

**QUESTIONS AND ANSWERS:****Patient-Centered Outcomes Research Institute Request for Proposals (RFPs) on:**

**Expert Stakeholder Interviews to Identify Evidence for Eliciting the Patient's Perspective in Patient-Centered Outcome Research (Interviews)**

**Review and Synthesis of Evidence for Eliciting the Patient's Perspective in Patient-Centered Outcome Research (Literature Review)**

---

**1) *Would PCORI be interested in having an academic medical center as the venue to host the stakeholder interviews?***

PCORI has no preference of venue but will consider the recommendations and reasons for why a particular venue would be best suited to fulfill the project requirements.

**2) *What is the payment schedule for the award money? i.e. will there be one payment upon completion of project or will there be a partial upfront payment to offset costs of staging interviews followed by the rest of the award payment upon successful completion of project?***

PCORI hopes to negotiate a mutually agreeable staged payment process with the successful applicant. It will include an initial installment with subsequent installments payable upon completion of specific milestones.

**3) *Pages 2 and 3 of the proposal, Section 'Eligibility' lists the types of applicants that are eligible to apply indicating the solicitation is full and open. However, on page 4 of the proposal under the Introduction to the Statement of Work states "We are soliciting applications from individuals and institutions that have done work in this area.....More than one institution or individual can co-apply..." Question: Please clarify whether all the entities listed under Eligibility are in fact eligible, or whether this solicitation is open only to individuals and institutions?***

Yes, eligibility extends to all entities listed. Past performance is an important evaluation criterion with a weighting of 25 points (out of a total of 100), but prior experience is not an absolute requirement. Partnering between institutions is encouraged to bolster the prior experience of the applicant's research team.

**4) *Is this RFA designed to be submitted primarily by a single individual (or with one Co-Investigator) or if a larger team of investigators could also be seen as appropriate?***

PCORI places no requirements or specific expectations on the size of the research team.

**5) Is a T&M budget and T&M contract acceptable to the PCORI? Is a FFP budget acceptable to the PCORI?**

Contracts will be awarded on a Firm Fixed Price basis.

**6) To develop our best proposal, we would appreciate knowing whether PCORI anticipates that there will be an opportunity for the contractor awarded this project and the one awarded the companion review of the literature contract to share preliminary findings. This question is prompted partly by the instruction on page 7 of the RFP, under Project Management Requirements, to include in status reports “specifics of the literature search and landscape scans.” We think that the reference to literature search refers to the other contract’s activities, but would like this confirmed, and also believe that preliminary exchanges between the two projects could strengthen both final reports.**

PCORI will be supportive of and facilitate communication between the recipients of the two awards, assuming that both parties are willing to collaborate.

**7) Will PCORI funding opportunities be managed like grants or like task orders?**

This project will be managed as a contract and tasks outlined in the proposal will be expected to be completed under the terms of the contract. In the future, there will be a mix of funding opportunities from PCORI. Some will involve RFP’s that lead to contracts (with a specific scope of work, tasks, and milestone-driven payments); others will involve PCORI Funding Announcements (PFA) that will essentially be grants.

**8) Is it disadvantageous if the responding teams come from a certain disease sector e.g. cancer with experience relevant to the RFPS largely conducted within that field or do teams that have members from different disease sectors say heart, endocrine etc. advantaged more in this process?**

This is for the potential contractor to judge, but in general, multidisciplinary teams may have a broader perspective on salient issues.

**9) PCORI’s authorizing legislation, Public Law 111-148, at Section 1181 (d) (2) (B) “Contracts for the Management of Funding and Conduct of Research” provides for the Institute to enter into contracts, but does not provide grant making authority.**

**a. Could PCORI please explain the origin and the rationale for a 40% cap on indirect costs? (p.2). The Institute is issuing procurements for very specific requirements, but not willing to pay the full costs of conducting the procured work. This is highly unusual and is a very onerous challenge for many institutions. Would PCORI please reconsider this policy given it will likely exclude many qualified contractors?**

PCORI weighed a broad range of considerations in making a decision on its indirect costs policy. PCORI is not a federal agency and is therefore not bound by the federally negotiated rate. PCORI expects a broader range of types of institutional applicants than many federal contracts or grants would receive, bringing a broader range of institutional expectations and practices. PCORI does not fund the types of research (e.g., laboratory science) that tend to account for substantial indirect costs estimates in some institutions. We believe this to be a fair and reasonable indirect rate, higher than that of many non-federal agencies that fund research; different from and modestly lower than most federally negotiated rates.

**b. *Why does the NIH salary cap apply when PCORI is an independent foundation? (p.2) Why are you asking contractors to subsidize the work you are procuring?***

PCORI believes that the NIH salary cap represents a fair upper bound on salaries for this type of research.

**c. *What is the legal contractual basis for requiring work after the expiration of the contract period, as in P7 – “a final report is due 90 days following the end of the funding period”?***

The RFP is confusing in this regard. The timing for the submission of the final, lay report will be negotiated and set forth in the contract. If the lay (non-technical) report is to be delivered at some point (no more than 90 days) after the full final report, 10% of total payment will be deferred until the lay report is produced.

**d. *How does the contractor get paid for costs incurred after the termination of the contract?***

See answer to “9 c” above.

**e. *Could the period of performance be extended to cover the costs of preparing the final report?***

Yes. See answer to “9 c” above.

**10) *On page 11 you ask asking contractors to commit to executing a contract by a set date. Please provide a copy of the contract terms we are being asked to commit to sight unseen.***

We agree with the questioner that execution of a contract can only occur after negotiations reach a mutual agreement, and it is not possible to begin negotiations until proposed terms are shared. THIS REQUIREMENT HAS THEREFORE BEEN REMOVED.

**11) *Use of Contracted Work (p.9):***

**a. *For material published only in part, what protections are available to the original authors of the entire report that their work “published in part” is not taken out of context, misrepresented, or misinterpreted?***

This concern can be negotiated in the contract. PCORI intends to fully acknowledge authors of reports that are incorporated, in whole or in part, into the Methodology Report. As part of the acknowledgement process, PCORI would share with such authors the verbatim portions of their reports that will be included in advance of publication. Thus, authors will have the opportunity to comment on and discuss any perceived misstatements.

**b. *What is meant by contracted authors are able to publish “other paper(s) derived from work conducted under the contract...”***

In conducting the interviews, or conducting the literature review, the authors may consider secondary hypotheses or research questions that are not directly related to the report, and they are free to publish papers on these questions.

**c. *Does that mean that data collected cannot be reported at all, or simply that the original report needs to be cited?***

In such reports that pursue other research questions, the original report should be cited if appropriate. For example, findings from the Methodology Report may be appropriately cited in the introduction or discussion sections of an “other paper”. It is also possible that aspects of the study methods from the Report could be cited rather than repeated in the “other paper.”

**d. *Does it mean that findings and conclusions in a final report cannot be used, or simply that they can be cited?***

See response to c. above.

**e. *What does “PCORI representatives” (as co-authors) mean?***

“PCORI representatives” refers to members of PCORI’s Board of Governors, Methodology Committee or staff, all of whom are subject to PCORI scientific publication policies.

**f. *How long would such review and approval by PCORI take, and who administers such review and approval?***

The maximum allowable time for review has not been finalized, but it is expected and intended to be quick – one week or less turnaround time.

**12) *Will reports published by PCORI give credit to the original (contractor) authors as the authors of the PCORI publication?***

Yes. We anticipate acknowledgement of all contributors. If a paper is published in which authors are named, we would follow ICMJE standards in determining authorship. Similarly if the publication is to be cited as authored, for example, “by the PCORI Methodology Committee”, contracting authors would be acknowledged.

**13) Would PCORI explain their proposal review process?**

**a. What role might members of PCORI Board have?**

It is likely that reviewers will include both Methodology Committee members and PCORI staff members. It is possible that one or more members of PCORI's Board of Governors may also participate as reviewers. All reviewers will be asked to disclose any possible conflicts of interest, including employment by the same institution or company as one of the applicants. These disclosures will be reviewed and potential reviewers will be removed if the disclosures real or apparent conflict of interest.

**b. What role might members of the Methodology Committee have?**

See answer to "13 a" above.

**14) We understand the importance of a high quality report being delivered on time as stressed on page 2. However, the criterion for judging that this is met is entirely subjective. Please indicate what portion of the full payment does PCORI intend to withhold based on this judgment, so contractors can assess their risk of doing business with the Institute.**

PCORI agrees with the applicant that the current RFP language makes this final payment decision quite subjective. The final payment will be dependent on the initial negotiation, but would typically be relatively small (e.g., no more than 25% of the total contracted amount). In addition, we believe that a PCORI finding that the product was inadequate should be accompanied by a negotiated extension of up to 30 days, during which the applicant, working with the Methodology Committee, will have the opportunity to remedy the perceived shortcomings. PCORI will also be committed to working with an applicant throughout the contract period, providing timely feedback on earlier stages of the work, identifying problems early, rendering dissatisfaction with the final project unlikely.

**15) To whom are status reports sent and when are they due? (e.g., 15 days after end of an 8-week period of performance, or simply every 8 weeks from the date of award, or the anticipated project start date?)**

These dates will be agreed upon between the Methodology Committee and the contractor upon award of contract. Gail Shearer will be the point of contact for the submission of status reports.

**16) Should the cost estimate include the cost of travel and lodgings to the PCORI workshop, or will PCORI support this separately? Is one-day of attendance sufficient?**

Yes

17) ***Is the workshop to be held between March and May, in May, or after that (the RFP states that the Methodology Committee report is due to PCORI board in May)?***

The workshop is tentatively planned for March 8 and 9, 2012.

18) ***While the final Methodology Committee report will be completed by March 1<sup>st</sup> as stated in the RFP, can the period of performance be extended to cover all activities mentioned in the SOW (e.g., the PCORI workshop attendance, nontechnical summary of study findings)?***

Yes

19) ***We note that you request an electronic copy and two hard copies of the proposal, and that the hard copies should be delivered no later than 1 day after email submission. We were wondering if you would accept hand-delivery from a courier in place of postal delivery. We also wanted to clarify whether the due date referred to the date of postmark or actual arrival at your office.***

PCORI does not require that print copies arrive through the U.S. Postal Service. Print copies are required and hand delivery by a courier, or other delivery service, is acceptable. The due date refers to the date of arrival at the office

**PLEASE NOTE: There was an error in the zip code shown in the RFP. The correct address for the PCORI office is:**

Patient-Centered Outcomes Research Institute (PCORI)  
c/o Gail Shearer  
ATTN: PCORI Request for Proposal - *INSERT RELEVANT SUBJECT LINE*  
1701 Pennsylvania Ave., NW, #300  
Washington, DC 20006

20) ***We have a standard budget shell that we use, and we just wanted to make sure that there was no special budget instructions or requirements that we would need to include that are particular to your office (aside from the stipulation regarding indirect costs and NIH salary caps).***

The RFP does not include a specific budget format. Therefore, applicants are free to use their own templates. However, personnel costs must be expressed as salary and fringe (not “fully loaded costs” which would obscure the indirect costs being requested).

**21) *As part of an environmental scan, we would typically conduct a series of key informant interviews as part of our methodological strategy. However, we note that you have issued another RFP that specifically calls for expert stakeholder interviews (PCORI-SOL-PCWG-002). We would welcome any clarification that you might offer as to how you envision that the environmental scan component of the lit review RFP differs from the stakeholder interviews called for in the other RFP.***

The literature review solicitation encompasses published evidence that addresses the questions posed in the solicitation. The contractor may propose a range of approaches to comprehensively identify these publications.

**22) *If possible, would you be willing to tell us how many other institutions have signaled an intent to bid on this RFP?***

PCORI has received 25 letters of intent for the stakeholder interview RFP and 26 for the literature review RFP.

###

*This Question and Answer document was published September 27, 2011.*