



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Merit Review Toolkit for Patient and Stakeholder Reviewers

The following guidance is meant to help patient and stakeholder reviewers bring their unique perspective to PCORI's merit review process.

Please refer to the actual Merit Review criteria presented in your Offline Critique Template or your Reviewer Training Manual as you evaluate your assigned applications.

Evaluating Merit Review Criteria “*from your perspective*”

Criterion 1. Potential for the study to fill critical gaps in evidence

From your perspective: Based on your experience as a representative of the healthcare community, do you see this study topic as one that is important and relevant?

Criterion 2. Potential for the study findings to be adopted into clinical practice and improve delivery of care

From your stakeholder community perspective:

- **Patients:** Would patients and caregivers be willing to participate in the study—why or why not? Are the interventions burdensome for participants and how would this affect the delivery of care? Would the study results be taken up by patient organizations? Would the study provide practical information to aid informed healthcare decisions?
- **Clinicians:** Are the proposed interventions realistic for the care settings where they would be implemented? Are staff considerations appropriate? Would the study results be taken up and applied in a clinical context? Would the study findings support daily decision making?

- **Hospital and Healthcare Systems:** What is the likelihood that the proposed intervention could be adopted in a hospital setting? Would study findings be useful to inform policy and best practices in our health system? Would study findings help ensure that both patients and clinicians have the best information available for making treatment decisions? Would the proposed intervention be ineffective, duplicative, or wasteful if provided to patients?
- **Training Institutions:** What are the limitations or potential for uptake of the proposed interventions? Would the results be easy to implement in a real-world setting? Could study findings facilitate earlier access and uptake of the proposed interventions? Would study findings facilitate educating students in health professions with the latest information in evidence-based practice?
- **Industry:** What are the risks and benefits of this intervention/strategy delivered in a real-world setting? Would this intervention facilitate earlier patient access to high-quality, safe, and effective products? Would this intervention require additional resources and staff injected into the product development lifecycle? What research is currently being conducted on the interventions proposed?
- **Researchers:** Would the study findings be generalizable to the community or population intended? Could the proposed interventions be sustained long-term? Would this study and its findings shape future patient-centered outcomes research and impact delivery of care?
- **Payers:** Would the proposed interventions improve care coordination and patient outcomes? What are the long-term impacts of this intervention? How would they affect out-of-pocket costs to the consumer? Would this research help enrollees understand treatment options available to them? Would study finding reduce variation and disparities in health care delivery and patient outcomes? Would the study results be taken up by your organization?
- **Purchasers:** Would the proposed interventions affect productivity? Would study findings stand to keep your employees healthy and engaged in business? Would study findings assist in improving health outcomes for employees and their families?
- **Policy Makers:** Would study findings be useful to inform policies and practices? Would study findings address problems in our healthcare system? Which projects address relevant questions about patient-centered health policy?

Criterion 3. Scientific merit (research design, analysis, and outcomes)

From your perspective: As a patient or other stakeholder reviewer, your role is not to try to evaluate the statistical or other technical aspects of the research design. You should respond to this criterion based on the community you represent:

- **Patient community:** Would patients and caregivers be willing to participate in the study as designed? Are the applicants likely to recruit as many participants as they propose? Are data collection plans reasonable and not too burdensome for patient participants?

- **Clinician community:** Would clinicians support participant recruitment? Is usual care, if included, appropriately described? How would data collection for the study influence clinician workload and work flow?
- **Payer, organizational, or other decision-maker communities:** Would the proposed outcome measures be convincing to your colleagues and beneficial for decision making?

Criterion 4. Investigators and environment

From your perspective: As a patient or other stakeholder reviewer, consider whether the research team has the experience (e.g., working with the target patient population) to successfully conduct the proposed study in the proposed research environment. Are the *patient and stakeholder* collaborators qualified to conduct the proposed activities? Comment on the leadership, governance, and organizational structures proposed in the study.

Criterion 5. Patient-centeredness

From your patient perspective: Would your participation in the research result in meaningful findings? Will the health care and treatment options being compared benefit your decision making? Does the study employ a research design that is informed and/or endorsed by patients?

From your stakeholder community perspective: Consider how a patient or caregiver would answer the questions contained in this criterion. Consider not only if patients report their own outcomes, but also if those outcomes are the ones that will make a real difference to patients, their families, and their providers.

Criterion 6. Patient and stakeholder engagement

From your perspective: Consider whether the *right* groups will be involved in the study. Are the plans for engagement and partnership tied closely to the aims of the study? Have the engagement plans been driven by the research questions and have the applicants identified barriers to implementation? Does the engagement plan feature an adequate timeline and allocation of resources to meaningfully engage patients and stakeholders throughout the study? Have patients and other stakeholders clearly been involved in research topic and study development, as appropriate for the project?

One size does not fit all for Patient and Stakeholder Engagement, so be sure to evaluate the match of engagement to research design for this study.

Methodology Standards

Patient and stakeholder reviewers can help PCORI evaluate adherence of investigators' proposed research to the Methodology Standards. Please see [standards PC-1 to PC-4](#), which relate to patient-centeredness and patient-reported outcomes.

Methodology 101

Training Booklet, Resource Guide and Glossary of terms

Not to be confused with the Methodology Standards, PCORI has developed this guidance document to explain comparative effectiveness and patient-centered outcomes research concepts for a lay audience. This document includes a glossary of research terms. Interested reviewers can download the document to use as a helpful tool when reviewing their assigned applications.

[View/Download: Methodology 101 Training Booklet & Resource Guide](#)

Human Subjects Protections

PCORI requires that research involving human subjects include adequate safeguards, and Institutional Review Boards selected by awardees have authority for ensuring the protection of human subjects.

Note that patient and stakeholder reviewers are not required to check the box about the adequacy of human subjects protections. If you are interested in learning more about how scientist reviewers evaluate human subjects protections, [click here](#).