PPRN Limited Competition Award*
Application Guidelines

*This limited competition funding opportunity was updated on November 20, 2019. This funding opportunity was initially opened through the Eugene Washington PCORI Engagement Awards Program. It has now been reclassified as a Research Infrastructure funding opportunity. Learn more in this blog post.

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: PPRN Limited Competition. Additional resources include the following:

- Engagement Award: PPRN Limited Competition **Application Checklist**: Provides a list of all required and relevant documents for submitting an application

- **For programmatic questions**, please contact pprn@pcori.org. **For administrative questions**, please contact pfa@pcori.org.

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 effectiveness research (CER), and to serve as channels to disseminate study results. 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 purpose of this Engagement Award: PPRN Limited Competition Funding Announcement is to provide guidelines for available funding support for Phase II PCORnet Patient-Powered Research Networks (PPRNs) to join in a network that capitalizes on the accomplishments of PPRNs in PCORnet, by continuing to develop and test innovative resources and approaches to involving patients and participants in research, and by articulating and modeling constructive roles that can be emulated by other such organizations to make clinical research more efficient, effective, and useful. This support is intended to make progress toward a future in which patient/participant-driven research organizations play a much greater role in guiding the entire clinical and care delivery research enterprise by providing strong, accessible, and reliable patient and caregiver voices for all aspects of research activities.

Maximum Budget and Project Award Period

Award total costs must not exceed $350,000, and the maximum project period is 24 months.

Applications will be considered nonresponsive for the PPRN Engagement Award if they propose the following:

- Research studies including randomized controlled trials, observational studies and pragmatic clinical studies
- 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 that involve patients only as subjects (i.e., individuals enrolled into a study as participants)
- Projects designed solely to validate tools or instruments
- Projects focused solely on writing research proposals or completing grant applications
- 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

- Projects without a clear focus on patient-centered outcomes research or comparative clinical effectiveness research

II.   Who Can Apply

Applications may be submitted by any organization that is part of a Phase II PCORnet Patient-Powered Research Network. 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 pprn@pcori.org.

III.   How to Apply

To submit an application including all required documents, follow the instructions provided in these guidelines and in the PCORI Engagement Awards Online Application System. 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 and an EIN, if applicable. International organizations should enter "999-99-9999" in the EIN field.

Step 1: Register

To apply for PCORI Engagement Award: PPRN Limited Competition, you must register in the PCORI Engagement Awards Online Application System. To register, you must provide a name, an email address, a password, and a security question and answer. Once signed in, you will be directed to the home screen. Select "Engagement Awards" to begin applying. PCORI strongly recommends that only the Project Lead (PL) create the application record, because whoever creates the record will have permanent access to it in PCORI Online. Please contact pprn@pcori.org with questions regarding the registration process.

Step 2: Complete the Full Application

Applicants must submit full applications through the PCORI Engagement Awards Online Application

System. For detailed instructions on how to navigate the system, reference PCORI Online Engagement Award: PPRN Limited Competition User Guide

In addition to the online application, applicants must submit required templates, available via Engagement Award: PPRN Limited Competition PFA page, 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 wider. 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).

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 3: 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

The Engagement Award: PPRN Limited Competition does not require a Letter of Inquiry (LOI), and a Full Proposal must be submitted by the application deadline on December 18, 2018, at 5 pm (ET).

V.   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 Online Application System.

Application Checklist

	Application	Submission Method	Length/Limit
☐	**Organization and PL Information**	Enter into online system	As noted

☐	**Project Information**
	
	   • Project Information
	
	   • Project Summary
		Enter into online system	As noted

☐	**Key Personnel**	Enter into online system	Limit 5 key personnel (not including PL)
☐	**Collaboration and Partnerships**	Enter into online system	As noted
☐	**Federally Negotiated Indirect Cost Rate ***	Upload	If used, must include documentation with Budget Justification, as noted
☐	**Recent Articles/Evaluations***	Combine and upload	
☐	**Project Workplan and Timeline**	Upload	
	• Workplan		15 pages
	• Timeline		2 pages
	• Patient and Stakeholder Engagement Plan		2 pages
	• Protection of Human Subjects (if applicable)		As needed
	• Subcontractor Agreements		As needed
	• References Cited		10 pages
☐	**Project Deliverables/Milestones**	Upload	As needed
☐	**Budget**	Enter into online system and upload	
☐	**Budget Justification and Other Sources of Project Support**	Upload	10 pages
☐	**Professional Profile/Biosketch**	Combine and upload	4 pages per individual
☐	**Letters of Support**	Combine and upload	Letters combined in 1 document
☐	**Authorization**	Enter into online system	Obtained from AO

* Items marked with an asterisk are optional.
Note: All character counts include spaces and other formatting.

Full Proposal

The application is divided into four tabs: **Details, Key Personnel, Attachments, and Budget, as described below.**

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.

Organization and Project Lead Information
Provide 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 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 co-lead 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 the appropriate use of funds awarded and for the performance of the PCORI-supported project or activities resulting from the contract. He or she cannot be the PL.

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):

  o **Project Name**—Include PPRN affiliation in the project title.

  o **Background**—Briefly state the problem or question that the project is designed to address.

  o **Proposed Solution to the Problem**—Briefly describe the manner in which the problem or question will be resolved, including your ***project's location*** (e.g., city, town, district) and ***setting*** (e.g., clinic, community center, school).

  o **Objectives**—Briefly describe the project aims, including the long-term objectives.

  o **Activities**—Provide a concise description of project activities that will occur throughout the project's duration.

  o **Outcomes and Outputs** (projected)—Specify the projected outcomes and state their significance. Describe what tangible outputs this project will produce (e.g., training

curricula, research agenda).

- o **Patient and Stakeholder Engagement Plan**—Describe who the patients and stakeholders involved in or affected by the project are, how they will be engaged, and how often they will be engaged in the planning and execution of the proposed project.

- o **Project Collaborators**—Specify which organizations or institutions are helping 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 other patient-/participant-driven research organizations and large clinical data networks, such as the People Centered Research Foundation.

Key Personnel Tab

These individuals 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 into the online system. Limit your application to five key personnel, not including the PL. When you finish 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. Disregard instructions in the application that direct you to upload the Board of Directors template, as it is NOT required for this application. 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 you finish 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 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.

- **Expected Project Outcomes and Impact**—Specify the key project 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 two 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 key elements of the project. 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, "Human Subjects Research Policy," from the Supplemental Grant Application Instructions for All Competing Applications and Progress Reports, which was issued by the US 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) of 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.* 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 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, such as minutes of major meetings of the project partners or results of surveys/meetings of patient/stakeholder partners. Space is provided to include a narrative summary of project deliverables. For due dates, use dates rather than months.

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.

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 within 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.

- In the personnel budget, list all personnel who dedicate effort to the project and their level of effort, even if they are not requesting salary support. In the Budget Justification and Detailed Budget, list the base salary for each person. In the Budget Justification, describe the individual's specific functions. Explain how the role supports the project's 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

- Applicants should budget for travel to Washington, DC, by two project personnel twice over the course of the award.

- Travel may include any domestic or international travel by project personnel or consultants directly related to, and necessary for, the project and within the limits explained below. PCORI uses the Federal Travel Regulations guidelines for per diem and other reimbursements.

- Travel should be devoted to programmatic activities necessary to conduct the projects, such as focus gropus, project team meetings, or data collection. Requests for travel to present at conferences or symposiums that are related to the topic al areas of the project may also be

included but should be limited in number and strongly justified. PCORI closely reviews all travel costs to ensure they are reasonable.

- Travel costs must be itemized per trip and must include the number of trips and a brief description of each one, including the number of people traveling and dates or duration of the stays.

- Airline or rail costs cannot exceed the customary standard commercial fare (coach or equivalent) or the lowest commercial discount fare. PCORI will not compensate upgrades.

- In the Budget Justification, 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, 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 each contractor's specific role and the aim or deliverable he or she will be supporting for 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 each subcontractor cost (direct and indirect). Subcontractors with third-tier providers must follow this budget guideline.

- Applicants that do not have a federally negotiated or independently audited indirect cost rate may assess up to 10 percent indirect costs, to be noted in the Budget Justification.

- Foreign applicants are eligible for no more than 10 percent indirect costs.

- A copy of the prime applicant's federally negotiated or independently audited indirect cost rate letter must be submitted with the application. Include these copies in a single file with the Budget Justification.

- If 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.

- Although consortium indirect costs must be noted in the prime applicant's direct cost budget, consortium indirect costs are not included in the applicant's direct cost budget cap.

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, 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 in 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, then 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 include the following:

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 all proposed collaborators. Letters of Support are not required for personnel who are not contributing in a substantive, measurable way to the project's development or execution (such as research assistants).

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.

Recent Articles/Evaluations

Articles by or evaluations of your organization (published or conducted within the past five years) may be included. Combine them into one document and upload as a PDF or Microsoft Word document into the PCORI Engagement Awards Online Application System.

Budget Tab

Provide details related to the budget. These subtotals should match the budget spreadsheet amounts. To begin creating a 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 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.

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 PL and his or her institution. The Office for Civil Rights website 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 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 that fail to meet the mutually agreed-on timelines and deliverables at any time during the contract. Proposed timelines and deliverables will be negotiated and finalized before contract activation.

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 publishing and disseminating all information and materials developed using PCORI funding, in accordance with its enacting legislation. All recipients of PCORI contracts must agree to these principles and must take steps to facilitate availability of data and samples.

Award Process

Applicants will be notified of the funding award decision in writing within 60 days of application review. If the full proposal is awarded, a PCORI staff member will coordinate arrangements to begin contract negotiations. Typically, contract negotiations take about six weeks.

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

VII. How Does PCORI Engagement Review and Score Applications?

PCORI rigorously reviews the applications it receives. Note that PCORI may eliminate applications from the review process for administrative or programmatic reasons. An 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 the Eugene Washington PCORI Engagement Awards Review Process for additional details about the review process. Applications will be considered nonresponsive for an Engagement Award if they propose the following:

- Research studies including randomized controlled trials, observational studies and pragmatic clinical studies
- 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 that involve patients only as subjects (i.e., individuals enrolled into a study as participants)
- Projects designed solely to validate tools or instruments
- Projects focused solely on writing research proposals or completing grant applications
- 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
- Projects 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 the 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—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—This is a notification to PCORI that an organization intends to apply.

Patient-Centered Outcomes Research—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—This system is 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, 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 to conduct 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 that 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, 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

- DATA PLANS (TABLETS AND OTHER MOBILE DEVICES)
- DOCKING STATIONS
- DOUBLE MONITORS
- ELECTRONICS PROTECTION PLANS
- OFFICE FURNITURE
- REPLACEMENT OF ITEMS PURCHASED ON AN EXISTING PCORI AWARD

Unallowable Costs

- ADVERTISING
- EXCESSIVE AIRFARE
- ALCOHOLIC BEVERAGES
- ALUMNI ACTIVITIES
- BAD DEBTS/ LOSSES
- DONATIONS
- FUNDRAISING
- PERSONAL EXPENSES
- STUDENT HOUSING AND STIPENDS
- IDLE FACILITIES
- INTEREST OF BAD DEBTS
- ENTERTAINMENT
- LOSSES ON OTHER GRANTS
- MEMBERSHIPS
- LOBBYING
- 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.