



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Tier I Cycle 3 Pipeline to Proposal Awards Application Guidelines

Published December 1, 2015



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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1.0 About These Guidelines

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

- [Pipeline to Proposal FAQs¹](#) cover common questions about PCORI, the Pipeline to Proposal 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 (p2p@pcori.org). PCORI will respond within three business days.
- For administrative, financial, or technical questions, please email p2p@pcori.org. PCORI will respond within three business days.

2.0 Programmatic Description and Guidelines

The PCORI Pipeline to Proposal Awards Initiative **supports the development of** patient-centered comparative effectiveness research (CER) **research ideas and proposals designed by partnerships of patients, caregivers, and other key stakeholders**. PCORI will award up to \$5.5 million during FY2016 as part of this initiative, also called Pipeline Awards. Pipeline Awards are **intended for those individuals or groups that are not usual applicants** for developing research questions, **particularly individuals and groups that have important ideas but don't have other opportunities to develop research ideas**. Any individual or group that meets the eligibility requirements and is focused on health-related topics that could become research ideas and align with the goals of the Pipeline Awards program is welcome to apply. Funding will support projects aimed at accelerating research proposal submissions, facilitating research results dissemination, and expanding the number of patients, stakeholders, and researchers able and ready to participate in patient-centered outcomes research (PCOR). Three funding tiers are awarded separately. Each tier has its own funding level and application requirements. **No research is funded by the Pipeline to Proposal Awards Initiative; the program supports only the development of research ideas and proposals** designed by partnerships of patients, caregivers, and other key stakeholders.

What makes these awards unique is that they are available to individual patients, stakeholders, and researchers and unofficial groups of patients, stakeholders, and researchers who are not "PCOR ready" for research funding. **These awards are for community engagement and capacity building at the local, state, and regional level**. PCORI's goal is to fund the development of research projects that answer a series of key questions from the patient perspective:

- What should I expect will happen to me?
- What are my options and what are the potential benefits and harms of those options?
- What can I do to improve the outcomes that are most important to me?
- How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?

¹ Available at: <http://www.pcori.org/sites/default/files/PCORI-Response-To-Questions-Submitted-for-Tier-1-Cycle-Pipeline-To-Proposal-Awards-111914.pdf>

The Pipeline to Proposal Awards Initiative aims to build a national community of patients, stakeholders, and researchers who have the expertise and passion to participate in patient-centered outcomes research, or PCOR, and to create partnerships within that community that lead to high-quality research proposals. The initiative's goals include:

- Successfully establish an infrastructure for patients, caregivers, and other stakeholders to increase CER information and engagement in research
- Strengthen relationships between researchers, patients, and stakeholders, particularly in communities that have been underrepresented in research
- Build capacity for researcher/non-researcher partnerships to create research questions and submit PCOR research proposals that can be considered for PCOR funding

The purpose of the Pipeline to Proposal Awards Initiative is to cultivate the development of proposals with sound scientific rigor and **robust patient engagement**. PCORI expects that Pipeline to Proposal projects will help individuals form new collaborations that can produce meaningful research proposals. **The emphasis in all three funding tiers is to actively integrate patients, caregivers, clinicians, and other healthcare stakeholders as members of the patient-centered outcomes research/comparative effectiveness research (PCOR/CER) process.** Applicants can be an individual or group of patients, stakeholders, or researchers focused on a particular health issue that can lead to a patient-centered comparative effectiveness research (CER) project. For Tiers I and II, **the specific comparative effectiveness research (CER) question does not need to be specified at the point of applying for funds.**

Tier I – Pre-Engagement/Community Projects: Up to \$15,000 for up to Nine-Month Project Term

- Tier I awards fund the building of a partnership and expansion of skills necessary to **develop a** patient-centered comparative effectiveness research (CER) **project**. The Tier I phase will generate a list of comparative effectiveness research (CER) **ideas** that address the health issue of interest to those in the partnership.
- Individuals or groups can receive this funding—no university, researcher, or incorporated entity is required in order to apply.
- **PCORI encourages those who are not usual candidates** for research funding to apply for Tier I. This program is intended to support those individuals and groups with critically important ideas who may not have other opportunities for funding. In order to qualify for Tier I funding, you must have demonstrated success in a past community-building project. The demonstrated success doesn't have to have been health-related. You need to explain how you engaged the community and formed partnerships to achieve your goal.
- **Tier I awards are not research awards**; the purpose of this funding is to build capacity and engage individual patients, stakeholders, researchers, and others who care about a particular health topic that can lead to a CER question—even if that question cannot yet be articulated.

- Building relationships and forming collaborative partnerships among patients, caregivers, researchers, and other stakeholders are critical components of Tier I awards.

Tier II – Partnership and Infrastructure Development Projects: Up to \$25,000 for up to 12-Month Term

- **Tier II awards are not research awards.**
- Tier II awards are **only** available for those who successfully participate in and complete a Tier I award. The purpose of funding for Tier II awards is to help Tier I partnerships mature, with the goal of refining the list of CER ideas to a single research question. The funds are to be used to strengthen the partnerships and further develop the infrastructure and governance developed during Tier I.

Tier III – Proposal Development Projects: Up to \$50,000 for up to 12-Month Term

- **Tier III awards are not research awards.**
- Tier III awards support the development of a health-related CER research question into a patient-centered research proposal. This funding is designed to advance research partnerships (those that are “almost there”) that could benefit from working with new partners to **draft** a strong patient engagement plan and a rigorous science **proposal**.
- Funding for Tier III is available for two types of applicants. The first type is well-established and mobilized groups that include at least a patient and a researcher partner; stakeholder partners are also strongly encouraged. Secondly, the Tier III awards are also for unsuccessful applicants to previous PCORI Funding Announcements, particularly those who were not funded and received recommendations from PCORI to strengthen the research partnership plan, and develop a solid patient and stakeholder engagement plan.
- By the completion of Tier III, applicants should have developed sound research models that integrate patients and stakeholders throughout the research process. It is our expectation that, upon successful completion of Tier III, the research team established will be able to apply for competitive traditional funding sources, such as a PCORI PFA or other non-PCORI patient-centered outcomes research. The ultimate output from Tier III is a well-vetted research proposal with a strong engagement component.

Additional information on the Pipeline to Proposal Awards, including a link to the application and a link to the projects PCORI funds through this program, can be found on the [PCORI Pipeline to Proposal²](#) web page.

3.0 Who Can Apply

Applications for Tier I awards may be submitted by individuals, consumer/patient organizations, clinician(s), researcher(s), or a combination of the above. Because we anticipate that most Tier I

² <http://www.pcori.org/content/pipeline-proposal-awards>
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awardees will be individuals or newly formed groups of people who are not organized as a nonprofit or a corporation, the Pipeline Award Program Offices (PAPOs) can also serve as fiscal agents—the distributors and managers of funding—to the Tier I awardees if needed, and will help to manage the funding coming to the award recipient, thus enabling funding for many individuals and groups that in the past were not eligible for funding.

We expect that many of the individuals or groups that receive Tier I Pipeline Awards will be just that—individual people or small groups of people that are not officially organized as a nonprofit or a corporation—so they will need a fiscal agent to help manage the award itself. Awardees can expect that the PAPOs will assist in developing community, creating infrastructure and strategic plans, and employing successful community capacity-building models to execute these awards, in accordance with the guidelines, expectations, and criteria for success set forth by PCORI.

For those who are applying from an organization, all US applicant organizations must be recognized by the Internal Revenue Service. Foreign organizations and nondomestic components of organizations based in the United States may apply, as long as there is demonstrable benefit to the US healthcare system, and US efforts in the area of patient-centered research can be clearly shown. Organizations may submit multiple applications for funding.

4.0 How to Apply

Follow the instructions provided in these guidelines and in the PCORI Pipeline to Proposal Awards Application System. All attached documents must be submitted as [PDF](#)³ files. Failure to follow these guidelines may result in removal of the application from the review process.

Step 1: Register

To apply for PCORI Pipeline to Proposal Awards funding, you must register in the PCORI Pipeline to Proposal Application System. Your first and last names, an email address, and a password are required for registration. The email entered will be your user name. Note that the PCORI Pipeline to Proposal Awards uses an online application system different from both PCORI's research funding announcements and Engagement Awards. Please contact us at p2p@pcori.org with questions regarding the registration process.

Step 2: Submit a Letter of Inquiry (LOI)

An LOI must be submitted *prior* to completion of a full proposal and must be completed through the PCORI Pipeline to Proposal Application System. See p. 11 for additional details. PCORI will meet on a regular basis to discuss submitted LOIs and will determine whether to deny or invite to submit a full

³ <http://office.microsoft.com/en-001/word-help/save-as-pdf-HA010064992.aspx>
PCORI Pipeline to Proposal Awards: Application
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proposal. Applicants will be notified via email of an approval/denial decision no later than 45 days after LOI submission deadline.

Step 3: Complete the Full Proposal

Full proposals may be submitted upon invitation only and must be completed through the PCORI Pipeline to Proposal Application System. If necessary, you may edit information submitted as part of the LOI in the full proposal.

Authorization

If an LOI or proposal is being submitted by an organization, the individual submitting the LOI and/or full proposal must be authorized by his or her organization to do so. Submissions **MUST** include this authorization.

5.0 When to Apply

The Pipeline to Proposal Awards follow a two-part submission process.

Letter of Inquiry: Applicants must submit an LOI by the application deadline. LOIs will be reviewed within 45 days of submission deadline.

Full Proposal: A full proposal, completed upon invitation only, should be submitted within 40 days of receiving the invitation and no later than the proposal submission deadline. Full proposals will be reviewed within 45 days of submission deadline.

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 Pipeline to Proposal Application System.

Application Checklist

(A) Letter of Inquiry (LOI)		Submission Method	Length/Limit
<input type="checkbox"/>	Contact 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 Description of how funds will be used Project Summary/abstract 		As noted 250 words 250 words
<input type="checkbox"/>	Authorization	Enter into online system	N/A
(B) Application		Submission Method	Length/Limit
<input type="checkbox"/>	Contact Information	Entered previously as part of the Letter of Inquiry; edit if needed (if not, leave blank).	As noted
<input type="checkbox"/>	Project Information	Some information entered previously as part of the Letter of Inquiry; edit if needed (if not, leave blank).	As noted
	<ul style="list-style-type: none"> Project Information Description of how funds will be used Project Summary/abstract 		250 words 250 words
<input type="checkbox"/>	Project Overview	Enter into online system	500 words
<input type="checkbox"/>	Background and Partnership Example	Enter into online system	500 words
<input type="checkbox"/>	Other Funding	Enter into online system	500 words
<input type="checkbox"/>	Pipeline to Proposal Workplan	Upload	5 pages
	Timeline	Upload	2 pages
<input type="checkbox"/>	Budget Details	Upload	500 words
<input type="checkbox"/>	Budget Justification	Upload	3 pages
<input type="checkbox"/>	Letters of Support	Combine and upload	As needed
<input type="checkbox"/>	Recent Articles/Evaluations	Combine and upload	As needed
<input type="checkbox"/>	Authorization	Enter into online system	N/A

(A) Letter of Inquiry

Applicants must register and log in to the [PCORI Pipeline to Proposal Application System](#)⁴ to create or continue an LOI. Once in the system, click the “Letter of Inquiry” link. You will be taken to the LOI form for completion. Required fields are marked with red asterisks. You must click the “Save Draft” button at the bottom of the LOI form in order to save your work. Drafts will be saved in the system for 21 days.

To Continue an LOI: Access saved work by hovering over the “Dashboard” tab on the top right of the main screen. Click the “My Submissions” link. You will be taken to the Dashboard, from which you may select open LOIs for editing and submission. Click the “Saved Drafts” tab on the top navigation to access your saved LOIs.

LOI Details:

Contact Information

Provide basic information about the Project Lead and Co-Lead (if applicable) and the primary and secondary organization (e.g., address), if applicable. The Contact Information section includes some basic information about the person or people applying and their affiliated organization(s) (if applicable). Be sure to answer this section completely.

For Tier I applications, the Project Lead is the primary person who will be doing the work on the project and will serve as the project’s lead point of contact with PCORI.

For Tier III applications, 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 the project’s lead point of contact with PCORI.

For both tiers, Project Leads can participate in other applications (from the same or other organizations) in a different role, such as co-lead or consultant.

Project Information

Provide a thorough description that allows PCORI to understand the project. Applicants invited to submit a full application will have an opportunity to add additional details. The following sections/questions make up the Project Information section of the LOI:

- Project Title
- Estimated Project Start and End Dates (All projects are expected to start on August 1, 2016)
- Total Funding Amount Requested and a brief explanation of how those funds will be used

⁴ Available at: <https://pcori.submittable.com/submit>

- Indication if you were a recipient of funding in a previous funding cycle
- Information regarding vulnerable/underserved populations, stakeholder communities, and disease(s)/condition(s) the project focuses on
- Indication of the geographic region in which your primary project activities occur
- A brief project summary/abstract that should not exceed 250 words. Use the following as guidance:
 - Describe the health issue that you want to learn about or study.
 - Describe the tasks and activities that will occur during the project period. You may want to list them in the order in which they will happen.
 - Be sure that the issue doesn't fall into an area that PCORI doesn't fund, like cost effectiveness or descriptive studies.

Authorization

If the LOI is being submitted by an organization, it must be submitted by an individual who is authorized by his or her organization to do so. Click the authorization checkbox to indicate authorization.

Save Draft Button

The "Save Draft" button allows you to save your LOI. You may log out and log back in at any time to continue working on your LOI. **Draft LOIs will be saved in the system for 21 days, after which time they will be deleted.**

Submission

Once your LOI is complete, click the "Submit" button at the bottom of the form. Incomplete required fields will be indicated throughout the form, in red. Once all required fields are completed, click "Submit." You will not be able to edit the LOI once it has been submitted. You may view your submitted LOIs by clicking on the "Dashboard" tab on the top right of the form, then by clicking the "My Submissions" link. Click on the title of the LOI to view your submission and for additional options to download and print the LOI.

(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. There are seven sections for the proposal, as follows:

Contact Information

Edit information you entered at the LOI stage, as needed. If you do not have edits, you may leave fields previously entered at the LOI stage blank.

Project Information

Edit information you entered at the LOI stage, as needed. If you do not have edits, you may leave fields previously entered at the LOI stage blank.

Provide additional information, as follows:

Project Overview

The Project Overview section of the application has five questions, as follows:

1. Describe who is on your team and what their role(s) will be.
2. Describe the health issue that you want to learn about or study.
3. Describe the key people and communities you plan to form connections with during the project period.
4. Describe the tasks and activities that will occur during the project period.
5. Explain any challenges you think you may face in carrying this project out and how you plan to get around those barriers.

Do not exceed 500 words for this section.

Background and Partnership Example

Provide an example of a time when you have helped to engage community or form partnerships to solve a problem. The example does not have to be health-related. Do not exceed 500 words for this question.

Budget

Describe how you plan to spend the award money. It may help to go back to the activities and tasks you listed in Question 4 in the Project Overview and describe what each of those will cost. Also include estimates for any travel and meeting expenses. **The total amount cannot exceed \$15,000.** Do not exceed 500 words for this question.

Other Funding

Describe if you are currently receiving any funding from other sources—not including money from your regular job or source of employment. We are interested in knowing whether you currently have funding from another award, grant, or contract that may have come from a community foundation, a private company like a pharmaceutical company, or a government source such as the National Institutes of Health, Agency for Healthcare Research and Quality (AHRQ), or a state agency. Please list this information, including the funding agency, the amount of funding, and the purpose of the funding. Do not exceed 500 words for this question.

Attachments

Upload documents by clicking the “Choose Files” button and following the system prompts. Documents should be formatted as PDFs.

Required and optional attachments are described below:

1. Pipeline to Proposal Workplan and Timeline

Upload the required templates. In this section, you will outline the activities and tasks expected to take place during the project period. Use the space below to identify dates for your milestones and supporting activities that you plan to conduct during the award period.

2. Budget Details

Upload the required template. Enter the expected costs associated with the activities and tasks included in the project workplan. Include all costs in the applicant worksheets.

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

A. Personnel Costs

- Provide a justification for salaries requested per person. Keep in mind that the intent of these awards is that partnerships are built. Budgets should demonstrate that that award funds are being spent on community engagement activities.
 - Not more than 50 percent of the award should go toward any one person’s salary
 - Not more than 60 percent of the budget should be for personnel costs
- *Allowable Costs:* If you are applying to this funding opportunity on behalf of an organization, 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.
- Salaries include wages earned by an employee, and eligible costs also include fringe benefits, including insurance and retirement plans. Note: Key Personnel include those who, if they left, would significantly impact the project.
- *Level of Effort:* Personnel contributing to a PCORI-funded Pipeline to Proposal project are expected to monitor their total percentage of 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 from the applicant organization who dedicate effort to the project should be listed on the personnel budget with their level of effort, even if they are not requesting salary support. Please list the base salary for such persons in the justification, using \$0 for base salary within the detailed budget.
- *Fringe Benefits:* These costs are calculated based on the institution’s own policy. As referenced above, there is no cap on the fringe benefits rate.

- *Personnel Costs:* In addition to noting the base salary for each scientific/technical staff member, you must note the base salary for each patient employee or stakeholder member of your project team, if these members are not accounted for in Section B: Consultant Costs.
- *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 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.

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 total cost of consultant(s) as well as names, expected number of hours, and hourly rate.
- For all consultant costs, provide computations for how applicants arrived at the specific number.
- Consultant costs are not included in the 60 percent cap for personnel costs.

C. Supply Costs

- Provide details and justify the need for specific supplies requested.
- Supplies are general-purpose 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 \$500 or more are considered equipment and cannot be accounted for under this category.
- 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 regional travel by an employee or other personnel directly related to and necessary for the project and within the limits explained below. Travel costs may include travel to meetings necessary to conduct tasks outlined in the workplan. Other guidelines to keep in mind are:

- Include the number of trips and a brief description of the trips. Include 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 for achieving programmatic objectives).
- Airline costs cannot exceed the customary standard commercial airfare (coach or equivalent) or the lowest commercial discount airfare.
- PAPO and PCORI review all travel costs for reasonableness.

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 travel costs or participation incentives for project subjects, publication costs, or service contracts.

F. Equipment Costs

- Provide details and justify the need for specific equipment requested.
- List each item of equipment and its cost.
- Equipment costs include tangible items with a cost of \$500 or more.
- Equipment costs must be approved by PCORI and must be reasonable and necessary for the project and not otherwise easily available or accessible at lower costs.
- In general, PCORI will allow equipment, when applicable, and only in the first year of the contract.

G. Indirect Costs

- Enter the amount for indirect costs, where applicable.
- 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 10 percent PCORI indirect cost cap.
- The PCORI indirect cost cap is 10 percent of the total direct costs.
- The Budget Template contains a tool to calculate the indirect costs.

3. Budget Justification

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. 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.

4. Professional Profiles/Biosketches

If you have NIH funding, please provide your NIH biosketch.

7.0 Additional Requirements

Awardees are required to comply with the following requirements:

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](#).⁵

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

The Department of Health and Human Services (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 (OCR).

Responsibility for decisions about applicability and implementation of the Privacy Rule resides with the Project Lead and his or her institution. [The OCR website](#)⁶ 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 at the [NIH website](#).⁷

⁵ Available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>

⁶ Available at <http://www.hhs.gov/ocr>

⁷ Available at <http://privacyruleandresearch.nih.gov/>

Contract Terms and Conditions of Award

The administrative and funding instruments used for funded projects are contracts, not grants. As a funding organization, PCORI retains the right to administer programmatic 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 milestones and deliverables at any time during the contract. Proposed milestones and deliverables should be presented in the application, but final milestones and deliverables will be negotiated in the post-award period before the beginning/activation of the funding period.

8.0 How Does PCORI Review and Score Pipeline to Proposal 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 reviewed to determine if it is a good programmatic fit. Both LOIs and full proposals will be scored based on the following criteria:

1. Program Fit: Does this fit the spirit of the Pipeline to Proposal Awards?
2. Project Plan and Timeline
3. Past Partnership or Community Engagement Experience
4. Budget/Cost Proposal

Please be mindful that Pipeline to Proposal projects must measure patient-centered outcomes and compare approaches to improving patient-centered outcomes with the intent to create a comparative clinical effectiveness research (CER) question. To reiterate, Pipeline to Proposal Awards are not research awards. This funding is for capacity building, community engagement, formation of partnerships, and other preparatory work. The activities taking place might include workshops, roundtables, conferences, meetings, and other information-sharing tasks.

Activities should **not** include:

- Conducting a small research study
- Conducting a pilot study
- Conducting a formal evaluation of a program, tool, or intervention
- Validating a program, tool, or intervention
- Gathering pilot data
- Activities requiring IRB approval or the informed consent of participants

Many applicants have been denied funding because they proposed to carry out activities that do not fit within the parameters of the Pipeline to Proposal program.

Examples of the types of activities that are **not** fundable through the Pipeline to Proposals are:

- Implementation or measurement of care delivery interventions
- Pilot projects
- Product or app development or improvement
- Recruitment for clinical trials
- Raising awareness for a given disease or health issue
- Standalone conferences or training activities that are not related to a broader effort to form a partnership and later build a PCOR proposal

While Pipeline to Proposal Awards do not fund research, successful awardees should ensure that their area of focus—the idea that they will eventually build a PCOR proposal around—does not fall outside of PCORI’s research funding programs.

PCORI research funding is **not** available for studies focused on:

- Cost effectiveness
- Efficacy (studies that ask “Does this work?” rather than “Which of these options works better?”)
- Causes of disease or descriptive studies
- Social determinants of health
- Development of clinical practice guidelines

See the PCORI [Pipeline to Proposal page](#)⁸ for additional details about the review process.

⁸ Available at <http://www.pcori.org/content/pipeline-proposal-awards>
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Appendix 1: Key Terms

Allowable Costs—A cost that is approved within the budget and is not otherwise disallowed under the PCORI Pipeline to Proposal 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.

Closeout—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.

Consultant—An individual hired to provide professional advice or services for a fee.

Contract—The legally binding document that PCORI uses to make awards for Pipeline to Proposal projects.

Employer Identification Number (EIN)—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.

Fringe Benefits—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—Costs not directly accountable to the project. Indirect costs include taxes, administration, personnel, and security costs. For Tier I Pipeline to Proposal Awards, indirect costs are limited to 10 percent.

Institutional Review Board (IRB)—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)—A notification to PCORI that an organization intends to apply. Submission of an LOI is a required prerequisite to submitting an application.

Patients—Individuals who have or have had the condition under study; it may include patient surrogates or caregivers as well. It does not necessarily mean, but does not exclude, patient advocates or patient navigators.

Patient-Centered Outcomes Research (PCOR)—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>.

PCORI Pipeline to Proposal Award Application System—PCORI’s Pipeline to Proposal Awards online application and management system, designed to facilitate the applicant’s submission of materials. The system can be found at <https://pcori.submittable.com/submit>.

Project Lead—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.

Professional Profile—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.*

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

Reasonable Costs—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—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—Includes 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.