

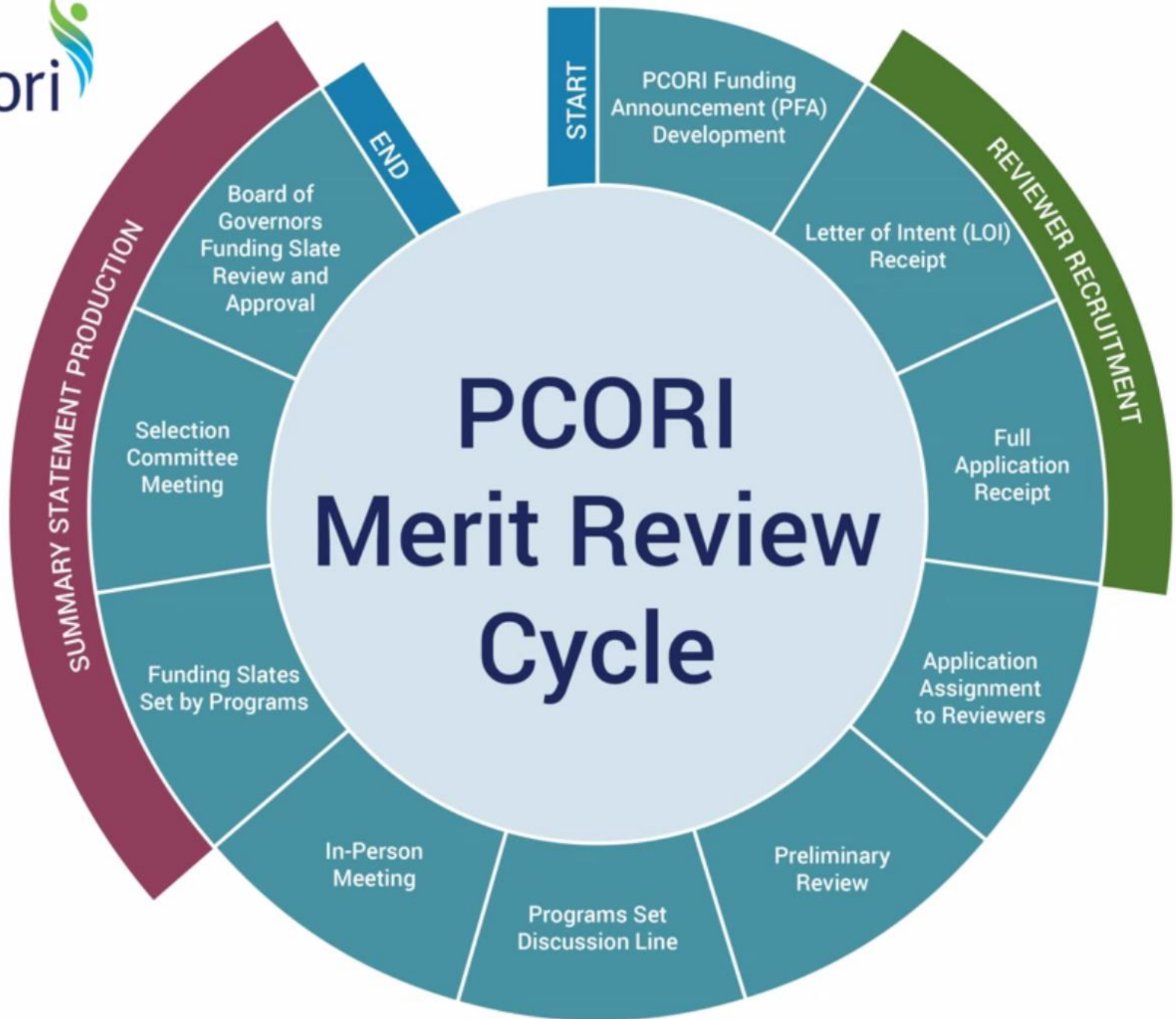
Northwestern University Feinberg School of Medicine



Getting Your Patient-Centered Outcomes Research Funded: A Reviewer's Perspective

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Reviewer Perspectives



Merit Review Criteria



Criterion #1: Impact of the condition on the health of individuals and population



Criterion #2: Potential for the study to improve healthcare and outcomes



Criterion #3: Technical merit



Criterion #4: Patient-centeredness



Criterion #5: Patient and stakeholder engagement

| Patient and Stakeholder Reviewers | Scientist Reviewers |
|-----------------------------------|---------------------|
| | ✓ |
| ✓ | ✓ |
| | ✓ |
| ✓ | ✓ |
| ✓ | ✓ |



Patient-Centeredness

The proposal demonstrates patient-centeredness at every stage of the research:

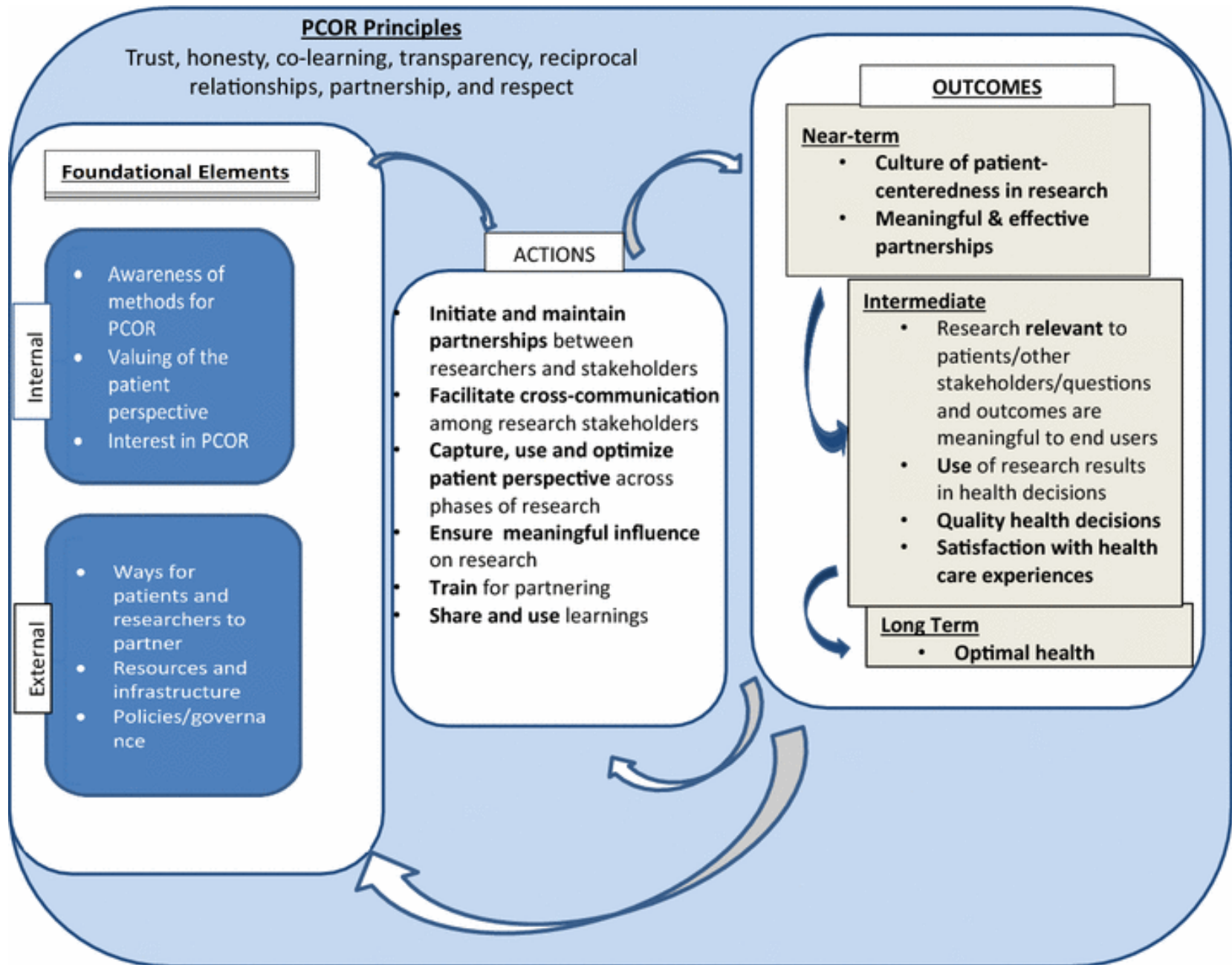
- Is the research focused on questions that affect outcomes of interest to patients and their caregivers?
- Does the research address one or more of the key questions mentioned in PCORI's definition of patient-centered outcomes research?



Patient and Stakeholder Engagement

The proposal demonstrates that people representing the population of interest and other relevant stakeholders are engaged in ways that are appropriate and necessary in a given research context:

- Are patients and other stakeholders engaged in formulating research questions; defining essential characteristics of study participants; identifying and selecting outcomes that the population of interest notices and cares about; monitoring study progress, designing/suggesting plans for dissemination and implementation activities
- Are the roles and the decision-making authority of all research partners clearly stated?
- Does the proposal demonstrate the principles of reciprocal relationships, co-learning, partnership, trust, transparency, and honesty?





In-Person Review Panel



What do the scores mean?

| Range | Score | Descriptor | Characteristics |
|--------|-------|--------------|---|
| High | 1 | Exceptional | Exceptionally strong with essentially no weaknesses |
| | 2 | Outstanding | Extremely strong with negligible weaknesses |
| | 3 | Excellent | Very strong with only some minor weaknesses |
| Medium | 4 | Very Good | Strong but with numerous minor weaknesses |
| | 5 | Good | Strong but with at least one moderate weakness |
| | 6 | Satisfactory | Some strengths but also some moderate weakness |
| Low | 7 | Fair | Some strengths but with at least one major weakness |
| | 8 | Marginal | A few strengths and a few major weaknesses |
| | 9 | Poor | Very few strengths and numerous major weaknesses |



Engaging Patients and Stakeholders in Research Proposal Review: The Patient-Centered Outcomes Research Institute

Rachael L. Fleurence, PhD; Laura P. Forsythe, PhD, MPH; Michael Lauer, MD; Jason Rotter, MHS; John P.A. Ioannidis, DSc, MD; Anne Beal, MD, MPH; Lori Frank, PhD; and Joseph V. Selby, MD, MPH

The inaugural round of merit review for the Patient-Centered Outcomes Research Institute (PCORI) in November 2012 included patients and other stakeholders, as well as scientists. This article examines relationships among scores of the 3 reviewer types, changes in scoring after in-person discussion, and the effect of inclusion of patient and stakeholder reviewers on the review process. In the first phase, 363 scientists scored 480 applications. In the second phase, 59 scientists, 21 patients, and 31 stakeholders provided a “pre-discussion” score and a final “postdiscussion” score after an in-person meeting for applications. Bland–Altman plots were used to characterize levels of agreement among and within reviewer types before and after discussion. Before discussion, there was little agreement among average scores given by the 4 lead scientific reviewers and patient and stakeholder reviewers. After discussion, the 4 primary

reviewers showed mild convergence in their scores, and the 21-member panel came to a much stronger agreement. Of the 25 awards with the best (and lowest) scores after phase 2, only 13 had ranked in the top 25 after the phase 1 review by scientists. Five percent of the 480 proposals submitted were funded. The authors conclude that patient and stakeholder reviewers brought different perspectives to the review process but that in-person discussion led to closer agreement among reviewer types. It is not yet known whether these conclusions are generalizable to future rounds of peer review. Future work would benefit from additional data collection for evaluation purposes and from long-term evaluation of the effect on the funded research.

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For author affiliations, see end of text.

In the Patient Protection and Affordable Care Act of 2010, PCORI was authorized “to assist patients, clinicians, purchasers, and policymakers in making informed health decisions through research and evidence synthesis” (1). Central to PCORI’s strategy is the engagement of patients, caregivers, and other health care stakeholders in key aspects of the research enterprise (2). One critical opportunity for engaging patients and stakeholders is in the research application review process. PCORI posted its first broad funding announcements for comparative effectiveness research on 22 May 2012 (www.pcori.org/funding-opportunities/funding-announcements/closed-opportunities). Awards were for a maximum of \$1.5 million in direct costs over 3 years. The first portfolio of projects was awarded on 18 December 2012 (www.pcori.org/pfaawards). Between May and November 2012, PCORI established and conducted a peer-review process that involved scientists; patients; and other stakeholders, such as clinicians, policymakers, and funders.

PCORI is the first major U.S. funding agency to systematically require the inclusion of reviewers who are not

It is speculated (but not proven) that participation of non-scientifically trained reviewers or scientists from very different fields may help correct these problems and may also improve the relevance of research to stakeholders who would implement study findings. In the context of health-related research, these end users include patients, caregivers, clinicians, and clinical policymakers. In this review, patients could either represent personal patient or caregiver perspectives or represent patients in their professional capacity (foundation or advocacy employees). They were not required to have or represent the condition discussed in a particular application. PCORI recognizes that there may be differences in these perspectives but sees value in both. Although scientists and stakeholders may also bring a patient perspective from their personal lives, reviewers who self-identified as scientific reviewers were categorized as such for the purposes of this review. This article explores the merit-review process of PCORI for its inaugural round of funding and investigates the contributions of scientist, patient, and stakeholder reviewers.

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