



Eugene Washington PCORI Engagement Awards Application Guidelines

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About PCORI

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

PCORI was authorized by the Patient Protection and Affordable Care Act of 2010 as a nonprofit, nongovernmental organization. PCORI's purpose, as defined by the law, is to help patients, clinicians, purchasers, and policy makers make better-informed health decisions by "advancing the quality and relevance of evidence about how to prevent, diagnose, treat, monitor, and manage diseases, disorders, and other health conditions."

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Contents

1.0	About These Guidelines	4
2.0	Programmatic Description and Guidelines	4
3.0	Who Can Apply.....	5
4.0	How to Apply	5
5.0	When to Apply	8
6.0	What to Include.....	8
7.0	Additional Requirements	23
8.0	How Does PCORI Engagement Review and Score LOIs and Full Proposals?.....	24
Appendix 1: Key Terms		25
Appendix 2: Allowable and Unallowable Costs.....		27



1.0 About These Guidelines

This document provides key information to help applicants respond to the Eugene Washington PCORI Engagement Awards with a Letter of Inquiry (LOI) and a full application. Additional resources include:

- [PCORI Engagement Award FAQs¹](#) cover common questions about PCORI, the Engagement Awards application process, and review criteria.
- For programmatic questions, or if you would like to schedule a call with program staff, please contact us by email (ea@pcori.org) or phone (202-370-9312). PCORI will respond within three business days.
- For administrative, financial, or technical questions, please email ea@pcori.org. PCORI will respond within three business days.

Funding Mechanism

In technical terms, the Eugene Washington PCORI Engagement Awards are issued as cost-reimbursable **“Service”** or **“Mission-Based” Contracts**. They are **not** research grants, 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.

2.0 Programmatic Description and Guidelines

The Eugene Washington PCORI Engagement Awards, named in honor of the first chair of PCORI’s Board of Governors, encourage active integration of patients, caregivers, clinicians/providers, industry, payers/purchasers, researchers, and other [stakeholders](#) as members of the research process. The Engagement Awards program provides a platform to expand the role of all stakeholders to support PCORI’s Engagement Imperative, defined in our [Strategic Plan](#). This includes PCORI’s goals to:

- **Develop the patient-centered outcomes research (PCOR) community** in order to successfully establish an infrastructure for patients, caregivers, clinicians/providers, industry, payers/purchasers, researchers, and other stakeholders to PCOR and comparative effectiveness research (CER) information and to engage them in research, dissemination, and evaluation.
- **Engage the community in the research process** in order to influence research and establish trust and legitimacy for successful uptake of research findings.
- **Promote dissemination and implementation** so that patients, caregivers, clinicians/providers, industry, payers/purchasers, researchers, and other stakeholders have PCOR/CER information they can use to make decisions that reflect their desired health outcomes and to speed implementation of our findings.

¹ FAQs are available at <http://www.pcori.org/content/eugene-washington-pcori-engagement-awards-faqs>.
Eugene Washington PCORI Engagement Awards: Application
Guidelines



PCORI will fund proposals in three categories:

- **Knowledge Awards**, which will build knowledge around how consumers of healthcare information receive and make use of PCOR/CER findings
- **Training and Development Awards**, which will promote the training and development of the “non-usual suspects” and others from the patient and stakeholder community to increase capacity for engaging in PCOR/CER
- **Dissemination Awards**, which will support such activities as disseminating information and encouraging adoption of PCORI-funded research results, as well as support best practices for engaging patients and other key stakeholders (e.g., caregivers, clinicians/providers, industry, payers/purchasers) in research

Additional information on the Engagement Award programs, including a link to the application and a link to the projects PCORI funds through this program, can be found on the [PCORI Engagement Awards site](#).²

3.0 Who Can Apply

Applications may be submitted by any private- or public-sector organization, including any nonprofit or for-profit organization; any research organization, including any university or college hospital or healthcare system, laboratory, or manufacturer; and any unit of state or local government. All U.S. applicant organizations must be recognized by the Internal Revenue Service (IRS) and must have an [Employer Identification Number](#) (EIN).³ International organizations also may apply; please enter 999-99-9999 in the EIN field in the LOI. Organizations may submit multiple applications for funding.

Individuals are not permitted to apply.

4.0 How to Apply

Follow the instructions provided in these guidelines and in the [PCORI Engagement Awards Online Application System](#).⁴ All required documents must be submitted as PDF, MS Word, or Excel files, as required under the Attachment Section listed below. Failure to follow these guidelines or to submit all

² Information on the Eugene Washington PCORI Engagement Awards is available at <http://www.pcori.org/content/eugene-washington-pcori-engagement-awards>.

³ Details on EINs are available from the IRS at [http://www.irs.gov/Businesses/Small-Businesses-%26-Self-Employed/Apply-for-an-Employer-Identification-Number-\(EIN\)-Online](http://www.irs.gov/Businesses/Small-Businesses-%26-Self-Employed/Apply-for-an-Employer-Identification-Number-(EIN)-Online).

⁴ The PCORI Engagement Awards Online Application System is available at <https://pcori.force.com/engagement/>. Eugene Washington PCORI Engagement Awards: Application Guidelines



required documents through this system may result in removal of the application from the review process.



Step 1: Register

To apply for PCORI Engagement Awards funding, you must register in the [PCORI Engagement Awards Online Application System](#). Click “Join Our Community” to register. Your first and last names, a “nickname” (e.g., your first name), an email address, and a password are required. The email entered will be your user name. Note that the PCORI Engagement Awards use an online application system different from PCORI’s research funding announcements. 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* completion of a full proposal. PCORI will convene on a regular basis to discuss submitted LOIs and will determine whether to deny or invite to submit a full proposal. Applicants will receive communication from PCORI no later than 20 days after LOI submission.



Note: A Project Lead may submit only one LOI to the Eugene Washington PCORI Engagement Awards program per application cycle. While a Project Lead may apply for other PCORI funding opportunities, the research topic/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/declined during the screening process.

LOIs appearing to be duplicative of already funded projects may also be declined.



Step 3: Complete the Full Proposal

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

Full proposals may be submitted upon invitation only and must be completed 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.

Required templates, available via [Eugene Washington PCORI Engagement Awards](#), must be formatted as follows:

- *Header:* Each page should include the name of the organization, project title, and full name of the Project Lead 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 size 11 Times New Roman for the main body of the text. Figures and captions may be in a smaller type.
- *Page Numbering:* Number each page of the document consecutively.
- *Spacing:* Use single spacing.
- *Document Format:* All uploaded documents must be in PDF, MS Word, or Excel format. The Budget document must be uploaded in 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.

NOTE:

- ANY PROPOSALS THAT DO NOT FOLLOW THESE GUIDELINES WILL BE SUBJECT TO IMMEDIATE REJECTION.
- You may not reorganize sections within the templates.
- Keep the main header questions of the templates within your submission.
- You may delete instructional text.



Step 4: Submit for Authorization

Both the LOI and the full proposal require documentation indicating that the individual submitting the LOI and/or full proposal is authorized by his or her organization to do so. Submissions **MUST** include this authorization from the organization's Authorized Official (AO). **The Principal Investigator (PI) and the AO may not be the same individual.** Only the AO may approve the final application for official submission to PCORI. The AO must review and approve the submission of the application to PCORI





before the submission deadline. **PCORI also encourages the PI to inform the AO when the application is ready for submission.** This will allow the AO to review and give the PI final permission to submit.

5.0 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 20 days of submission.

Full Proposal: A full proposal, submitted upon invitation only, should be submitted within 40 days of receiving the invitation. Full proposals will be reviewed within 40 days of submission.

Note: Deadlines are 5:00 p.m. ET on the due date.

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

6.0 What to Include

Applicants are encouraged to review this entire section and to print and complete the Application Checklist to ensure the application is submitted correctly and completely. Additional instructions for some questions are included above the relevant question in the PCORI Engagement Awards Online Application System.



Application Checklist

(A) Letter of Inquiry		Submission Method	Length/Limit
<input type="checkbox"/>	Organization and Project Lead Information	Enter into online system	As noted
<input type="checkbox"/>	Project Information	Enter into online system	As noted
	<ul style="list-style-type: none"> Project Information Project Summary Authorization 		As noted 1,000 to 2,000 characters/spaces each Obtained from AO
(B) Application		Submission Method	Length/Limit
<input type="checkbox"/>	Organization and Project Lead Information	Entered previously as part of the Letter of Inquiry; review and modify if needed.	As noted
<input type="checkbox"/>	Project Information	Entered previously as part of the Letter of Inquiry; review and modify if needed.	As noted
	<ul style="list-style-type: none"> Project Information Project Summary 		
<input type="checkbox"/>	Key Personnel	Enter into online system	Limit five Key Personnel (not including Project Lead)
<input type="checkbox"/>	Collaboration and Partnerships	Enter into online system	5,000 characters/spaces
<input type="checkbox"/>	Federally Negotiation IDC	Upload	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, including Timeline, and Deliverables	Upload	21 pages total: 15 for Workplan, 2 for Timeline, 2 for Deliverables, and 2 for Patient Engagement Plan
<input type="checkbox"/>	Budget Summary	Upload	As needed



<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
<input type="checkbox"/> Authorization	Enter into online system	Obtained from AO

(A) Letter of Inquiry

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

LOIs not consistent with program goals, or those substantially overlapping with existing projects, will not be invited to submit a full application.

Applicants must register and log in to the [PCORI Engagement Awards Online Application System](#) to create or continue an LOI. Once in the system, click the “Foundation Connect” link in the top navigation.

Applicants will receive an email notification regarding the status of their LOI 20 days after the LOI deadline.

To Create an LOI: Click “Create LOI” in the “Grantee Links” menu.

To Continue an LOI: Access saved work by clicking on the “Grantee Dashboard” link in the “Grantee Links” menu. You will be taken to the Grantee Dashboard, from which you may select open LOIs for editing and submission.

There are two tabs for the LOI: “Details” and “Review and Submit,” described below. When working on an LOI, **remember to click “Save” before exiting the system.**

Details Tab

The “Details” tab includes the four main sections of the LOI: Organization and Project Lead Information, Project Summary, Project Information, and Authorization.

Organization and Project Lead Information

Provide basic information about your organization (e.g., address), the Project Lead, and the Project Lead’s experience.

The Project Lead is the lead representative of the organization/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. Project Leads can participate in other applications (from the same or other organizations) in a different role, such as co-lead or consultant.

The Organization CEO or Executive Director should list your organization's AO. He or she 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/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 PI.

Project Summary

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:

- Project Name
- Background—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.
- Objectives—Briefly describe the aims of the project, including the long-term objectives.
- Methods—Provide a concise description of project methods that will be employed.
- Outcomes (projected)—Specify the projected outcomes and state their significance.
- Brief summary of the patient and stakeholder engagement plan—Explain who the patients and stakeholders are, how they will be engaged, and how often they will be engaged in the project.
- 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 Project Lead's previous experience similar to this project
- Project start and end dates
- Information regarding vulnerable/underserved populations and stakeholder communities

Project Information

Indicate the type of Engagement Award you are responding to and whether you were invited by PCORI to submit a proposal. Indicate whether you are responding to an initiative announcement.



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.

Authorization

The LOI must be reviewed and the submission approved by an authorized AO on behalf of the applicant organization. **PCORI encourages the PI to inform the AO when the application is ready for submission, so it may be reviewed before final approval and submission by the AO.** Click the authorization checkbox to indicate concurrence, and certify that authorization has been obtained. The AO and the PI may not be the same person.

Review and Submit Tab

The “Review and Submit” tab allows you to review, print, and submit your completed LOI.

Submission

Once your LOI is complete, click “Save” in the “Details” tab. Required fields will be indicated in red at the top of the LOI form. Once all required fields are completed, click “Continue” (or click “Edit” to continue working on the LOI). You will be taken to the “Review and Submit” tab, where you may submit the LOI to PCORI by clicking “Submit.” You may also print the LOI by clicking “Print.” You will not be able to edit the LOI once it has been submitted.

(B) Full Proposal



Applicants may submit a full proposal upon 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 “Review and Submit,” as described below. You must click “Save” at the top or bottom of the page to continue to the next tab. 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, Stakeholder Compensation, Collaboration and Partnerships, and Authorization.

Organization and Project Lead Information



Review and edit information as needed. Provide additional information regarding the organization's fiscal year calendar.

Project Summary

Review and edit information as needed. Provide additional information, as follows:

- A description of the unique capabilities of the Project Lead and/or 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

Project Information

Review and edit information as needed.

Stakeholder Compensation

Indicate whether patient and/or stakeholder partners engaged in the project will receive financial compensation for their role(s) and, if yes, describe this compensation.

Collaboration and Partnerships

Enter information in the online system. Provide the name of organizational collaborators or partners, and describe the role the organization will play in meeting the goals and objectives of the project. Collaborator/partner organizations are project contributors that are *not* subcontractors (i.e., have no fiscal relationship to the applying organization).

Authorization

The application must be reviewed and the submission approved by the organization's AO. Click the authorization checkbox to indicate concurrence, and certify that authorization has been obtained.

PCORI encourages the PI to inform the AO when the application is ready for submission, so it may be reviewed before final approval and submission by the AO. The AO and the PI may not be the same person.

Key Personnel Tab

Click "New" to enter new Key Personnel in the online system. Limit your application to five Key Personnel, *not* including the Project Lead. When finished entering your Key Personnel, click "Continue" to be taken to the next tab of the application.

Attachments Tab

Upload required documents by clicking "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, MS Word files, or Excel files only. When finished uploading all required files, click “Continue” to be taken to the next tab of the application.

Required attachments are described below:

Board of Directors Template

Upload the required template. List your organization’s current board of directors, including board role and affiliations.

Project Workplan, including Timeline, and Deliverables

Upload the required template in a Word format, following required page limits. See details below.

Project Workplan

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 is 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.

In addition, describe past performance, including any similar projects you/your organization has conducted, any past experience with PCORI, or any additional relevant experience.

Project Timeline

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

Project Deliverables

List at least 2 deliverables that will be submitted to PCORI during each 12-month period of the project. In general, deliverables are measurable and verifiable outputs or objects, such as minutes of major meetings of the project partners, survey instruments, or results of surveys of patient/stakeholder partners. Calculate the projected deliverable date based on the projected start date noted in your application.



These deliverables are in addition to two required yearly deliverables—an interim report and either a year-end report or final report, depending on project year. A Final Financial Report is required at the completion of the project.

Optional: Space is provided to include a narrative summary of project deliverables.

Patient Engagement Plan

Describe the plan to engage patients and stakeholders meaningfully throughout the proposed project. The proposal should integrate patients and stakeholders in the development of the project plan and in the project's key elements. The patient engagement plan should address the following questions:

- Does the proposal 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, describe the protection of human subjects involved in your project. For additional guidance, refer to [Section 5.0, "Human Subjects Research Policy,"](#)⁵ from the *Supplemental Grant Application Instructions for All Competing Applications and Progress Reports*, issued by the U.S. Department of Health and Human Services (HHS).

Subcontractual Arrangements

Describe the project components that will be performed by subcontracted organizations. 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.

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



References Cited

Provide a list of references cited in the Project Workplan, including Timeline, and Deliverables, if applicable. 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.

Budget Summary

Upload the required template in Excel format. Enter detailed budgets for Years One and Two. 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](#) to understand acceptable and unacceptable uses of PCORI contract funds.

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 staff member, employee patient or stakeholder partner, or other personnel on your project, if these members are not accounted for in Section B: Consultant Costs.
- **Allowable Costs:** PCORI will pay compensation for personnel as long as the costs are consistent with and do not exceed what the applicant would normally pay under its own policy. Such compensation may include salaries and fringe benefits. See [Appendix 2: Allowable and Unallowable Costs](#) for more information.
- **Salaries** include wages earned by an employee, and fringe benefits may include insurance and retirement plans.
- **Level of Effort:** Personnel contributing to a PCORI-funded research project are expected to monitor their total percent effort across all funding (PCORI or others), and may not exceed 100 percent. Effort must be reported by the percentage of time over the course of the project year. All personnel dedicating effort to the project, along with their level of effort, should be listed on the personnel budget. Please list the base salary for such persons in the Budget Justification and Detailed Budget. Before the application can be submitted, the AO must confirm that all Key Personnel will not exceed 100 percent commitment if funded.



- **Salary Cap:** The PCORI base salary cap for personnel is \$200,000 annualized per individual, per year, exclusive of fringe benefits. An individual who earns less than \$200,000 should use his or her actual base salary to calculate personnel costs. An individual with a full-time employee base salary 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 and all subcontractors. If funded, PCORI will verify these costs with the applicant and any subcontractors.

B. Consultant Costs

- Provide the names, fees, and other costs associated with consultants.
- Consultant costs are for those individuals who have dedicated time to the project neither as an employee of the applicant organization nor under a subcontract agreement as a member of the contractor staff. Payments to non-employee patient and stakeholder representatives are included.
- Consultant costs must be expressed in an hourly rate.
- Consultant costs must be reasonable and justified within the Budget Justification.
- Provide the total cost of the consultant(s) as well as name, expected number of hours, and hourly rate.
- For all consultant costs, provide computations for how the applicant arrived at the specific number.

C. Supply Costs

- Provide details and justify the need for specific supplies requested.
- Supplies must be directly allocable and allowable to the proposed project and not part of general or administrative use. Supplies are consumable items that are used on a regular basis or other tangible items that do not meet the definition of equipment. Include the category of supplies needed and the cost for each.
- Tangible items with per-unit costs of \$5,000 or more are considered equipment and cannot be accounted for under this category.
- Indicate general categories such as glassware, chemicals, and animal costs, including an amount for each category.
- In the space provided, include details for each cost that exceeds \$1,000. You will be asked to provide further detail for each of these costs in the Budget Justification template.
- For all supply costs, provide computations for how you arrived at the specific number.



D. Travel Costs

- Provide destinations and number of people traveling.
- Travel may include any domestic and/or international travel by study personnel or consultants directly related to and necessary for the project and within the limits explained below. As a matter of policy, PCORI uses the Federal Travel Regulations as the guidelines for per diem and reimbursement.
- Travel costs should be itemized per trip and described as either scientific travel or programmatic travel, as outlined below:
 - Scientific travel includes travel to present at conferences, symposia, and similar events. Scientific travel is capped at \$10,000 over the full project period, including costs for applicant organization and subcontractor personnel.
 - **Programmatic travel includes travel needed to conduct the project (i.e., focus groups, consultants, and others). While there is no cap on programmatic travel funds, PCORI closely reviews all travel costs for reasonableness.**
- Other travel guidelines to keep in mind are:
 - The number of trips, and the number of people traveling and dates or duration of the stay.
 - In the Budget Justification, provide added detail to explain the basis for the costs listed and describe how the travel is directly related to the proposed project (and is necessary to achieve programmatic objectives).
 - Airline costs cannot exceed the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare.
 - PCORI reviews all travel costs for reasonableness. In the Budget Justification, applicants must provide additional detail to explain the basis for the costs listed and describe how the travel is directly related to the proposed research and necessary to achieve programmatic objectives.

E. Other Expenses

- Provide details and justify the need for other expenses requested.
- List the total for all other costs in the appropriate rows. Indicate general categories, such as printing costs, publication costs, and service contracts, including an amount for each category.
- Use this section to include direct costs that cannot be accounted for in other budget categories. These costs may include participation incentives for project subjects, publication costs, or service contracts. Items such as requests for food and beverage will need a strong justification to be considered.
- In the space provided, include details for each cost that exceeds \$1,000. You will be asked to provide further detail for each of these costs in the Budget Justification template.



F. Equipment Costs

- Equipment costs include tangible items that have a per-unit cost of \$5,000 or more and a life of greater than five years.
- Up to three quotes for each item of proposed equipment can be included with the Budget Justification.
- Costs must be reasonable and necessary for the project. Equipment must not be available or accessible at a lower cost.
- Equipment costs will be analyzed and must be approved by PCORI during the award negotiation phase for projects that are funded. In general, PCORI will allow equipment, when applicable, and only in the first year of the contract.

G. Subcontractor Costs

- Provide a breakdown of costs proposed for each consortia or contractor. Each subcontractor's budget should be placed on a different tab.
- This category includes all consortium, contractual, and fee-for-service costs. A Subcontractor Arrangement is required for an individual's participation if the criteria listed below are met. If the criteria listed below are not met, a Consulting Agreement is more likely required (see Section B: Consultant Costs).
 - The time a person is devoting is on behalf of his or her employer and becomes part of his or her duties.
 - An individual'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.
 - The applicant organization is required to pay the subcontractor indirect costs associated with his or her participation.
- As stated above, complete a set of worksheets (Years One and Two) for each subcontractor. Subcontracted organizations must adhere to all budget policies detailed in these guidelines, including allowable and unallowable costs.
- Enter the total amounts for the direct and indirect costs in the appropriate rows.
- Direct costs:
 - Subcontractor personnel should be listed as Key Personnel and included in that section of the application if they contribute to the scientific development or execution of the project in a substantive and measurable way.
 - Subcontractor direct costs entered in the applicant's budget detail (Years One and Two) must represent the total direct costs across all subcontracts.
- Indirect costs:



- Indirect costs for the project may be calculated according to the subcontractor's own negotiated or audited indirect cost rate; however, the total indirect costs charged to the project cannot exceed the PCORI indirect cost cap of 40 percent (see Section H: Indirect Costs). The Budget and Budget Justification template has a tab that includes a tool to calculate the subcontractor indirect cost cap for your application.
- The calculation used for subcontractor indirect costs is the same as that used for applicant organization indirect costs (see Section H: Indirect Costs).

H. Indirect Costs

- Enter the amount for indirect costs. Provide a copy of federally negotiated IDC from HHS.
- Indirect costs for the project may be calculated according to the applicant's own negotiated or audited indirect cost rate; however, the total indirect costs charged to the project cannot exceed the PCORI indirect cost cap of 40 percent.
- Applicants without an established and confirmed indirect cost rate may assess up to 10 percent indirect costs. Foreign applicants may not request more than a 10 percent indirect cost rate.
- 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.
- Submit a copy of the applicant's federally negotiated or independently audited indirect cost rate letter. Include these copies after the Budget Justification, in a single file of budget materials uploaded to PCORI Online.
- The Budget template contains a tool using the formula shown below to calculate the PCORI indirect costs cap.

PCORI Indirect Cost Cap



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 the required template. If multiple profiles/biosketches are needed, combine them into one PDF or MS Word document for uploading.

Complete a Professional Profile/Biosketch section for the Project Lead and each person listed in the Key Personnel section (limit five Key Personnel, not including the Project Lead). 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 Project Lead 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 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 from the leadership of your organization an LOI indicating that the organization would implement the project findings if they are 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 development or execution of the project.

Letters of Support must be addressed to the Project Lead, combined into one PDF or MS 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 MS Word document in the PCORI Engagement Awards Online Application System.

Review and Submit Tab

The “Review and Submit” tab allows you to review, print, and submit the completed application. Again, the application must be reviewed and submission approved by the organization’s AO. Click the authorization checkbox to indicate authorization has been obtained from the AO. The AO and the Project Lead may not be the same person. Once your application is complete, and has been reviewed and approved by the AO, including all required attachments, click “Submit.” Required information will be indicated at the top of the application form in red. Once all required fields are completed and all required attachments are uploaded, click “Submit” to submit the application to PCORI. You may also print the application by clicking “Print.” You will not be able to edit the application once it has been submitted.



7.0 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 personnel listed in the application as Key Personnel. The policy is available [from the NIH website](#).⁶

PCORI Public Access Policy

PCORI contracts require all awardees to adhere strictly to publication policies that will be elaborated by PCORI during contract activation.

Standards for Privacy of Individually Identifiable Health Information

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 HHS Office for Civil Rights.

Decisions about applicability and implementation of the Privacy Rule reside with the Project Lead and his or her institution. [The Office for Civil Rights website](#)⁷ provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on “Am I a covered entity?” Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found on the [NIH website](#).⁸

Contract Terms and Conditions of Award

The administrative and funding instruments used for the Eugene Washington PCORI Engagement Awards is a cost-reimbursable “**Service-**” or “**Mission-Based**” Contract. They are not research grants, 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

⁶ Available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

⁷ Available at <http://www.hhs.gov/ocr>.

⁸ Available at <http://privacyruleandresearch.nih.gov/>.



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 the beginning/activation of the funding period.

Co-funding

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

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 in order to facilitate availability of data and samples.

8.0 How Does PCORI Engagement Review and Score LOIs and Full Proposals?

PCORI rigorously reviews the LOIs and proposals it receives. Note that LOIs and proposals may be eliminated from the review process for administrative or programmatic reasons. An LOI or 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/or in the PCORI Engagement Awards Online Application System. A proposal 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.



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 (1) it is incurred solely to advance the work under the project; or (2) 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 of Governors 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 non-wage 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—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>.

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 results of the project will be relevant.



Appendix 2: Allowable and Unallowable Costs

Allowable costs (i.e., those costs that can be included in a proposed detailed budget in applying for a PCORI Funding Award and charged to the award) may include the following costs that derive from and directly support the project:

- (i) salaries and fringe benefits for study investigators and other project staff (including engaged patient and stakeholder study partners) related to their percentage of effort in conducting the project (such costs should not include personnel who deliver patient care as a component of their participation in the research project)
- (ii) consultant fees
- (iii) travel for mandatory investigator meetings
- (iv) travel that is otherwise necessary for conducting the research project
- (v) supplies
- (vi) equipment
- (vii) subcontracts
- (viii) expenses related to conducting engagement activities with patients and other stakeholders
- (ix) other direct expenses
- (x) indirect costs

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

- In general, costs for study interventions that constitute the procedures, treatments, interventions, or other standard clinical care ("patient care") that are being proposed for comparison in the research project ("patient care costs") will not be covered by PCORI. Patient care costs should be covered by the host healthcare delivery system, third-party payer, manufacturer of the product, developer of an intervention, or other interested party.



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

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

Allowable Costs

Unallowable Costs

