



Getting the Word Out: PCORI's Proposal for Peer Review of Primary Research and Public Release of Research Findings

Name of person or organization submitting comments:

PCORI Advisory Panel on Clinical Trials

Please identify which stakeholder group you represent:

- Researchers: Epidemiologists, Clinical Trialists, Biostatisticians
- Experts in Ethical Dimensions of Clinical Trials
- Patients, Caregivers, and Patient Advocates
- Experts in Scientific and Health Services

Please provide comment on the specific sections of the proposal:

Section 1: PCORI's proposed research peer-review process

1. Registration at ClinicalTrials.gov, RoPR, or PROSPERO, and dissemination on PCORI's website.
PCORI should require grantees to register studies at ClinicalTrials.gov or a comparable site for their study design. Grantees should publish both positive and negative results. Postings on the PCORI website should be easy to find and include a link to relevant external posting(s).

Registration at ClinicalTrials.gov should take place prior to the enrollment of the first patient (as is being required by many journals now), and ideally much before that. In addition to addressing issues related to transparency and ensuring that the study design and objectives are defined up front, such postings are helpful for subjects interested in participating in such studies. PCORI might consider revising the time requirement to also align with project milestones.

Agreement regarding the relevant external posting site should be established up front and be part of the contract between PCORI and awardees, and should be a milestone for PCORI awards.

2. Production of a draft final report, scientific abstract, and standalone results table
Final reports by grantees to PCORI should include a scientific abstract, a summary of results written in lay language, and a results table. The results table should include essential elements for conducting a systematic review.

The format of the draft report should contain a clear re-statement of the study objectives or a link to the ClinicalTrials.gov posting at the front. The discussion section should put study findings into the broader context of the prior literature. PCORI should be funding research that advances

the science for a given research topic, so it is important to review the results and contrast those results with other relevant studies.

As currently proposed, limitations of the study appear within both the discussion and conclusions sections, which may lead to some confusion and has the potential to dilute such discussion. Limitations need to be clearly stated and understood. PCORI may want to consider having limitations as a standalone section, or provide clarity on where they should be presented.

While the discussion section also includes “considerations specific to certain sub-populations,” PCORI might want to consider “implications for relevant stakeholders” – which is not adequately captured with the current format. Inclusion of such a section may help to ensure that PCORI-funded research adequately meets the needs of patients and relevant stakeholders.

3. PCORI peer review process of the draft final report

PCORI should give feedback to grantees on final reports. This should include suggestions regarding the success of the overall study design, patient engagement, and specific feedback on the researchers' success in enrolling a diverse population of patients, when appropriate.

PCORI has an important role in advancing methodological standards for patient-centered outcomes research. As methodology standards evolve, it is important that a particular study be evaluated based on the methodology standards that were in place at the time that the study was awarded, and not by standards that did not exist at that time.

For the peer-review process, PCORI will be following a process similar to that used by medical journals, but it is important to note that there may be opportunities for PCORI to improve upon some of the challenges/issues with peer-review by medical journals. 1) Effective peer review should ensure that study design and objectives are clearly described and appropriate; that results and interpretation of the results are sufficiently detailed, consistent with the study design and free of bias; and that the conclusion is aligned with the study design and results, and avoids unsubstantiated interpretation and speculation. 2) PCORI should consider the appropriateness of the peer-reviewers based on their qualifications and expertise as content experts. 3) There can be better quality controls to ensure that manuscripts are being reviewed by appropriate individuals at a satisfactory level.

Although the assigned methodologist and program officer will be responsible for ensuring the study design and methods adequately conform to PCORI's methodology standards, content reviewers should also be mindful of them. One recommendation is ensuring that all peer-reviewers go through training on PCORI values and methodological standards.

PCORI envisions involvement of patients and patient-representatives throughout the entire research process, but patients and patient-representatives are noticeably absent from the peer review process. Although the proposed process does incorporate lay summaries of the research, further consideration should be made to how patients and other relevant stakeholders can be involved.

Section 2: Making Research Findings Publicly Available

1. Providing a version of the results summary that will be useful and comprehensible for use by patients and the general public

One of the most important aspects of research is sharing the results with the public. This leads to a better-informed populace, and can also aid recruiting for future studies. PCORI should give specific guidance to investigators on how to prepare reports for the public that are written in lay language.

In terms of participant notification, PCORI should require that some results be shared with participants prior to publication of those results. Such sharing should be done in a way that is consistent with journal policies on prior publication. Specific guidance should also be developed for investigators on how to report such information to study participants, including an opt-out procedure on consent forms. PCORI need not start from scratch; NIH DAIDS and its Office of HIV/AIDS Network Coordination and the non-profit CISCRP have resources and policies on this issue.

PCORI should also require that clinicians and their professional societies be included in the active dissemination of results. In particular, clinicians will be an important link to patients and will likely help translate the results of trials to their patients.

2. Submission of results table to ClinicalTrials.gov and/or other sites as appropriate, with a link to the abstract and standalone results table on PCORI's website

This should be required even if, as is well known, many studies have negative outcomes. The public should be made aware of all results of the study, positive and negative. Other researchers may also benefit because this may result in fewer repetitive studies.

3. Public posting of full final reports on PCORI's website

PCORI should post results and publicize the results of PCORI-funded trials. Publication of final reports on a central site will help the general population and the research community. The final reports can be posted on PCORI's website and also on other websites that collect data on best practices, e.g. rtips.cancer.gov/rtips, AHRQ, SAMSHA, etc.

PCORI should create a webpage for each project that includes timelines, status updates, milestones (including accrual), and links to conference presentation and journal article by investigators. This should also include a public notice if a trial is prematurely stopped for any reason, including safety, insufficient patient recruitment, or budgetary concerns. Study subjects should be given the URL.

4. Awardee institution notification to PCORI of submission to journals and subsequent publication of papers resulting from funded projects

All research results must be shared in a public forum and arena, regardless of whether research results are positive or negative. PCORI's awareness of article submissions will help this process.

5. Timeline of the proposed peer review and public release process

It is pertinent to share outcomes of the research conducted through PCORI. However, an adequately prepared report cannot be completed within the proposed three-month period. A sound analysis of completed studies will not be as detailed if put together in a short window. The proposed timeline for the full report should be extended.

Section 3: Questions about the proposal as a whole

1. Please rate how well the proposal meets PCORI's obligations under its authorizing legislation
Somewhat Well

2. Please rate how well the proposal provides a clear understanding of the peer review and public release process
Somewhat Clear

Please add any comment about your rating:

There is repetitive language used in much of the PCORI proposal. This language makes it difficult to understand the main points of the proposal.

3. Please comment on the proposal's feasibility given any competing obligations that awardee institutions funded by PCORI, or their investigators, may face.

The PCORI proposal is both reasonable and feasible, though the timeline should be adjusted. Researchers should have one year, rather than three months, to prepare final reports and publicize study results.

4. The law requires that PCORI both conduct peer review of our funded primary research and make it available publicly within a specific timeframe. We propose to conduct peer review first, and then post the results, so they can benefit from the review process. Do you agree or disagree with the sequencing of this process?

Somewhat Agree

Please add any comment about your rating:

The timeline proposed by PCORI should be revised, as noted above.

5. Please provide any additional comments that you have not already provided about any aspect of this proposal.

In general, rigid rules here might not fully appreciate some of the complexities of the subject. It would at least be helpful if the 90-day rule could be interpreted as 90 days following the publication (or acceptance) of research findings in a peer-reviewed journal. Research results might not be finalized until they have gone through that journal peer-review process and so would not be considered final until the final version of the paper is ready.