Independent Tier III Pipeline to Proposal Awards
Application Guidelines

Published May 26, 2016
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.”
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 FAQs**: 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 aim 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 the following:

- Strengthen relationships between the partnership team, particularly in communities that have been underrepresented in research. The partnership team should include a researcher and at least one patient partner.
- Build capacity for community partnerships to create and refine research questions, and submit PCOR research proposals that can be considered for PCORI funding.
- Engage partnerships in the research process and development of dissemination and implementation plans.
- Successfully establish an infrastructure for patients, caregivers, and other stakeholders to increase comparative effectiveness research (CER) information and engagement in research, dissemination, and evaluation.

The awards are managed regionally through Pipeline Award Program Offices (PAPOs) that have been selected for the West, Midwest, South, and East Regions, as well as a National Office to assist with projects that extend beyond a single region. The PAPOs support and manage all tiers of the PCORI Pipeline to Proposal Initiative across the country. They serve as portfolio managers, supporters of programmatic work, and fiscal agents (if needed) in support of Pipeline awardees. The PAPOs will provide training—which is created by PCORI—and technical assistance to the awardees and will have regular communication with the awardees.

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.

---

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](http://www.pcori.org/sites/default/files/PCORI-Response-To-Questions-Submitted-for-Tier-1-Cycle-Pipeline-To-Proposal-Awards-111914.pdf)

PCORI Pipeline to Proposal Awards: Application Guidelines
in accordance with the guidelines, expectations, and criteria for success set forth by PCORI. The PAPOs work collaboratively across regions with other PAPOs to solve problems as the projects progress, and expand interest/involvement in PCOR across the nation.

Through this funding program, patients, other stakeholders, and researchers will gain a better understanding of the history and culture of patient engagement, participatory research, and patient-centered outcomes research. They will be able to build capacity, form important relationships, and eventually develop a patient-centered research proposal to study an issue that is important to them.

This funding announcement is for an Independent Tier III opportunity.

- **Independent Tier III** – This funding mechanism will increase the cadre of PCOR-ready research teams. This opportunity is targeted at those applicants who are a part of a well-established partnership, including at least one patient and one researcher. The researcher should have a track record of successful research and have already identified a research question. These applicants are not appropriate for the standard progression through established the pipeline. Instead, they can enter the pipeline farther along the continuum.

  Purpose of Funding – Proposal development, targeting advanced potential research partnerships (those who are “almost there”) that could benefit from working with awardee partners to draft a strong patient engagement plan and enhance a rigorous science proposal.

  Other Pipeline to Proposal Award opportunities include progressive Tiers I, II, and III, which build upon one another and are explained below.

  **Tier I – Pre-Engagement/Community Projects**
  
  Purpose of Funding – Building of the community and capacity necessary to later develop a patient-centered CER project addressing the issue of interest to the awardee.

  **Tier II – Partnership and Infrastructure Development Projects**
  
  Purpose of Funding – Maturation of research partnerships with the goal of receiving PCORI or other CER project funding. The funds are to be used to strengthen the partnerships and further develop the infrastructure and governance structures laid out during Tier I and to lay groundwork for the ultimate drafting of a patient-centered CER proposal.

  Tier II awards are available for only those who successfully participate in and complete a Tier I award.
Tier III – Proposal Development Projects
Purpose of Funding – Proposal development, targeting advanced potential research partnerships (those who are “almost there”) that could benefit from working with awardee partners to draft a strong engagement plan and a rigorous science proposal.

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 Proposal\(^2\) web page.

3.0 Who Can Apply
Applications for Independent Tier III awards may be submitted by a research partnership that includes at least a patient and a researcher partner. Special focus will be given to the following:

- Those who have submitted proposals to PCORI and were not funded but received recommendations from PCORI to strengthen the Engagement Plan. Caveat: even if these applicants strengthened the plan, this does not guarantee funding.

- Those whose topics of interest are aligned with PCORI science funding priorities: Assessment of Prevention, Diagnosis, and Treatment Options; Improving Healthcare Systems; Communication and Dissemination Research; Addressing Disparities; Accelerating Patient-Centered Outcomes Research; and Methodological Research. More information on our science funding priorities can be found here.\(^3\)

- Those whose partners or populations of interest are aligned with populations that are typically underrepresented in research.

For those who are applying from an organization, all US applicant organizations must be recognized by the Internal Revenue Service. Organizations may submit multiple applications for funding.

---

\(^2\) Available at: [http://www.pcori.org/content/pipeline-proposal-awards](http://www.pcori.org/content/pipeline-proposal-awards)

\(^3\) Available at: [http://www.pcori.org/research-results/research-we-support/national-priorities-and-research-agenda](http://www.pcori.org/research-results/research-we-support/national-priorities-and-research-agenda)

PCORI Pipeline to Proposal Awards: Application Guidelines
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 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 page 10 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 proposal. Applicants will be notified via email of an approval/denial decision no later than 45 days after the 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.

---

PCORI Pipeline to Proposal Awards: Application Guidelines
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 that 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.
<table>
<thead>
<tr>
<th>(A) Letter of Inquiry (LOI)</th>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Contact Information</td>
<td>Enter into online system</td>
<td>As noted</td>
</tr>
<tr>
<td>□ Project Information</td>
<td>Enter into online system</td>
<td>As noted</td>
</tr>
<tr>
<td>• Project Information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Description of how funds will be used</td>
<td></td>
<td>250 words</td>
</tr>
<tr>
<td>• Project Summary/abstract</td>
<td></td>
<td>250 words</td>
</tr>
<tr>
<td>□ Authorization</td>
<td>Enter into online system</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(B) Application</th>
<th>Submission Method</th>
<th>Length/Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Contact Information</td>
<td>Entered previously as part of the LOI; edit if needed (if not, leave blank). Some information entered previously as part of the LOI; edit if needed (if not, leave blank).</td>
<td>As noted</td>
</tr>
<tr>
<td>□ Project Information</td>
<td></td>
<td>As noted</td>
</tr>
<tr>
<td>• Project Information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Description of how funds will be used</td>
<td></td>
<td>250 words</td>
</tr>
<tr>
<td>• Project Summary/abstract</td>
<td></td>
<td>250 words</td>
</tr>
<tr>
<td>□ Project Overview</td>
<td>Enter into online system</td>
<td>500 words per section</td>
</tr>
<tr>
<td>□ Background and Partnership Example</td>
<td>Enter into online system</td>
<td>500 words</td>
</tr>
<tr>
<td>□ Other Funding</td>
<td>Enter into online system</td>
<td>500 words</td>
</tr>
<tr>
<td>□ Pipeline to Proposal Workplan</td>
<td>Upload</td>
<td>5 pages</td>
</tr>
<tr>
<td>Timeline</td>
<td>Upload</td>
<td>2 pages</td>
</tr>
<tr>
<td>□ Budget Details</td>
<td>Upload</td>
<td>500 words</td>
</tr>
<tr>
<td>□ Budget Justification</td>
<td>Upload</td>
<td>3 pages</td>
</tr>
<tr>
<td>□ Letters of Support</td>
<td>Combine and upload</td>
<td>As needed</td>
</tr>
<tr>
<td>□ Recent Articles/Evaluations</td>
<td>Combine and upload</td>
<td>As needed</td>
</tr>
<tr>
<td>□ Authorization</td>
<td>Enter into online system</td>
<td>N/A</td>
</tr>
</tbody>
</table>
(A) Letter of Inquiry

Applicants must register and log in to the PCORI Pipeline to Proposal Application System\(^5\) 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 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 Independent Tier III 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. Applications for Independent Tier III awards may be submitted by a research partnership that includes at least a patient and a researcher partner.

Project leads can participate in other applications (from the same or other organizations) in a different role, such as co-lead or consultant. It is recommended that a minimum of 15 percent Full Time Equivalent (FTE) is dedicated from the project lead.

The project co-lead is involved with the project lead in the development or execution of the project. The co-lead (collaborator) can be an individual or the co-lead can be employed by or affiliated with the applicant/recipient organization or another organization participating in the project under a consortium agreement. A co-lead typically devotes a specified percentage of time to the project and is considered senior/key personnel.

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

\(^5\) Available at: [https://pcori.submittable.com/submit](https://pcori.submittable.com/submit)

PCORI Pipeline to Proposal Awards: Application Guidelines
Provide a thorough description that allows PCORI to understand the project. Applicants invited to submit a full application will have an opportunity to supply 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 February 1, 2017.)
- Total funding amount requested and a brief explanation of how those funds will be used
- Indication if you were a recipient of funding in a previous Pipeline to Proposal funding cycle or other PCORI funding
- 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 intend to learn about or study.
  - Share the already developed CER question.
  - 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 occur.
  - Why do you think engagement is important to the proposed project and its success?
  - How will each of the partners contribute to the development and implementation of the project?
  - How did each of the partners contribute to the submission of this LOI?
  - 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, each section has a 500 word limit:

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.

Activities within the funding period shall include:

- Report or presentation to community about CER question, current research being conducted by the research team, and future proposals
- Finalized and thorough governance document that describes how all partners engage and have equal contribution in decision-making and strategic planning
• Completion of PCORI-required training, which will include such topics as patient engagement, research methodology training, monthly webinars with PAPOs, patient engagement technical assistance, and mentoring calls that demonstrate movement toward partnership development, including identifying challenges and obstacles that PAPOs and mentors can assist with
• Completion of quarterly reports, mid-project report, regular technical assistance calls, and other/additional reporting as required by PCORI
• List of ideas developed by all partners that will drive changes, additions, and improvements in the team’s proposed research project (http://www.pcori.org/content/patient-centered-comparative-effectiveness-research)
• Workplan for a full PCORI application that describes how the partnership will work together to develop a patient-centered research proposal
• LOI submitted for a PCORI broad funding announcement
• Draft proposal for a PCORI Funding Announcement (PFA)

Background and Partnership Example
Provide an example of a time when you have helped to engage a community or formed partnerships to solve a problem. The example does not have to be health-related. Do not exceed 500 words for this answer.

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 $50,000. Do not exceed 500 words for this answer.

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 answer.

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 as well as 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. Please note that more than 50 percent of the award should not go toward any one person’s salary; as these are community engagement awards, it is expected that at least 25 percent of this award should be shared with your partners.

- 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. Key personnel are those participants whose contribution is so significant that their absence, should they leave, would significantly impact the project.

- Level of Effort: It is recommended that at least 15 percent FTE of the project lead should be directly billed to this project. Personnel contributing to a PCORI-funded Pipeline to Proposal project are expected to monitor their total percentage effort across all funding (PCORI or others), and it 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 employee patient 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. For those applying from organizations, payments to non-employee patient and stakeholder representatives are included. For those individuals applying, payments to researchers and collaborative partners 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.

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 include the following:
  - 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.
- Please note that PCORI has the right to request that you return to PCORI any equipment over $500 at the end of your project.

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 for the Pipeline to Proposal program 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.
Authorization
If applying on behalf of an organization, the application 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 proposal. You may log out and log back in at any time to continue working. Draft full proposals will be saved in the system for 21 days, after which time they will be deleted.

Submission
Once your full proposal is complete, click the “Submit” button at the bottom of the form. Incomplete required fields will be indicated in red throughout the form. Once all required fields are completed, click “Submit.” You will not be able to edit the full proposal once it has been submitted. You may view your submitted LOIs and full proposals 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/full proposal to view your submission and for additional options to download and print the submission(s).

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
If awarded, the activities covered by PCORI funding must not be research, but regardless we must advise you that PCORI requires all applicants to adhere to NIH policy on education on 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
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)

---

6 Available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html
PCORI Pipeline to Proposal Awards: Application Guidelines 17
of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the HHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the project lead and his or her institution. The OCR website 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.

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 LOIs and Applications?

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

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.

Available at http://www.hhs.gov/ocr
Available at http://privacyruleandresearch.nih.gov/.
PCORI Pipeline to Proposal Awards: Application Guidelines
Activities should not include the following:

- 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.

The following are examples of the types of activities that are not fundable through the Pipeline to Proposals:

- 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
- Stand-alone conferences or training activities that are not related to a broader effort to form a partnership and later build a PCOR proposal

Although 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 the following:

- 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 for additional details about the review process.

---

9 Available at http://www.pcori.org/content/pipeline-proposal-awards
PCORI Pipeline to Proposal Awards: Application Guidelines
Appendix 1: Key Terms

Allowable Costs—Costs that are approved within the budget and are 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.

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.

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

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.

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.