



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

## **Pipeline to Proposal Awards Applicant Resources**

### **RESPONSE TO QUESTIONS SUBMITTED FOR TIER I CYCLE 1 PIPELINE TO PROPOSAL AWARDS**

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## **About PCORI**

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

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

## An Applicant Resource: Response to Questions Submitted for Tier I Cycle 1 Pipeline to Proposal Awards

**Q1. I am an Assistant Research Professor at an academic research center and I wanted to inquire into your Tier 1 Pipeline to Proposal Awards. A colleague of mine attended the PCORI workshop held in ABQ last year where the Pipeline applications were discussed. I wanted to confirm information he received at that meeting in that he was told that applications from large universities are not encouraged as PCORI wants grass-root organizations to apply for the pipeline applications.**

A1. Affiliation with a university does not disqualify an applicant. When reviewing this funding opportunity, be sure to explore carefully whether Tier II or III, which will be available in 2014, may better suit your goals. The majority of this funding is intended to benefit individuals or groups who are not usual candidates for research funding. These dollars are targeted to those individuals and groups with critically important ideas who may not have other opportunities for research funding. Any individual or group of patients, stakeholders, or researchers that meets the eligibility requirements and has research ideas that align with the goals of the Pipeline to Proposal Tier I Awards is welcome to apply.

**Q2. How is a PCORI contract different than a grant? Are there different considerations/requirements?**

A2. Yes—per PCORI’s enabling legislation, it is restricted to funding through contracts. The primary difference is that contracts require deliverables and/or milestones. In most cases, payments are tied to the successful completion of deliverables (i.e., progress on your project).

**Q3. These pipeline awards are a wonderful way to allow individuals and small groups to be engaged in the capacity and community building process. But once these 3 Tiers are achieved, does the application for the main PCORI funding need to go through “usual” channels of a major healthcare entity or educational institution? If so, how will PCORI ensure that we, as individuals/original stakeholders, remain a part of the funded research project after laying all of the groundwork?**

A3. It is our expectation that, upon successful completion of Tier III, the research team established will be able to apply through competitive traditional funding sources, such as a PCORI PFA or other non-PCORI patient-centered outcomes research award. Recall that all funded projects at PCORI must

### About This Document

This document answers questions that were asked for the Tier I Cycle 1 funding opportunity.

Questions are listed as they were received. Language that includes personal or organization identifiers has been redacted. General terms (underlined) have been substituted to protect privacy.

Additional questions may be submitted up to December 10th at [p2p@pcori.org](mailto:p2p@pcori.org).

The Patient-Centered Outcomes Research Institute (PCORI) is an independent organization created to help people make informed healthcare decisions.

**1828 L St., NW, Suite 900  
Washington, DC 20036  
Phone: (202) 827-7700  
Fax: (202) 355-9558  
Email: [ea@pcori.org](mailto:ea@pcori.org)**

**Follow us on Twitter: @PCORI**



demonstrate patient and other stakeholder engagement in the research proposal, and the ultimate output from Tier III is a well-vetted research proposal with a strong engagement component.

The purpose of the Pipeline to Proposals initiative is to cultivate proposals with sound scientific rigor and robust patient engagement. By the completion of Tier 3, applicants should have developed sound research models that integrate patients and stakeholders throughout the research process. Accordingly, all applications that are submitted for PCORI funding announcements must come from an organization recognized by the IRS, and can include academic research, private sector research, or study-conducting entities. PCORI expects the Pipeline to Proposals project will help individuals partner or form new organizations that can produce meaningful research projects.

**Q4. If an individual gets funding and it goes through a Pipeline Award Program Office (PAPO), then when applying for a full PCORI grant, would that also be done through this PAPO, or would it have to go through the academic or healthcare entity?**

A4. No, PAPOs are involved only in the management of the Pipeline contracts. If an applicant has completed a Tier III Pipeline Award and is ready to apply for a research contract (known as a PFA), that applicant will apply directly to PCORI.

**Q5. I would like to learn more about one of the specifications in the grant information for the "Pipeline to Proposal" awards that states the grants are *"targeted to those who are not eligible or equipped to apply for funding from most other research funding sources, and the approved use of these funds is limited to community and capacity building."* Can you please give some specifics about what "most other research funding sources" are? We feel we would qualify for the award but want to be sure before we get involved in the process.**

A5. 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 should be used for community engagement and capacity building at the local, state, or regional level. Because this is a competitive funding process, PCORI cannot advise you on whether or not your particular application is a good fit.

**Q6. If we are a group applying for the Tier I opportunity, the "group" be homogenous (IE a group of patients, a group of researchers, OR a group of clinicians), or may a small group of diverse stakeholders seek out the opportunity to increase the reach, diversity, and capacity of the existing group?**

A6. Yes, an applicant can be a group that includes diverse stakeholders, or a group that includes only patients, only stakeholders, or only researchers. Applicants may also be individual patients, stakeholders, or researchers.

**Q7. Is there a waiting period for an unsuccessful applicant to apply again?**

A7. An unsuccessful applicant would have to wait until the next call for proposals in the region for which they are located.

**Q8. Can the Tier 1 proposal focus on health behavior change as an outcome among a patient population? For instance, smoking cessation or dietary modification**

A8. Because the funding awarded through the Pipeline to Proposal Awards is issued through a competitive RFP, PCORI cannot advise you whether or not the specific health questions of individual applicants would be a good fit for a Tier I Award.

**Q9. What is the evidence of partnership that PCORI looks for?**

A9. For Tier I, neither letters of support nor memoranda of agreement are required. It is at this stage that awardees are expected to begin developing their partnerships. In Tier II, awardees should continue to enhance those partnerships. Applicants are asked to identify their partnership team—as in whom they anticipate developing partnerships with or with whom they have already developed partnerships. Your proposal should explain what your proposed partnership would accomplish.

Applicants may want to consider how stakeholders who are affected by the health issue will be informed of project efforts. Applicants should also state whether or not there is support, or a plan to get buy-in, from community partners and other stakeholders.

**Q10. In tier 1, can this be a mixture where it's led by a researcher who wants to build a relationship with patients in the community?**

A10. Yes, in Tier I, the partnership team can be led by a researcher who is interested in building a relationship with patients in a community.

**Q11. Please further define "researchers not already connected to major funding opportunities." Does this mean a researcher with NIH funding for other types of research at a well-known academic center would probably be less likely to be funded?**

A11. Neither past NIH funding nor affiliation with an academic center disqualifies an applicant. When reviewing this funding opportunity, be sure to explore carefully whether Tier II or III, which will be available in 2014, may better suit your goals. This funding is intended for those individuals or groups who are not usual candidates for research funding. These dollars are targeted at those individuals and groups with critically important ideas who may not have other opportunities for research funding. Any individual or group of patients, stakeholders, or researchers who meets the eligibility requirements and who has research ideas that align with the goals of the Pipeline to Proposal Tier I Awards is welcome to apply.

**Q12. Are the costs of attending PCORI training paid for by PCORI? Or does it need to be in the grant app budget?**

A12. PCORI will require that all Tier I awardees undergo PCORI awardee training that is facilitated through a Pipeline Award Program Office. Each PAPO will provide training, contract administration, and any other technical assistance the awardee requires. Because PCORI encourages web-based training, there are no expected additional costs for training. However, in the RFP, applicants are reminded that they should include travel costs for a convening of all Tier I awardees, where awardees are expected to share their project experiences.

**Q13. As a research clinician who focuses on family violence, parenting, and parental mental health, what opportunities are there for PCORI funding if my research--while it has health and medical implications--focuses on behavioral health and behavioral interventions. I do look at health outcomes of family violence, but I am not doing a health intervention.**

A13. Because this funding is issued through a competitive RFP, PCORI cannot advise you whether or not the specific health questions of individual applicants would be a good fit for a Tier I Award...

Please note that PCORI funds patient-centered clinical comparative effectiveness research, so ideas and topics described in Tier I proposals must be capable of conversion into a patient-centered clinical comparative effectiveness research question by the Tier III stage.

**Q14. We are getting funding to do a survey that will collect information which ultimately will provide a platform to create research based on those findings. Can we include this survey in our proposal, or because it is funded through a pharma company would it be disqualified?**

A14. Applicants are asked to inform us if they are currently receiving any funding from other sources. However, funding through a pharmaceutical company would not disqualify an applicant. PCORI will consider all cost proposals and budget models. PCORI will evaluate budgets and make award decisions for those applications that clearly tie the proposed costs to the project plan. Please note that PCORI funds patient-centered clinical comparative effectiveness research, so ideas and topics described in Tier I proposals must be capable of conversion into a patient-centered clinical comparative effectiveness research question by the Tier III stage.

**Q15. What's a CER question?**

A15. CER refers to Comparative Effectiveness Research, which is designed to inform healthcare decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options. The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care, for example, a type of healthcare research that compares the results of one approach for managing a disease to the results of other approaches. Comparative effectiveness usually compares two or more types of treatment, such as different drugs, for the same disease. Comparative effectiveness also can compare types of surgery or other kinds of medical procedures and tests.

**Q16. What is the difference between describing the "partnership group" and the "key stakeholders that you want to connect with"?**

A16. Applicants are asked to identify their proposal partnership team—as in whom they anticipate developing partnerships with or with whom they have already developed partnerships. The proposal should explain what the proposed partnership would accomplish.

In the Team and Environment review criteria, the applicant is asked to describe how “key stakeholders” affected by the health issue are going to be informed about the project efforts. PCORI generally defines “stakeholders” as all of those individuals critical to the healthcare system, including patients, caregivers, patient/caregiver advocacy organizations, and “other stakeholders,” including clinicians, hospitals/health systems, payers, purchasers, industry, policy makers, researchers, and training institutions.

**Q18. Who will be screening these applications? Doctors? Clerks? It would be useful to know to whom the proposal is being directed.**

A18. The review team will be a panel of researchers, patients, and stakeholder reviewers.

**Q19. Does the grant have to be for a health or medical issue? Or can I research something around improving the patient experience?**

A19. Because this funding is issued through a competitive RFP, PCORI cannot advise you whether or not the specific health questions of individual applicants would be a good fit for a Tier I Award. However, please see the RFP and Training materials for more information about the types of projects PCORI funds.

**Q20. Do applicants need to have an established researcher as a PI for their study? Or, can clinicians and/or patients collectively serve as investigators.**

A20. No. Tier I Awards are not research awards; the purpose of this funding is to build capacity and engage community. Funding for Tier 1 Awards is available to an individual patient, stakeholder, or researcher, or group of patients, stakeholders, or researchers, oriented around a particular issue that can ultimately lead to a CER question—even if that question cannot yet be articulated. This funding is targeted to those who are not PCOR ready or equipped to apply for funding from other typical funding sources, and the approved use of these funds is limited specifically to community and capacity building.

**Q21. How do we discern if our research question is unique? Is there a clearing house or publication that contains patient centered research we should consult in order to choose a unique and innovative research question?**

A21. Because this is a competitive funding announcement, we cannot advise an individual applicant on the merit of a particular topic or research idea. However, to determine if your question is unique, you may want to review the relevant medical literature or consult [clinicaltrials.gov](http://clinicaltrials.gov).

**Q22. How will you fund individuals or organizations that don't have an official IRS designation? What will the funding mechanism be?**

A22. At the Tier I Pipeline Award level, Pipeline Award Program Offices (PAPOs) will serve as “fiscal agents” 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.

**Q23. If we have a program/project that will ultimately cost more than the \$15,000 award, can the Tier I pay for a portion of the project/program. For instance we are planning on having a first stakeholders meeting and then developing a web-based communication portal for stakeholders to work through the issues that are defined at the meeting.**

A23. PCORI will consider all cost proposals and budget models. PCORI will evaluate budgets and make award decisions for those applications that clearly tie the proposed costs to the project plan.

**Q24. Is there a page limit for Tier application?**

A24. The application fields have a word limit. We ask that all applicants adhere to the posted word limits when completing their applications.

**Q25. Will an established researcher eventually be required? i.e. should clinicians begin recruiting an established researcher? Or, can those clinicians serve as researchers for PCORI funding? (Sorry to have to ask this further question. I just want to be sure we know where we're headed if we pursue PCORI funding). Thank you**

A25. No. Tier I Awards are not research awards; the purpose of this funding is to build capacity and engage community. Funding for Tier 1 Awards is available to an individual patient, stakeholder, or researcher, or group of patients, stakeholders, or researchers, oriented around a particular issue that can ultimately lead to a CER question—even if that question cannot yet be articulated. This funding is targeted to those who are not eligible or equipped to apply for funding from other typical funding sources, and the approved use of these funds is limited specifically to community and capacity building.

**Q26. What will the Tier I awardee training consist of?**

A26. Awardees and partners will undergo science training from which they should develop an understanding of PCOR and “research done differently” via PCORI-created training. PCORI Awardee training will also include information about how to engage patients and stakeholders in research projects.

**Q27. Funding: Is the funding provided up-front or in installments? Will the full amount of the award be granted if milestones can be achieved in less than the 9 month timeframe?**

A27. Funding is provided as installments. Yes, the full amount of the award can be provided if milestones can be achieved in less than the 9-month timeframe.

**Q28. Do you expect at the end of the award, the group must identify a health issue that is ready for CER?**

A28. At the end of the Tier I project period, assuming awardees have successfully completed the tasks of the Tier I award, we anticipate that they will develop a project plan for a Tier II Award and have a general notion of the ultimate CER area in which they will focus.

**Q29. If we have are a university program looking to partner with a patient group, can the university program submit the proposal or should the patient group do that?**

A29. Both the university and the patient group are eligible to apply.

**Q30. Will feedback be provided to applications that are not funded to help with revision for future applications?**

A30. Feedback will be given to those unsuccessful applicants who request it.

**Q31. What/who are Pipeline Award Program Offices?**

A31. To better reach patient, stakeholder, and research groups around the country, PCORI will work with groups called “Pipeline Award Program Offices” (PAPOs) that are designated by PCORI and have experience with funding community engagement and capacity-building efforts. The PAPOs will also be well versed in PCORI practices and the principles of patient-centered research. The PAPOs will provide training—which is created by PCORI—and technical assistance to the awardees and will have regular communication with the awardees. At the Tier I Pipeline Award level, the PAPOs will also serve as “fiscal agents” 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.

**Q32. For the Tier 1 Grant application, we need to submit a request for waiver of indirect costs to our OSP, however can avoid this process if there is a published indirect rate for PCORI. I know for the larger grants it is 40%, but was hoping something was published for the pipeline to proposal grants.**

A32. We have set a limit on indirect goals for this particular funding call at 10%. We review budgets very carefully and are focused primarily on reviewing the budgets to ensure that the majority of the resources are being directed to the actual activities of the project, rather than indirect costs that do not support project goals. The budget for these awards is \$15,000 total, including any indirect costs. Considering this is a small-dollar, nontraditional funding initiative with an emphasis on applying dollars to the program, we will be especially interested in reading through the rationale for the proposed indirect rates of all of the proposals.

**Q33. Are participant incentives (gift cards, meals, etc.) allowable in the budget proposal?**

A33. PCORI will consider all cost proposals and budget models. This is a unique funding opportunity geared to provide an introduction to patient-centered outcomes research. Some awardees may choose to use all of the funding to support staff expenditures, while other awardees may propose to subcontract or distribute the funding to research partners. PCORI will evaluate budgets and make award decisions for those applications that clearly tie the proposed costs to the project plan.