior to submission of the full proposal.

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**Step 4: Format and Complete Required Full Proposal Templates**

Required full proposal templates are in the Applicant Templates section of the PFA you are applying to (You can access the PFA from the [PCORI Funding Opportunities](#) webpage). 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 where indicated.

• Adherence to font size, type density, line spacing, and text color requirements is necessary to ensure readability and fairness.

• Applicants that exceed the specified page limit in a template may have their submission rejected from the review process.

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 in a specific file format, specifically:
  
  o The Budget template must be uploaded in Microsoft Excel format.
  
  o The Milestones/Deliverables Table template must be uploaded in Microsoft Excel format.
  
  o The Workplan template must be uploaded in Microsoft Word 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 template. 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. Full proposals that include attachments that do not conform to the minimum requirements listed above may be withdrawn from consideration.

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**Step 5: Upload Required Full Proposal Documents**

Follow the [Submission Checklist](#) 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 Engagement Awards User Guide and Cheat Sheets section of the [PCORI Online Applicant Training](#).

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**Step 6: Submit Full Proposal for Authorization**

Once you have completed and uploaded all required information, select “Review/Submit” in the upper right corner, verify the information in your full proposal, and then select “Submit” to forward the full proposal to your Administrative Official (AO). The AO must approve and submit the final full proposal 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 full proposal 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 full proposal.

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**IV. When to Apply**

Deadlines for each funding cycle are noted in the PFA and on the [PCORI Funding Opportunities](#) webpage. 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 Engagement Award Submission Instructions, or in PFAs are not valid issues warranting consideration of a deadline extension.

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**V. Letter of Intent (LOI) Requirements**

An LOI must be submitted by the applicant and evaluated for programmatic fit by PCORI to determine if the applicant will be invited to submit a full proposal.

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¹ See [adobe.com](http://adobe.com) for more information on Adobe Acrobat Professional.
The content included in the LOI is the primary source of information for PCORI’s competitive screening process. PCORI will not invite an applicant to submit a full proposal 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. See the PFA for more information about the Review Process.

Refer to the Engagement Award User Guide and Cheat Sheets in the PCORI Online Applicant Training for step-by-step instructions on navigating PCORI Online to submit your LOI. The information below is intended to give programmatic guidance on the type and format of information that applicants should submit.

**Key Roles**

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

**Project Lead (PL)**

- **Description:**
  - The PL is responsible for the project’s activities.
  - If electing to submit an application with a co-PL, you must designate one individual as the Contact PL in field ‘Project Lead 1 (Contact PL)’ and the other individual as a co-PL in field ‘Project Lead 2 (co-PL).’
  - The Contact PL must be an employee or board member of the primary organization/institution on the application.
  - The Contact PL is responsible for submitting the application and will serve as PCORI’s primary point of contact for all communication. **No more than two PLs can be named on an application.**
  - PLs can participate in other applications during the same funding cycle (from the same or other organizations/institutions) in a different role, such as project lead designee or consultant.
  - Applicants may identify up to two Project Lead Designees on an application. The PL Designee role is an authorized user who may access and contribute to application and project information in PCORI Online. The PL Designee cannot submit the LOI or full proposal to PCORI. The PL Designee is not required to be an employee or board member of the primary organization/institution on the application.

- **Activities:**
  - The PL (or PLs) assumes responsibility and accountability for project execution, compliance, and organizational conduct.
  - The PL (or PLs) manages day-to-day project operations.
  - The PL (or PLs) acts as the applicant organization’s lead project representative.
If electing to submit an application with a co-PL, the designated Contact PL 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 PL, and it is their responsibility to share PCORI communications with the co-PL.

Administrative Official (AO)

- **Description:**
  - The AO is responsible for matters related to the award and administration of the agreement.
  - The AO cannot be the PL.
  - The AO must be an employee or board member of the primary organization/institution on the application.
  - The AO’s signature certifies that the applicant organization/institution will be accountable for appropriately using the funds awarded and for performing the PCORI-supported project.

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

**Note:** Because PCORI’s Engagement Award program includes different funding opportunities for different types of engagement projects, it is permissible for a PL to submit up to one LOI per available Engagement Award funding opportunity per funding cycle. Projects whose scope overlaps with existing projects, or those that appear to be duplicate submissions with other PCORI funding opportunities, may be removed or declined during the screening process. LOIs appearing to be duplicative of already-funded projects may also be declined.

**LOI Form**

The LOI form includes several required sections, as listed below. Applicants must adhere to any character count limitations specified in the question prompts. Questions specific to the PFA you are applying to are presented on each tab in PCORI Online.

**Contact Information Tab**

Identify the Project Lead 1 (Contact PL), AO, and the primary institution or organization applying for the award.

Optionally, identify the Project Lead 2 (co-PL), PL Designee 1, and PL Designee 2.

**Note:** The Project Lead 1 (Contact PL) and AO must be an employee or board member of the primary organization/institution on the application.
When searching for and selecting the individual(s) to serve in these roles, 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.

Once saved, all individuals identified on the Contact Information Tab will have access to the LOI by navigating to the Engagement Awards Dashboard in PCORI Online.

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 will be considered nonresponsive and removed from the review process. See the Engagement Award PFAs for a full list of categories of nonresponsiveness.

Organization & Project Lead Details Tab

Provide responses to the questions about the organization, PL, previous funding, and this project’s leadership plan.

Project Summary Tab

Provide detailed, but brief descriptions that allow PCORI to understand the project without having to review a full proposal. (Please remember that the Engagement Awards program funds projects, not research. The preferred term to describe the sum of proposed activities is “project,” rather than “study.”) Applicants invited to submit a full proposal will have an opportunity to add additional details in response to these questions.

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.

If applying for the Engagement Award: Dissemination Initiative, identify which funding track you are applying to – Building Capacity for Dissemination or Active Dissemination.

Additional Project Information Tab

Provide information about the budget, requested agreement period, the stakeholder communities your project seeks to engage, and special areas of interest the apply to your project idea, if any.

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 award as specified in the funding announcement you are responding to.

For the Engagement Awards October 2021 Cycle, the agreement start date should be planned for no earlier than June 1, 2021 and no later than November 1, 2022.
If the proposed project leverages the project team’s previous work funded by PCORI, please describe how.

If applying for the Engagement Award: Stakeholder Convening Support, identify the dates of the main stakeholder convening(s) to be held during your project.

If applying for the Engagement Award: Stakeholder Convening Support, identify if your proposal focuses on the Special Area of Interest: Consideration of the Full Range of Outcomes Data.

If applying for the Engagement Award: Capacity Building or Engagement Award: Stakeholder Convening Support, identify if your proposal focuses on either the Special Area of Interest: Intellectual and Developmental Disabilities or the Special Area of Interest: Maternal Morbidity and Mortality. Please see the funding announcements for more information about special areas of interest to PCORI.

Using PCORI-funded Evidence & Tools Tab

Follow prompts to respond to questions specific to the PFA you are applying to:

- If applying for the Engagement Award: Capacity Building, identify if your proposed Engagement Award project will use or adopt a PCORI-funded engagement tool or resource. Follow the question prompts to provide required information.

- If applying for the Engagement Award: Dissemination Initiative, identify if your proposed Engagement Award project will (1) actively disseminate eligible PCORI-funded evidence, (2) build capacity for dissemination of PCORI-funded evidence, and (3) use or adopt a PCORI-funded research or engagement tool or resource. Follow the question prompts to provide required information.

- If applying for the Engagement Award: Stakeholder Convening Support, identify if your proposed Engagement Award project will (1) actively disseminate eligible PCORI-funded evidence and (2) use or adopt a PCORI-funded research or engagement tool or resource. Follow the question prompts to provide required information.

Applicants should review the PFA they are applying to for specific guidance on eligible evidence for dissemination (if applicable), and using or adopting a PCORI-funded tool or resource.

Attachments Tab (for the Engagement Award: Dissemination Initiative PFA only)

The Engagement Award: Dissemination Initiative requires the completion of a supplementary document that includes additional questions about the proposed project. The Engagement Award: Dissemination Initiative LOI Supplemental Template can be downloaded from the funding announcement and must be completed and uploaded to PCORI Online as part of the LOI submission.
Authorizations Tab

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 LOI 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 an agreement and not a grant, and that the applicant institution is able to accept the agreement terms and conditions without alteration.

VI. Full Proposal Requirements

The following sections are applicable only if PCORI invites you to submit a full proposal. Invitations will be sent to the PL and AO via email, along with instructions on how to access the full proposal. PCORI staff may additionally provide reviewer feedback to inform the development of a full proposal.

Information entered as part of the LOI submission will automatically appear in the full proposal in PCORI Online and must be reviewed in full and edited as needed prior to the submission of the full proposal.

The full proposal is divided into several tabs:

- Contact Information, Pre-Screen Questionnaire, Organization & Project Lead Details, Project Summary, Additional Project Information, Using PCORI-funded Evidence & Tools, Key Personnel, Attachments, Budget, and Authorizations.

Additional guidance is provided for specific sections of the full proposal, as listed below.

Contact Information Tab

Review the user role and organization selections transferred from your LOI, and update as needed.

If the PL or organization applying for the award has changed from the LOI submission, you must inform PCORI and provide justification prior to submission of the full proposal by emailing ea@pcori.org.
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 proposal will be considered nonresponsive and removed from the review process. See the Engagement Award PFAs for a full list of categories of nonresponsiveness.

Organization & Project Lead Details Tab

Closely review the information transferred from your LOI, and update as needed. Additionally, provide information about your organization’s fiscal year calendar.

Project Summary Tab

Closely review the information transferred from your LOI, and update as needed. Provide additional information, as follows:

- If applying for the Engagement Award: Dissemination Initiative, identify which funding track you are applying to – Building Capacity for Dissemination or Active Dissemination.
- Identify if the proposal is a resubmission of a Engagement Award LOI or full proposal submitted to a previous funding cycle.
- 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 aims of the project.
  - **Activities**—Provide a concise description of project activities that will occur throughout the duration of your project.
  - **Outcomes and Outputs** (projected)—Specify the projected short-term (during the PCORI-funded project period), medium-term (0-2 years post-project period), and long-term outcomes (3+ years post-project period) and state their significance. In addition, clearly describe your intended outputs and deliverables for the PCORI-funded project period.
  - **Patient and Stakeholder Engagement Plan**—Who are the patients and stakeholders involved in and/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?

If your project is approved for funding, the PCORI will edit your summary to ensure it is consistent with PCORI style. The final version will be sent to you for review and approval to post publicly on PCORI’s website.

Additional Project Information Tab

Closely review the information transferred from your LOI, and update as needed. Provide additional information, as follows:

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

- Describe unique capabilities the PL, project team, and organization have to address the issues identified in the proposal.

- Provide the name of organizational collaborators or partners, and describe the organization’s role in meeting the project’s goals and objectives. 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 Tab

Closely review the information transferred from your LOI, and update as needed.

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.

FAQ: How Many Key Personnel Can Be Listed?

- Limit your full proposal to five key personnel.
- The Project Lead 1 (Contact PL) should not be included under this tab and is not counted as one of the five key personnel.

When finished entering your key personnel, select “Next” to be taken to the next tab of the full proposal.
Attachments Tab

Required applicant templates vary by Engagement Award PFA and are listed under the Applicant Resources section of the PFA you are applying to:

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

Applicants must use the applicant templates attached to the October 2021 Cycle PFAs. Old applicant templates cannot be re-used for new funding cycles.

We recommend naming the file LOI Number-Organization Name/Acronym-Template Name (i.e., 12345-PCORI-Workplan.doc or 12345-PCORI-Budget_Justification.xls). 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 templates must be uploaded in Microsoft Excel format.
- The Workplan template must be uploaded in Microsoft Word format.

Only one file should be uploaded per required document. Combined all Biosketches and Letters of Support into one PDF or Microsoft Word file.

Upload required documents by selecting “Choose File” and following the system prompts for each document type.

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

**Required applicant templates are described below:**

**Workplan**

The Workplan applicant template is unique for each Engagement Award PFA and must be downloaded from the Applicant Resources section of the specific funding announcement. Applicants should review the document header and footer to verify they are using the correct version for this funding cycle prior to entering information into the template.

Strictly follow all instructions and page limits specified in the template. Complete all sections, as directed.

When complete, upload the required template to PCORI Online in Microsoft Word file format only.
Note: At this time, PCORI strongly discourages all in-person convening activities, and encourages applicants to consider alternative plans for any in-person convening activities within applications for future awards. When submitting a full proposal, the Workplan and Budget Justification applicant templates must include a detailed contingency plan for activities and costs related to travel and in-person meeting should the COVID-19 pandemic interfere with travel-related activities. PCORI expects all applicants to implement the most stringent safety protocols as determined by all applicable public health authorities and state and local guidelines.

Note: Appendices are not permitted as part of the Workplan proposal attachment. All graphs, charts, or graphics apply towards the specified page limits and must be included in the body of the Workplan.

Additional guidance is provided for the following sections of the Workplan template:

- **Project Timeline**: Describe the project’s major activities and expected milestones. Information should be provided month-by-month. Do not copy and paste the Milestone/Deliverable Table into this section.

- **Project Summary**: Summarize your project for the general public. Follow instructions in the template. Applicants are permitted to duplicate their response to the Project Summary question in PCORI Online.

- **Protection of Human Subjects**: If applicable, in this component, 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, “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 full proposal 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:** 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; journal or book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow standard citation practices in providing citations for source materials used in preparing any section of the full proposal. PCORI suggests using American Medical Association citation style, but other citation styles are accepted. 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. 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**

Strictly follow all instructions specified in the template. Do not edit any guidance text. Format the cells as directed. Ensure you are completing the applicant template attached to this funding cycle’s PFA.

When complete, upload the required template to PCORI Online in Microsoft Excel file 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 and final reports already listed in the table. 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 in the ‘Description’ column.

For due dates, please use numerical dates formatted as XX/XX/XXXX, rather than generic months, date ranges, or written dates. Milestones and deliverables should be submitted on a rolling basis as completed throughout the project period. It is not recommended to hold the submission of milestones and deliverables until an interim progress report is due. All entries must be listed in chronological order.

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.

Interim reports are pre-populated in the table with specific intervals for submission, depending on your proposed agreement period.
A draft final report is a required deliverable pre-populated in the table, to be submitted to PCORI one month prior to the end of the project period.

The final report is a required deliverable pre-populated in the table, 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 at the same time as the Final Report submission. For reference, 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**

Strictly follow all instructions specified in the template. When complete, upload the required template to PCORI Online in Microsoft Excel file 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. Each subcontracted organization should have its own subcontractor worksheets.
Applicants must provide a budget that reflects the time and contributions of all partners, including patients and stakeholders. Fair financial compensation demonstrates that patients, caregivers, and patient/caregiver organizations’ contributions to the project, including related commitments of time and effort, are valuable and valued. (See our Financial Compensation of Partners Framework and Budgeting for Engagement Activities for more information. Though these documents discuss compensation in research, the concepts are relevant for Engagement Award projects.)

Budgets should account for all costs associated with proposed activities and note any in-kind support or external funding.

Applicants should keep personnel costs (applicant organization/institution staff) below 50 percent of the total project budget. However, higher personnel costs may be considered with strong justification (in the Budget Justification).

Applicants should check with their institution to verify the stakeholder compensation arrangements (i.e., potential institutional restrictions or policies regarding the method or process for compensating project participants) in the proposed project prior to submission of the full proposal.

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 funds.

Note: The award total costs include 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 must consider alternative plans for any convening activities within the project 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/agreement 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.

• 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. If you are not requesting salary support, use $0 for base salary. Describe the individual’s specific functions in the Budget Justification and 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, applicants must provide a verification of the fringe benefit rate policy for the prime organization.

• Applicants should keep personnel costs (applicant organization/institution staff) below 50 percent of the total project budget. However, higher personnel costs may be considered with strong justification (in the Budget Justification).

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 individual 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. These letters of support from consultants may be provided in excess of the five letter maximum.

• Applicants should check with their institution to verify the stakeholder compensation arrangements (i.e., potential institutional restrictions or policies regarding the method or process for compensating project participants) in the proposed project prior to submission of the full proposal.

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.

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

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:

  o Detailed explanation of why purchasing these items is necessary to complete the proposed project
  o Statement verifying that the requested items are not currently available for the PL’s use
  o Statement ensuring that the items will be purchased in accordance with applicable cost principles
D. Travel Costs

- Applicants must consider alternative plans for any convening activities within the project should an in-person meeting not be feasible. Please consult [PCORI’s Applicant and Awardee FAQs Related to COVID-19](https://www.pcori.org/appendixes/qa.html) 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. Description should include hotel rate, number of nights, airfare expense, meals, and incidentals. Please refer to the GSA travel resources for appropriate per diem rates.

- 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.

- Engagement Award funding may not be used for travel to the PCORI Annual Meeting.

E. Other Expenses

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

- 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:
  - 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.

**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 each subcontract.
- 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, approved indirect cost rate letter **must be submitted with the full proposal** if requesting in excess of 10 percent indirect costs. Include the rate letter 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 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

Follow all instructions specified in the template. When complete, upload the required template to PCORI Online.

Note: At this time, PCORI strongly discourages all in-person convening activities, and encourages applicants to consider alternative plans for any in-person convening activities within applications for future awards. When submitting a full proposal, the Workplan and Budget Justification applicant templates must include a detailed contingency plan for activities and costs related to travel and in-person meeting should the COVID-19 pandemic interfere with travel-related activities. PCORI expects all applicants to implement the most stringent safety protocols as determined by all applicable public health authorities and state and local guidelines.

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.

The Budget Justification narrative should describe a budget that reflects the time and contributions of all partners, including patients and stakeholders. Fair financial compensation demonstrates that patients, caregivers, and patient/caregiver organizations’ contributions to the project, including related commitments of time and effort, are valuable and valued. (See our Financial Compensation of Partners Framework and Budgeting for Engagement Activities for more information. Though these documents discuss compensation in research, the concepts are relevant for Engagement Award projects.)

Applicants should keep personnel costs below 50 percent of the total project budget. However, higher costs may be considered with strong justification.

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.

PCORI will not fund a project activity 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/agreement, awardees must disclose all current and pending support.

Note: If requesting greater than 10 percent indirect costs, provide a copy of the organization’s federally negotiated, or independently audited, approved indirect cost rate letter. This document
must be attached to the Budget Justification and submitted as one single PDF file with the full proposal.

**Biosketch**

Follow all instructions specified in the template. Each individual providing a Biosketch may select from two versions of the Profile/Biosketch included in the PCORI template – Professional or Patient and Stakeholder Partner. Complete a Profile/Biosketch for the PL and for each person listed in the Key Personnel section of the full proposal (for a total of six Biosketches, including the PL). See the Key Personnel section above for who may qualify for that designation. Combine the Biosketches into one PDF or Microsoft Word document for uploading to PCORI Online.

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 similar to the proposed project, including past performance, specific PCOR/CER experience, and training in the field of PCOR (if applicable) that has prepared them 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/CER experience, please outline appropriate collaborative arrangements with PCOR/CER experts.

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.

**Letters of Support**

Submit Letters of Support as a single PDF file for uploading to PCORI Online. Do not submit Letters of Support as a PDF Portfolio; PCORI Online is not compatible with PDF Portfolio files.

Provide up to five Letters of Support addressed to the PL that demonstrate the commitment of key personnel, participating patients and stakeholders, and supporting 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 and applicants are encouraged to use discretion to show the support from the diverse stakeholders involved with the project while limiting the number of letters submitted. Applicants are 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.

You may consider having like stakeholders co-sign a letter in order to adhere to the five-letter maximum.

Please include Letters of Support from each consultant and/or subcontractor, 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, if necessary.
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**, **Engagement Award: Dissemination Initiative**, or **Engagement Award: Stakeholder Convening Support**, and using or adopting a PCORI-funded tool or resource, the applicant must provide a Letter of Support from the relevant copyright or other intellectual property rights owner of the tool or resource. This will typically be from the awardee institution of the original PCORI award (it is up to the applicant to determine from whom to receive such support). The relevant owner must grant the applicant rights to the tool(s)/resource(s) sufficient to carry out the project. This additional Letter of Support does not count towards the five-letter maximum.
  - The purpose of this letter to ensure that (1) an applicant will be able to fulfill the proposed project and avoid any roadblocks that may prevent fulfillment, and (2) past PCORI awardees are made aware that their tool/resource is being used in another PCORI project.
  - If an applicant is unable to secure such a letter of support or otherwise receive a preliminary license to the intellectual property, the applicant shall notify PCORI prior to the full proposal submission deadline with a determination as to whether (1) the proposed project must be modified to work without such rights, or (2) the proposed project must be abandoned.
  - All letters of support must be attached to the full proposal and submitted no later than the stated full proposal submission deadline.
  - Any revisions to the proposed project due to failure to secure a letter of support must be completed prior to the stated full proposal submission deadline.

- If applying for **Engagement Award: Dissemination Initiative** or the **Engagement Award: Stakeholder Convening Support**, and actively disseminating eligible PCORI-funded evidence, 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 comparative clinical effectiveness research (CER) study whose **published primary CER results** are being actively 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.

**FAQ: How Many Letters of Support Can I Provide?**

- Up to five letters of support demonstrating the commitment of key personnel, participating patients and stakeholders, and supporting organizations to the proposed project (including a letter of support from the leadership of the applicant organization, if warranted).
- In addition to the five letter maximum, if applicable, letters of support from each consultant and/or subcontractor, verifying the work to be performed and how the negotiated rate was established.
• In addition to the five letter maximum, if applicable, letters of support from the relevant copyright owner of the PCORI-funded tool or resource being used or adopted in the project.
• In addition to the five letter maximum, if applicable, letters of support from the PI – or another member of the original research team who played a significant role – of each PCORI-funded study whose published primary CER results are being actively disseminated in the project.

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 (non-requisite) attachments you may wish to submit:

Recent Articles/Evaluations (optional)

Provide up to three articles by or evaluations of your organization (published or conducted within the past five years). Combine into one document and upload as a PDF or Microsoft Word document in PCORI Online. Do not submit articles/evaluations as a PDF Portfolio; PCORI Online is not compatible with PDF Portfolio files.

Board of Directors Template (optional)

Follow all instructions specified in the template and upload PCORI Online. 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 PCORI Online should match the information entered into the Budget applicant template.

• 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 full proposal, and are ready to submit, click “Review/Submit.” This will show a read-only view of the full proposal. 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 full proposal is submitted for the applicant’s internal approval, the AO will receive an email notification and can log in to PCORI Online to review, approve, and submit the full proposal 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 agreement.

**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 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.

**Agreement 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” agreements. 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 agreement 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 or agreements must agree to these principles and must take steps to facilitate availability of data and samples.
VIII. Engagement Award Review Process

PCORI rigorously reviews the LOIs and full proposals it receives. Please follow all instructions closely, including both content, administrative and formatting (e.g., page limits, font size, etc.) requirements. Note that PCORI may eliminate LOIs and full proposals from the review process for administrative or programmatic reasons. An LOI or full proposal 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 PCORI Online. An application will be programmatically 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 full proposals will be considered nonresponsive for an Engagement Award if they propose:

- Projects solely intended to increase patient engagement in healthcare 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, quality improvement, 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 solely on social determinants of health, with no focus on patient-centered outcomes research/comparative clinical effectiveness research (PCOR/CER)
- Planning for dissemination or dissemination initiatives without including PCORI-funded research or related products
- Implementation of PCORI findings in a clinical practice setting (PCORI funds 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/comparative clinical effectiveness research (PCOR/CER)
- Engaging in any activities that are for the purpose of directly or indirectly influencing any federal, state, or local laws, regulations, judicial decisions, or the like including, preparation or planning activities, research, and other background work related to or in contemplation of lobbying activities
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 full proposal requirements above.

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

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 full proposal; they should enter “99-999999” in the EIN field in the Letter of Intent (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 Intent (LOI)—This is a notification to PCORI that an organization intends to apply. Submission of an LOI is a required prerequisite to submitting a full proposal.

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 Online—PCORI Engagement Awards’ Online Application and Management System, designed to facilitate the applicant’s submission of materials. PCORI Online 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/agreement or application for funding. He or she serves as PCORI’s primary point of contact for that contract/agreement 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

The PCORI Cost Principles, in conjunction with the applicable award/contract terms and conditions, serves as a means for identifying expenses that are considered allowable under a PCORI award/contract. This information will provide your organization with an understanding of the requirements associated with managing PCORI funds. Subcontractors for prime awardees are subject to the requirements and provisions of these cost principles.

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 negotiation. The actual award amount may vary. For more information, please see PCORI Cost Principles.
## Appendix 3: Submission Checklist

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

<table>
<thead>
<tr>
<th>LOI Form (Tabs)</th>
<th>Submission Method</th>
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<tbody>
<tr>
<td>□ Contact Information</td>
<td>Enter into PCORI Online</td>
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<tr>
<td>□ Pre-Screen Questionnaire</td>
<td>Enter into PCORI Online</td>
</tr>
<tr>
<td>□ Organization &amp; Project Lead Details</td>
<td>Enter into PCORI Online</td>
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<tr>
<td>□ Project Summary</td>
<td>Enter into PCORI Online</td>
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<tr>
<td>□ Additional Project Information</td>
<td>Enter into PCORI Online</td>
</tr>
<tr>
<td>□ Using PCORI-funded Evidence &amp; Tools</td>
<td>Enter into PCORI Online</td>
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<tr>
<td>□ Attachments (only for Engagement Award: Dissemination Initiative PFA)</td>
<td>Upload to PCORI Online</td>
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<tr>
<th>LOI Submission</th>
<th>Submission Method</th>
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<tbody>
<tr>
<td>□ Authorizations</td>
<td>PL obtains authorization from Administrative Official (AO); PL enters authorization into PCORI Online for official submission to PCORI</td>
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### Step 2: Full Proposal Checklist

<table>
<thead>
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<th>Proposal Form (Tabs)</th>
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<td>Attachments Tab</td>
<td>Workplan</td>
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<td>Milestones/Deliverables Table</td>
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<td>Budget</td>
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<td>Budget Justification</td>
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<td>• Indirect Cost Rate Letter (if applicable)</td>
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<td>Board of Directors List (optional)</td>
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<td>Recent Articles/Evaluations (optional)</td>
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<td>Budget Tab</td>
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<tr>
<td>Full Proposal Submission</td>
<td>Authorizations</td>
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