



Eugene Washington PCORI Engagement Award: Capacity Building Application Guidelines

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About PCORI

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

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

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I. About These Guidelines

This document provides key information to help applicants prepare for and respond to the Eugene Washington Patient-Centered Outcomes Research Institute (PCORI) Engagement Award: Capacity Building. Additional resources include:

- [PCORI Engagement Award FAQs](#):¹ Covers common questions about PCORI, the Engagement Awards application process, and review criteria
- Engagement Award: Capacity Building [Application Checklist](#): Provides a list of all required and relevant documents for submitting an application
- **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 two business days.

Administrative Considerations

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

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

Funding Mechanism

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.

Programmatic Description and Guidelines

Background

The Eugene Washington PCORI Engagement Award program, named in honor of the first chair of PCORI's Board of Governors, is intended to bring more patients, caregivers, clinicians, and other healthcare stakeholders into the research process. The goal is to support projects that will build a community that is better able to participate in patient-centered outcomes research (PCOR) and comparative clinical effectiveness research (CER), and to serve as channels to disseminate study results.

¹ FAQs are available at <https://help.pcori.org/hc/en-us/categories/200202940-Engagement-Awards>



This is central to PCORI's mission to fund useful CER that will help patients and those who care for them make better-informed healthcare decisions.

Many organizations, including patient groups and research institutions, have developed and implemented successful PCOR-focused trainings and programs, and there is a growing body of literature in this field. Unfortunately, successful methods and best practices for increasing patient and stakeholder engagement in research are not currently being disseminated at a pace consistent with the demands for patient-centered CER.

Additionally, it is vital that PCORI support organizations to lay the groundwork to actively disseminate PCORI-funded research findings to potential users of the information. Disseminating and promoting the uptake of research findings is part of [PCORI's legal mandate](#) to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policy makers make better-informed health decisions.

Funding Announcement

The Eugene Washington PCORI Engagement Award: Capacity Building program, a research support—not research—funding opportunity, is now accepting applications (letters of inquiry) for projects up to two years in duration, and up to \$250,000 in total costs. These projects will build a community of individuals and organizations better able to participate in PCOR/CER, and/or develop infrastructure and partnerships to disseminate PCORI-funded research results.

Examples of projects of interest include but are not limited to the following:

- Projects to support organizations with strong ties to patients, caregivers, clinicians, and other [stakeholders](#) to equip them to engage as partners in PCOR/CER. These projects will focus on building the knowledge, competencies, and abilities of patients and other stakeholders to be [meaningful partners in research](#) from topic selection through design and conduct of research to dissemination or implementation of results. These projects may also fund activity to strengthen the skills of researchers to be better partners to patients and other stakeholders involved in PCOR/CER.
 - Applicants must clearly explain how the capacity that is developed through an award will be applied to existing or planned PCOR/CER partnership opportunities.
 - Applicants must also identify and describe any tools/trainings/programs that will be used as part of the project, as well as share the evidence base for the resources that will be used. Applicants are encouraged to use or adapt available resources whenever possible, rather than develop new products and tools.
- Projects to support organizations with strong ties to end-user audiences to lay the groundwork for disseminating and implementing PCOR/CER results. PCORI intends for these projects to focus on strengthening the infrastructure and relationships necessary to actively disseminate and implement research results or products derived from PCORI or related studies. Project activities may include developing, demonstrating, and evaluating the processes/pathways/tools necessary to incorporate PCOR/CER results into decision-making settings.



- For these types of projects, applicants must identify existing or emerging PCOR/CER findings highly relevant to their target population. Research results should also be placed within the context of the existing body of evidence in the topic area identified.
- Applicants must clearly explain how the infrastructure and relationships developed to disseminate and implement PCOR/CER could be sustained over time. Additionally, applicants should indicate whether the project may have the potential to be scaled to reach an even greater audience or if it could be a vehicle for disseminating and implementing additional PCOR/CER findings.

The projects selected for an Engagement Award are expected to further PCORI's goals of promoting the relevance of research to target audiences and the uptake of research results by end-users. PCORI is committed to using and sharing successful approaches.

Note: Organizations that have previously received an Engagement Award are eligible to apply if their current/former project is being expanded, the content will be delivered in new formats, and/or the geographic breadth and/or audience reach will be broadened.

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 or care protocols
- 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
- Writing research proposals or completing grant applications, grant making
- 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
- Conferences that are scheduled to occur less than six months from the application due date
- Projects or meetings without a clear focus on patient-centered outcomes research, or clinical comparative effectiveness research

II. Who Can Apply

Applications may be submitted by any private-sector research organization, including any nonprofit or for-profit organization; any public-sector research organization, including any university or college



hospital or healthcare system; any laboratory or manufacturer; or any unit of local, state, or federal government. The Internal Revenue Service must recognize all US applicant organizations. International organizations also may apply. Organizations may submit multiple applications for funding to the same funding announcement. Individuals may not apply. If you have questions about eligibility, contact EA@pcori.org.

III. How to Apply

To submit an LOI and application (if invited), including all required documents, follow the instructions provided in these guidelines and in the [PCORI Engagement Awards Online Application System](#).² All required documents must be submitted as PDF, Microsoft Word, or Microsoft Excel files, as required under the Checklist Section through PCORI Online. Failure to follow these guidelines or to submit all required documents through this system may result in removal of the application from the review process.

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](#)³ and [an EIN](#),⁴ if applicable. International organizations should enter “999-99-9999” in the EIN field in the Letter of Inquiry (LOI).



Step 1: Register

To apply for PCORI Engagement Award: Capacity Building funding, you must register in the [PCORI Engagement Awards Online Application System](#).⁵ 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 “Engagement Awards” 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.



Step 2: Submit a Letter of Inquiry (LOI)

An LOI must be submitted *before* completing a full application. [To submit an LOI, go into PCORI Online, complete the required fields](#). For detailed instructions on how to navigate the system, reference [PCORI](#)

² The PCORI Engagement Awards Online Application System is available at <https://pcori.force.com/engagement/>.

³ <https://www.dandb.com/credit-resources/duns-number/how-to-get-and-maintain-a-duns-number/>.

⁴ [http://www.irs.gov/Businesses/Small-Businesses-&-Self-Employed/Apply-for-an-Employer-Identification-Number-\(EIN\)-Online/](http://www.irs.gov/Businesses/Small-Businesses-&-Self-Employed/Apply-for-an-Employer-Identification-Number-(EIN)-Online/).

⁵ Additional information is available at <https://pcori.force.com/engagement/CommunitiesCustomLogin>



[Online: Pre-Award User Guide for Engagement Awards](#)⁶. PCORI will convene on a regular basis to discuss submitted LOIs and will determine whether to deny or invite an applicant to submit a full application. Applicants will receive communication from PCORI no later than **40 days** after the LOI submission deadline.



Note: A Project Lead (PL) may submit only one LOI to the Eugene Washington PCORI Engagement Awards program per application cycle. Although a PL may apply for other PCORI funding opportunities, the research topic and project must be distinct. 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.



Step 3: Complete the Full Application

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

Applicants must submit full applications through the PCORI Engagement Awards Online Application System. Information entered as part of the LOI submission will be saved and can be edited as needed.

In addition to the online application, applicants must submit required templates, available via [Engagement Award: Capacity Building PFA page](#),⁷ and they must be formatted as follows:

- *Header:* Each page should include the name of the organization, the project title, and the full name of the PL in the header's left corner.
- *Margins:* Use half-inch margins or greater. The header may fall within the top margin, but the body text should not begin closer than one-half-inch from the edge of the page.
- *Font:* Use font size 11 Calibri for the main body of the text. Figures and captions can be in font size 8.
- *Page Numbering:* Number each page of the document consecutively.
- *Spacing:* Use single spacing.
- *Document Format:* All uploaded documents must be in PDF, Microsoft Word, or Microsoft Excel format. The Budget document must be uploaded in Microsoft Excel format. The Workplan document must be uploaded in Word format.
- *File Name:* The system will automatically rename your file with the following information: document type, project name, year, and original file name. We recommend naming the file Organization Name-File Type (i.e., PCORI-Workplan).

⁶Available at <https://www.pcori.org/sites/default/files/PCORI-Engagement-Awards-Pre-Award-User-Guide.pdf>

⁷ Available at <https://www.pcori.org/funding-opportunities/announcement/engagement-award-capacity-building>



Please note:

- Any applications that do not follow these guidelines may be subject to immediate rejection.
- Do not reorganize sections within the templates.
- Do not alter the templates' main header questions within your submission.
- You may delete instructional text.



Step 4: Submit for Authorization

Once you have completed and uploaded all required information, select “Review & Submit,” and then select “Submit” to forward the application to your Administrative Official (AO) to authorize and submit. The AO must approve and submit the final application for official submission to PCORI before the deadline. **PCORI Online will email the AO, but the 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. Both the AO and the PL will receive an email confirming that PCORI has received the application.

The AO acknowledges PCORI’s contractual mechanism as a contract and not a grant, and accepts the contract terms and conditions on behalf of the institution without alteration. The PL may select the authorization check box to indicate authorization has been obtained from the AO.

IV. When to Apply

Most Eugene Washington PCORI Engagement Awards follow a two-part submission process.

Letter of Inquiry: Applicants must submit an LOI by the application deadline. LOIs will be reviewed within 40 days of LOI deadline.

Full Application: A full application should be submitted within 40 days of receiving the invitation. Full applications will be reviewed within 40 days of submission. If the full proposal is awarded, a PCORI staff member will coordinate arrangements to begin contracting negotiations. Typically contracts negotiations take about six weeks.

PCORI may also release targeted funding announcements, called Engagement Award Initiative Notices (EAINs), with specific deadlines, tasks, or objectives for both the LOI and the full application. EAINs and associated deadlines will be posted on the [Funding Opportunities](#)⁸ web page, as well as on the [PCORI Engagement Awards](#)⁹ web page.

V. What to Include

Applicants are encouraged to review this entire section and to print and complete the [Application](#)

⁸ Available at: <http://www.pcori.org/funding-opportunities>.

⁹ Available at: <http://www.pcori.org/funding-opportunities/programmatic-funding/eugene-washington-pcori-engagement-awards>.



[Checklist](#) to ensure the application is submitted correctly and completely. Additional instructions for some questions are included above the relevant question in the Online Application System.

Application Checklist

(A) Letter of Inquiry (LOI)	Submission Method	Length/Limit
<input type="checkbox"/> Organization and Project Lead (PL) Information	Enter into online system	As noted
<input type="checkbox"/> Project Information <ul style="list-style-type: none"> • Project Information • Project Summary • Authorization 	Enter into online system	As noted Obtained from Administrative Official (AO)
(A) Application	Submission Method	Length/Limit
<input type="checkbox"/> Organization and PL Information	Entered previously as part of the LOI; review and modify if needed	As noted
<input type="checkbox"/> Project Information <ul style="list-style-type: none"> • Project Information • Project Summary 	Entered previously as part of the LOI; review and modify if needed	As noted
<input type="checkbox"/> Key Personnel	Enter into online system	Limit 5 key personnel (not including PL)
<input type="checkbox"/> Collaboration and Partnerships	Enter into online system	As noted
<input type="checkbox"/> Federally Negotiated Indirect Cost Rate (IDC)*	Upload	If used, must include documentation with Budget Justification, as noted
<input type="checkbox"/> Board of Directors List*	Upload	2 pages
<input type="checkbox"/> Recent Articles/Evaluations*	Combine and upload	Up to 3 articles or evaluations
<input type="checkbox"/> Project Workplan and Timeline <ul style="list-style-type: none"> • Workplan • Timeline • Patient Engagement Plan • Protection of Human Subjects (if applicable) 	Upload	15 pages 2 pages 2 pages As needed



	<ul style="list-style-type: none"> • Subcontractor Agreements • References Cited 	As needed	
<input type="checkbox"/>	Project Deliverables/Milestones	Upload	As needed
<input type="checkbox"/>	Budget	Enter into online system and upload	
<input type="checkbox"/>	Budget Justification and Other Sources of Project Support	Upload	10 pages
<input type="checkbox"/>	Professional Profile/Biosketch	Combine and upload	4 pages per individual
<input type="checkbox"/>	Letters of Support*	Combine and upload	Maximum of 5 letters combined in one document
<input type="checkbox"/>	Authorization	Enter into online system	Obtained from AO

*Items with an asterisk are NOT required. They are optional.
 All character counts include spaces and other formatting.



An LOI must be submitted and evaluated for programmatic fit for PCORI to determine if you will be invited to submit a full application. LOIs that are not consistent with program goals, or those substantially overlapping with existing projects, will not be invited to submit a full application. Applicants will receive an email notification regarding the status of their LOI no later than 40 days after the LOI deadline.

Refer to the [Online User Manual: Submit a Letter of Inquiry](#) for step-by-step instructions on navigating the PCORI Engagement Awards Online Application System. The information below is intended to give programmatic guidance on the type and format of information that applicants should submit.

LOI Details Tab

The Details tab includes the four main sections of the LOI: Contact Information, Pre-Screen Questionnaire, Details, and Review/Submit.

Contact Information

Provide basic information about your organization (e.g., address), the PL, and the PL's experience.

The PL is the lead representative of the organization or institution for the project. He or she must be affiliated with the primary institution or organization applying for the award, and he or she serves as PCORI's lead point of contact. PLs can participate in other applications (from the same or other organizations) in a different role, such as colead or consultant.

The AO must be affiliated with the primary institution or organization applying for the award, and he or she serves as the person responsible for matters related to the award and administration of the contract. The AO's signature certifies that the organization or institution will be accountable for both the appropriate use of funds awarded and the performance of the PCORI-supported project or activities resulting from the contract. He or she cannot be the PL.

Pre-Screen Questionnaire

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 list of activities considered out of scope is in the Funding Announcement section of the guidelines.

Details

Provide a thorough description that allows PCORI to understand the project without having to review the full application. Applicants invited to submit a full application will have an opportunity to add additional details. You must include the following sections, taking into consideration that the goal is to support projects that will build a community better able to participate in PCOR and CER, as well as serve as channels to disseminate study results:

- Project name
- Background, objectives, methods, and outcomes



- Stakeholder Engagement Plan
- Amount requested from PCORI
- Total project budget amount
- A brief budget narrative describing how the amount requested from PCORI will be used
- A description of the PL's previous experience similar to this project
- Project start and end dates (please note: start dates should be no sooner than 90 days from application submission deadline)
- Information regarding vulnerable and underserved populations and stakeholder communities

Project Information and Authorizations

If you answer “yes” to the question “Is this a previously existing project that has been funded by others?,” then describe previous funders, note what has been learned, and indicate whether funding has ended.

Select “Yes” to certify that you are authorized by your organization to submit this LOI. Click “Save.”

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 that 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.

Full Proposal



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.

The proposal application is divided into four tabs: **Details, Key Personnel, Attachments, and Budget, as described below. Note that some information in the Details section will be carried over from the LOI.**

Details Tab

The Details tab includes the six main sections of the application: Organization and Project Lead Information, Project Summary, Project Information, Patient and Stakeholder Compensation, Collaboration and Partnerships, and Authorization.

Project Summary



Provide additional information, as follows:

- A description of the unique capabilities of the PL and the organization to address the issues described in the project description and background
- A project summary that may be made public on the PCORI website or in other PCORI-related publications (up to 3,500 characters/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?

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.

Key Personnel Tab

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.



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

Attachments Tab

Upload required documents by selecting “Select File” and following the system prompts for each document type. Required documents are noted for each document type. Note that the system will automatically rename the attachment with the document type, name of project, year, and original file name. Maximum file size for all documents is 10 MB. Documents should be PDFs, Microsoft Word files, or Microsoft Excel files only. The Budget and Milestone Deliverables Table document must be uploaded in Microsoft Excel format. The Workplan document must be uploaded in 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:

Project Workplan and Timeline

Upload the required template in a Microsoft Word format, following required page limits. 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.
- **Project Timeline**—Describe the project’s major activities and expected milestones, by month.

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.

Patient and Stakeholder Engagement Plan

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](#),¹⁰ which was issued by the U.S. Department of Health and Human Services (Department of HHS).

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 Summary and Budget Justification.

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.

Project Deliverables/Milestones

Each project year should yield a minimum of four and a maximum of five deliverables, in addition to two

¹⁰ See <http://grants.nih.gov/sites/default/files/supplementalinstructions.docx>.



required yearly deliverables—an interim report and either a year-end report or final report, depending on project year. There should be at least one milestone or deliverable in the period between each of the required reports.

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. Space is provided to include a narrative summary of project deliverables, but this is optional. For due dates, please use numerical dates rather than generic months or written dates.

Budget Summary

Upload the required template in Microsoft Excel format. Enter detailed budgets for Years 1 and 2. Include all costs for your organization in the applicant worksheets. If applicable, include all costs for each subcontracted organization in the subcontractor worksheets for each year of the project. See [Appendix 2: Allowable and Unallowable Costs](#) and [Cost Considerations: Description of Allowable Direct Costs under a PCORI Award](#) to understand acceptable and unacceptable uses of PCORI contract funds. Please note that indirect costs (not to exceed 40% of the allowable direct cost base) should be included in the budget, which must not exceed \$250,000. If applicant organizations have a federally negotiated rate below 40%, the organization must use that rate.

Keep the following guidelines in mind as you complete each section of the worksheet:

A. Personnel Costs

- Personnel Costs: These include the base salary for each scientific and technical staff member, employee patient or stakeholder partner, or other personnel on your project who are or are not accounted for in Section B: Consultant Costs. Provide a clear distinction between individuals who are considered key personnel and those considered “other personnel.”
- 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 with the Budget Justification.
- Level of Effort: Personnel who contribute to a PCORI-funded research project are expected to monitor their total percentage of effort across all their active funding so 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. Effort must be reported by the percentage of time over the course of the project year. If salary support is not being requested, use \$0 for the base salary.



- List all personnel who dedicate effort to the project 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 Detailed Budget. Describe the individual's specific functions in the Budget Justification. Provide an explanation of how the role supports the project aims and note any overlap in job functions.
- Salary Cap: The PCORI base salary cap for personnel is \$200,000 annualized per individual, per year, excluding fringe benefits. An individual who earns less than \$200,000 must use his or her actual base salary to calculate personnel costs. An individual with a full-time employee base salary of more than \$200,000 must use \$200,000 as the base salary rate in determining the amount of salary and time to charge to the project.
- Fringe Benefits: These costs are calculated based on the institution's own policy. In the budget upload, following the Budget Justification, applicants must provide a verification of the fringe benefit rate policy for the prime organization.

B. Consultant Costs

- Consultant costs apply to 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 names, expected number of hours, and hourly rate.
- Include the daily consultant fee, travel expenses, nature of the consulting effort, and why 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 you established the negotiated rate. See the [Letters of Support](#) section for more detailed information.

C. Supply Costs

- Supplies must be directly allocable and allowable to the proposed project and not part of general or administrative use. Include the category of supplies needed and the cost for each.
- Indicate general categories such as mailings and printing. Provide detailed explanations in the Budget Justification for all costs exceeding \$1,000.
- For all supply costs, provide computations for how applicants arrived at the specific number.



Note: PCORI considers computers, tablets, docking stations, mobile data and protection plans, and software to be general office supplies that are not allowable as direct-cost charges. If these items are proposed as essential 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

- 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 costs must be itemized per trip. PCORI closely reviews all travel costs for reasonableness.
- 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.
- Include the number of trips and provide a brief description of the trips, including the number of people traveling and the dates or duration of the stay.
- In the Budget Justification, applicants must provide additional detail to explain the basis for the costs listed and describe how the travel is directly related to the proposed research project and necessary for achieving programmatic objectives.

E. Other Expenses

- Indicate and include general categories such as printing, publication, illustration costs, and nonconsulting service contracts, when applicable.
- Use this section to include direct costs that cannot be accounted for in other budget categories. For example, these costs may include warranties, computer services, data warehousing, or participant incentives.
- In the space provided, include a detailed explanation for items exceeding \$1,000. Applicants must provide additional detail for each of these costs in the Budget Justification.
- When applicable, provide computations for how applicants arrived at the specific number.

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

- Applicants and subcontractors may assess their indirect costs, not to exceed 40 percent (or 10 percent for foreign organizations and those without a federally negotiated rate), on the first \$25,000 of all subcontractor costs combined (direct and indirect). Subcontractors with third-tier providers must follow this budget guideline.
- Applicants who do not have a federally negotiated or independently audited indirect cost rate may assess up to 10 percent indirect costs, to be noted in the Budget Justification.
- Foreign applicants are eligible for no more than 10 percent indirect costs.
- A copy of the prime applicant’s federally negotiated or independently audited indirect cost rate letter must be submitted with the application. Include these copies in a single file with the Budget Justification.
- In the event that an indirect cost rate agreement is more restrictive than that of PCORI’s accepted indirect cost application, PCORI will allow the applicant to use the less-restrictive rule when calculating indirect costs on submitted budget categories.

PCORI Indirect Cost Cap

40% of...
The total of these annual costs...

 PERSONNEL	 CONSULTANT FEES	 TRAVEL COSTS	 SUPPLIES	 OTHER DIRECT COSTS
--	---	---	---	--

Plus these costs over the full project period...

 SUBCONTRACTOR DIRECT & INDIRECT COSTS	OR	 \$25K
(WHICHEVER IS LESS)		



Budget Justification and Other Sources of Funding

Upload the required template. Provide a justification that supports the costs proposed in the budget for the applicant organization and for each subcontracted organization (if applicable) for all years.

- *Applicant Organization*: Provide the detail needed to understand both the basis for costs and the reason why the costs are necessary to the project for each budget category, providing adequate detail to understand any major cost variances.
- *Subcontracted Organization Justification(s)*: Provide a detailed justification for each subcontractor agreement by budget category. Specify any other sources of funding direct to the subcontractor in support of its portion of the project (see below).

Professional Profiles/Biosketches

Upload a biosketch for each of the key personnel, including the PL. If a biosketch is not available, please use the PCORI [biosketch template](#). If multiple profiles/biosketches are needed, combine them into one PDF or Microsoft Word document for uploading.

Complete a Professional Profile/Biosketch section for the PL and each person listed in the Key Personnel section (limit five key personnel, not including the PL). At a minimum, each profile must include the person's name, title, and degrees; however, PCORI is especially interested to know each individual's previous experience, past performance, and training in the field of PCOR (if applicable) and that team members are appropriately trained and well suited to carry out the proposed project. Information from National Institutes of Health (NIH) biographical sketches can be incorporated. If the PL does not have PCOR experience, please outline appropriate collaborative arrangements with PCOR experts.

Note: PCORI recognizes that not all sections of the Professional Profile/Biosketch may apply to patient or other stakeholder members of the project team.

Other (nonrequisite) attachments you may wish to submit:

Letters of Support

Provide Letters of Support, including any letters necessary to demonstrate the support of subcontract participants and collaborators, such as stakeholder associations and other significant contributors included in the contract application. 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. Letters of Support are not required for personnel (such as research assistants) who are not contributing in a substantive, measurable way to the project's development or execution.

Letters of Support must be addressed to the PL, combined into one PDF or Microsoft Word document, and uploaded into the PCORI Engagement Awards Online Application System. Provide no more than five Letters of Support.



Recent Articles/Evaluations

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

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

Budget Tab

Provide details related to the budget. These subtotals should match the budget spreadsheet amounts. To begin creating budget, click "+New." Enter the subtotal dollar amount for each of the following line items for both Year 1 and Year 2 of the budget.

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

Click "Save" to save the new budget record.

Review and Submit Tab

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."

VI. Additional Requirements

Awardees are required to comply with the requirements listed below.



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

PCORI requires all applicants to adhere to NIH policy on education in the protection of human subject participants in the conduct of research. This applies to all individuals listed in the application as key personnel. The policy is available [from the NIH website](#).¹¹

PCORI Public Access Policy

PCORI contracts require all awardees to adhere strictly to publication policies that PCORI will elaborate on during contract activation.

Standards for Privacy of Individually Identifiable Health Information

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

Decisions about applicability and implementation of the Privacy Rule reside with the PI and his or her institution. [The Office for Civil Rights website](#)¹² provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on “Am I a covered entity?” The [NIH website](#)¹³ provides 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.

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.

Award Funding Conditions

PCORI reserves the right to discontinue funding for awardees who fail to meet the mutually agreed-upon timelines and deliverables at any time during the contract. Proposed timelines and deliverables will be negotiated and finalized in the post-award period before contract activation.

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

¹¹ Available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

¹² Available at <http://www.hhs.gov/ocr>.

¹³ Available at <http://privacyruleandresearch.nih.gov/>.



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.

VIII. How Does PCORI Engagement Review and Score LOIs and Full Applications?

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 programmatically triaged if it is not responsive to these guidelines. See Eugene Washington PCORI Engagement Awards [Review Process](#)¹⁴ 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 or care protocols
- 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
- Writing research proposals or completing grant applications, grant making
- 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
- Conferences that are scheduled to occur less than six months from the application due date

¹⁴ Available at <https://www.pcori.org/funding-opportunities/research-support-funding-opportunities/eugene-washington-pcori-engagement-2>



- 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 (See irs.gov/businesses/small/article/0,,id=102767,00.html). International applicants are not required to enter an EIN in the electronic LOI or application; they should enter “999-99-999” in the EIN field.

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 research 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 study investigators and other research project staff (including engaged patient and other stakeholder research study partners) related to their percentage of effort on conducting the research project. (Such costs may not include personnel who deliver patient care as a component of their participation in the research project.)
- Consultant fees
- Travel 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 research project. A notification of pending award is subject to budgetary review and successful contract negotiation. The actual award amount may vary. For more information, please see [PCORI Cost Considerations](#).

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

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

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