



PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

## Reviewer Manual

**Funding Program: Limited PCORI Funding Announcement:  
Dissemination and Implementation of PCORI-Funded Patient Centered  
Outcomes Research Results and Products in Real-World Settings**

**Review Cycle: Cycle 1 2017**

### **Relevant Dates:**

- **June 9<sup>th</sup>, 2017:** One complete written critique (for one application) is due in PCORI Online or to the MRO.
- **July 7<sup>th</sup>, 2017:** Written critiques and scores for all assigned applications are due in PCORI Online.
- **August 3<sup>rd</sup>, 2017 Washington DC metro area:** In-person Merit Review Panel Meeting.
- **November 2017:** Funding decisions are announced.



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## Chapter 1. Setting the Stage

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### PCORI's Mission and Strategic Goals

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's Strategic Goals:**

- *Increase quantity, quality, and timeliness of useful, trustworthy research information available to support health decisions*
- *Speed the implementation and use of patient-centered outcomes research evidence*
- *Influence research funded by others to be more patient-centered*

PCORI seeks to **fund comparative effectiveness research** that will produce information that allows patients to weigh the benefits and risks of clinical alternatives. This will ensure that people receive care according to their needs and have the opportunity to achieve the best possible health outcomes.

PCORI also actively **encourages the healthcare community's use of important results from the research that it funds and is** committed to (1) enhancing awareness of evidence useful to people and organizations as they make health decisions and (2) speeding the integration of this evidence into practice.

More information about PCORI-funded comparative effectiveness research, as well PCORI awards aimed at closing the gap between evidence development and implementation of that evidence in practice, is provided below.

### PCORI funds Comparative Clinical Effectiveness Research (CER)

Per its authorizing legislation, PCORI funds research that supports comparative clinical effectiveness research (CER)—comparing health outcomes and the clinical effectiveness, risks, and benefits of two or more approaches to healthcare. PCORI is not interested in funding efficacy<sup>1</sup> studies.

#### ***CER answers patient-centered questions, such as:***

- Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?
- What are my options, and what are the potential benefits and harms of those options?
- What can I do to improve outcomes that are most important to me?
- How can clinicians and the care delivery systems they work in help me make the best decisions about my health and health care?

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<sup>1</sup> Effectiveness is the extent to which an intervention does more good than harm across a broad mix of patients in a range of clinical settings. In contrast, efficacy is the extent to which an intervention does more good than harm in ideal patients under ideal circumstances.



**Evidence Gap: PCORI-funded CER studies address important research topics and questions with known evidence gaps.** An evidence gap is an area of missing information that would help patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders make better decisions about health care. Evidence gaps are usually identified through systematic research reviews that demonstrate unclear or incomplete guidelines, or they may be identified as a high priority as recommended by research, clinical, and/or stakeholder groups, including specific recommendations for CER.

**Usual Care:** PCORI funds research that compares at least two alternative treatments or interventions, both of which must be available in the real world. If “usual care” is proposed as a comparator, it must be justified as the best comparison for the particular condition or intervention, carefully described and measured in the study, and be a realistic choice faced by patients and other stakeholders.

**PCORI does NOT fund the following:**

- Cost Effectiveness Analysis (CEA), which examines both the costs and health outcomes of alternative intervention strategies and typically presents results in the form of costs per particular health outcomes or life year saved, etc. Per its founding legislation, PCORI does not fund studies that include formal cost-effectiveness analysis (CEA) or directly compare the costs of care between two or more alternative approaches to providing care.<sup>2</sup>
- Development of Decision Aids<sup>3</sup>: Although PCORI is not currently interested in funding the development or testing of decision aids, if the application describes how their research could be used in decision making or later guideline development, that is acceptable.
- Research where findings will include: creation of clinical practice guidelines or instruments to measure outcomes, insurance coverage recommendations, payment or policy recommendations, establishing efficacy for a new clinical strategy or in a tightly controlled environment, pharmacodynamics (studies that focus purely on the effects of drugs and the mechanism of their action), study of the natural history of disease or comparison of patient characteristics rather than treatment strategies, and fundamental science or study of biological mechanisms, or how medications work in the body.

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<sup>2</sup> Note: PCORI does have an interest, however, in studies that address questions about conditions that lead to high costs to the individual or to society. This includes studies that (1) examine the effect of costs on patients, such as patients’ out-of-pocket costs, hardship or lost opportunity, or costs as a determinant of or barrier to access to care; (2) address cost-related issues, such as the resources needed to replicate or disseminate a successful intervention, and (3) evaluate interventions to reduce health system waste or increase health system efficiency.

<sup>3</sup> Decision aids are tools meant to help patients and their caregivers facing complex decisions. Aids do not replace providers, but function to support a team approach to decision-making between the patients and their healthcare providers. Examples of decision aids could include brochures, audiovisual materials, educational sessions, websites, counseling sessions, and computer programs.



### PCORI also funds Dissemination and Implementation Awards

PCORI is interested in projects that actively disseminate and implement patient-centered outcomes research/comparative effectiveness research (PCOR/CER) results and products of PCORI-funded studies using creative strategies consistent with best practices in the context of established dissemination and implementation models and frameworks in real-world settings.

Note that Dissemination and Implementation Awards are distinct from PCORI CER awards in that their intent is to disseminate the findings and/or products resulting from PCORI CER awards. Thus, there is no comparative requirement.

#### Definitions of Dissemination and Implementation:

- **Dissemination** is the intentional, active process of identifying target audiences and tailoring communication strategies to increase awareness and understanding of evidence and to motivate its use in policy, practice, and individual choices. The purpose of dissemination is to spread and sustain knowledge and the associated evidence-based interventions.
- Note that passive dissemination, sometimes called research diffusion, is an untargeted dissemination process whereby new evidence is absorbed and acted upon by a small body of highly motivated recipients.
- **Implementation** is the deliberate, iterative process of integrating evidence into policy and practice through adapting evidence to different contexts and facilitating behavior change and decision making based on evidence across individuals, communities, and healthcare systems.

## Chapter 2. Dissemination and Implementation PFA

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PCORI informs the research community of opportunities to apply for funding opportunities via PCORI Funding Announcements (PFAs). Reading your assigned PFA will help provide context for the applications that you review.

The Dissemination and Implementation PFA seeks to fund projects that are proposing creative and well-informed strategies for actively disseminating and implementing PCOR results and corresponding products aimed at increasing their use, implementation, and impact among diverse populations of patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders.

PCORI's objectives underlying this funding announcement are:

- To provide PCORI awardees the opportunity to disseminate important findings pertaining to the original PCORI research that can improve practice on a timely basis
- To stimulate the development, application, and evaluation of D&I approaches that will increase the use and application of PCOR/CER research results, as well as products derived from PCORI-funded studies, by diverse populations of end-users including patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders
- To gain and apply generalizable knowledge from feedback and evaluation of dissemination and implementation strategies to better understand the barriers and facilitators of evidence dissemination and uptake, and to inform improvements in future D&I efforts and ensure applicability to a wide range of audiences
- To explore the development, application, and evaluation of mechanisms for incorporating CER findings in decision making by diverse groups of stakeholders. This includes identifying best practices for approaching D&I in PCORI priority areas and with priority populations

[Please click here to access the Dissemination and Implementation PFA.](#)

Through the Dissemination and Implementation PFA, PCORI seeks to fund:

- Projects designed to actively disseminate and implement the results of PCORI-funded studies that are informed and guided by established dissemination and implementation models and frameworks, in the context of real-world settings.



REMEMBER: All research results and products proposed for dissemination and implementation in the applications undergoing merit review were previously funded PCORI research studies.

Dissemination and Implementation interest areas include (but are not limited to):

- Translation and adaptation of the context or delivery mechanism of CER research results and products found effective to improve their penetration and use at the policy, health system, clinical practice, caregiver, and patient levels

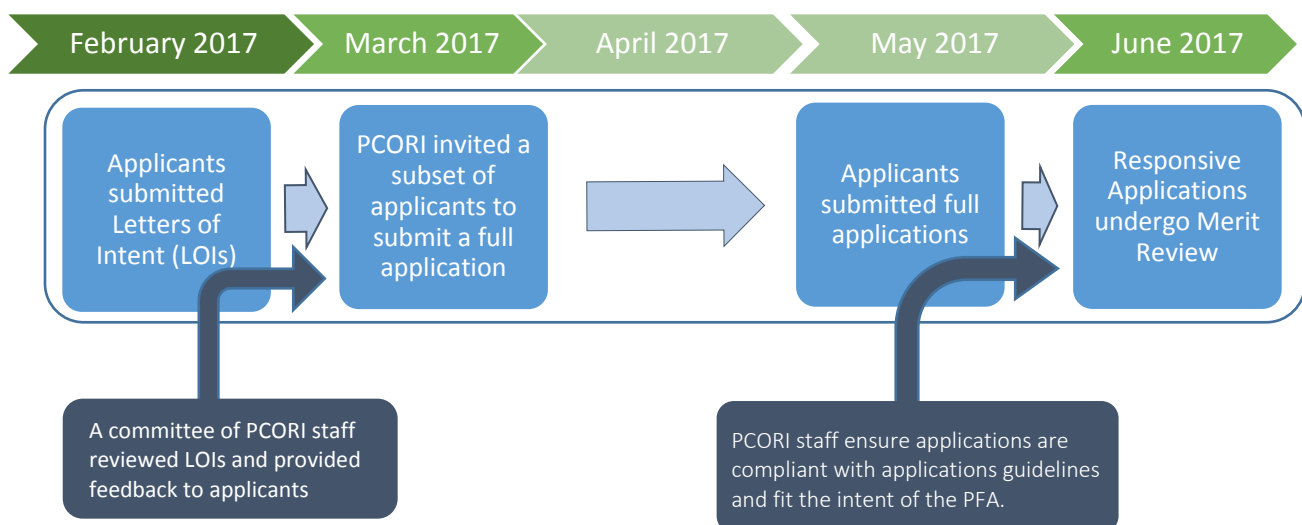
- Development, demonstration, and evaluation of processes or products to incorporate PCORI research results and products into decision-making settings for patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders
- Translation, adoption, and dissemination of PCORI research results and products within the context of the existing body of evidence in the topic area targeted to one or more defined audiences or stakeholder groups with specialized needs (PCORI priority populations)
- Demonstration of the capacity and ability to take research results and products found effective through PCORI research studies “to scale” in diverse settings and populations
- De-implementing or reducing the use of strategies and procedures that are not evidence-based, have been prematurely widely adopted, or are harmful or wasteful, in place of evidence-based approaches

The Dissemination and Implementation PFA is NOT interested in projects that:

- Propose a dissemination plan that is dependent upon passive dissemination strategies (e.g., untargeted mass mailings or scientific publications and/or presentation to scientific audiences) as its primary dissemination methods
- Aim to develop or validate a new tool or system for patients or clinicians without the primary purpose of actively disseminating or implementing evidence. [Note that PCORI will consider tools and systems proposed as the primary mechanism for actively disseminating and implementing evidence.]

If you identify either of these issues in an application you are reviewing, let your MRO know right away. You should continue to review the application while the MRO investigates the issue.

The figure below describes the process by which applications are screened by Merit Review and Program Staff to ensure that the applications comply with PCORI guidelines and fit the intent of the PFA. These applications will then move forward to online review and undergo rigorous evaluation by merit reviewers against the D&I merit review criteria.





### Successful D&I Projects

Successful D&I projects will lead to the increased use, implementation, and/or impact of PCOR among targeted populations of patients, caregivers, healthcare providers, policy makers, and/or other relevant stakeholders.

#### Questions to keep in mind while reviewing applications:

- ***Are the PCORI findings/results well described, meaningful, and actionable?***
  - ➔ This question is addressed in Merit Review Criterion 2
- ***Is the scope of the proposed D&I effort appropriate?  
Are plans clearly described, rigorous, and feasible?***
  - ➔ This question is addressed in Merit Review Criterion 3
- ***Does the proposed D&I effort have strong potential to lead to uptake of the PCORI findings/results/products and to result in changes in practice and improvements in healthcare and health outcomes?***
  - ➔ This question is addressed in Merit Review Criterion 1





## Chapter 3. Merit Review Overview

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### Merit Review Goals

PCORI's Merit Review process is designed to support the following goals:

- To identify applications that have the strongest potential to help patients, caregivers, clinicians, policy makers, and other healthcare system stakeholders make informed decisions to improve patient outcomes;
- To implement a transparent, fair, objective, and consistent process to identify these applications;
- To elicit high-quality feedback that reflects a diversity of perspectives to ensure that the research funded by PCORI reflects the interests and views of patients and those who care for them and that it meets the criteria for scientific rigor;
- To fund projects that fill important evidence gaps and have strong implementation potential;
- To regularly evaluate and continually improve the merit review process and policies in support of PCORI's mission.

### Preliminary Review Overview

All reviewers should begin the Preliminary Review by reading the full PCORI Funding Announcement (PFA) for the applications they are reviewing, to make sure they understand PCORI's programmatic and organizational goals. They should then carefully evaluate their assigned applications according to PCORI's Merit Review criteria.

For each of their assigned applications, reviewers will:

- Write a critique highlighting the application's strengths and weaknesses
- Assign scores for each of the criteria that align with their written critiques
- Write a summary evaluating the application as a whole
- Provide an overall score for the application

### Merit Review Criteria

Each application is reviewed by two scientists, one patient, and one stakeholder reviewer. All reviewers will evaluate the six merit review criteria for each assigned application. Focusing on the Merit Review criteria will help reviewers approach each application in a fair, objective, and consistent way.

Reviewers should evaluate the strengths and weaknesses of each application based on PCORI's Merit Review criteria. In your critique, evaluate the application's adherence to the themes indicated by the bulleted questions under each criterion described below.

### Criterion 1: Importance of research results in the context of the existing body of evidence

- Does the application sufficiently identify and describe the original evidence gap that the PCORI-funded research addressed? Does the application sufficiently demonstrate that the evidence gap persists and is important?
- Does the application clearly describe the PCORI research results being proposed for dissemination?
- Does the application sufficiently discuss how the PCORI research results relate to the body of evidence in the existing literature? Specifically, does the application address the extent to which the PCORI results align with or contradict the existing evidence base?
- Will further uptake of these results, beginning with the project proposed, constitute a change in practice and lead to improved healthcare and health outcomes?

### Criterion 2: Readiness of the research results for dissemination

- Does the application sufficiently describe the strength of the results of the original PCORI study in terms of their clinical and statistical significance?
- Does the application sufficiently address the generalizability of the PCORI research results to populations beyond the immediate study sample?
- Does the application identify the decision-making context in which the PCORI results are most relevant beyond the initial study setting?

### Criterion 3: Technical merit of the proposed dissemination or implementation project (project design, outcomes, and evaluation)

- Does the application sufficiently describe the group that will be the target of the proposed dissemination activity? Does it describe the setting in which the dissemination will take place? Are these targeted users and settings generalizable?
- Does the applications use a D&I framework or model to inform the project design and evaluation outcomes and to address the potential longer-term implications of the proposed D&I project on clinical practice and patient-centered outcomes?
- Does the application provide a clear approach for disseminating the described research results?
- Does the application propose appropriate measures and describe the plan for evaluating success in sufficient detail, including an appropriate balance of measureable process and short-, intermediate-, and longer-term outcomes to capture timely information on the effectiveness of the proposed D&I activities?
- Does the application consider factors that may help or hinder the use of research results, including specific barriers to user implementation and how to mitigate them, within the context of the proposed project?
- Does the applications address scalability, including a clear path for future efforts to bring these research results into wider use?
- Is the proposed timeline realistic, including specific project milestones?



#### Criterion 4: Project Personnel and Environment

This criterion should assess the appropriateness (e.g., qualifications and experience) of the project personnel/team and capacity of the environment (e.g., resources, facilities, and equipment) to support the proposed project. It should not be an assessment of the institution's quality.

- How well-qualified is the project team (e.g., PIs, collaborators, and other stakeholders) to conduct the proposed activities?
- Does the investigator (or co-investigator) have demonstrated experience conducting projects of a similar size, scope, and complexity?
- If the project is collaborative or dual-PI, do the investigators have complementary and integrated expertise? Are the leadership, governance, and organizational structures appropriate for the project?
  - (Dual-PI Option Only) Does the Leadership Plan adequately describe and justify roles and areas of responsibility of the PIs?
- Is the level of effort for each team member appropriate for successful conduct of the proposed work?
- Does the application describe adequate availability of and access to facilities and resources (e.g., collaborative or partnering arrangements) to carry out the proposed project?
- Is the institutional support appropriate for the proposed project?

#### Criterion 5: Patient-centeredness

- Does the application demonstrate a clear link between the proposed D&I project and ultimate benefit/value to patient?

#### Criterion 6: Patient and stakeholder engagement

- Does the application demonstrate that stakeholders central to the proposed project are engaged with planning and execution of the project? Have patients or their representatives been engaged to inform the dissemination strategy or other relevant aspects of the project?
- Has the application demonstrated a sufficient willingness and readiness of the healthcare systems and settings in which dissemination will occur to use and embrace these research results?
- Does the application demonstrate clear interest of **personnel** at target settings in the D&I of the PCORI research findings and clear commitment to participate as active partners in the project?
- Does the application demonstrate the principle of reciprocal relationships, co-learning, partnership, trust, transparency, and honesty?

#### Human Subjects Protections

If applicable, applicants should describe the protection of human subjects involved in their proposed dissemination and implementation project. If human subjects protection is not applicable, applicants should provide a justification. The final determination of whether protections are needed is up to the Institutional Review Board overseeing the project, but reviewers are asked to comment on whether they see any concerns regarding planned protections or justification for not including such plans. For more information on human subjects protections, [click here](#).

## Evaluating Budgets

All applicants submit a detailed budget and justification for the duration of the proposed project. The budget reflects the work outlined in the application and must support all objectives.

If a project is awarded, the applicant moves into the post-award phase. Budgets are carefully scrutinized to ensure that the proposed budget is appropriate for the size and scope of the project and does not have any unallowable costs. Since PCORI awards contracts, not grants, negotiations between the awarded organization and PCORI can work out issues in the budget or projected project milestones.

As you look over the application, it is appropriate for reviewers to flag in your critiques any issues with the proposed budget – for example if the budget is not sufficiently described or justified. If it is unclear how to comment about budget concerns, please touch base with your MRO.

## “Greater Than” Budget/Time Requests

Some investigators have submitted D&I applications requesting either a longer project duration (greater than 2 years) or a larger budget (greater than \$350,000 in direct costs).



**For these applications, please be sure to review the Greater Than Budget Justification section of the application.**

## Chapter 4. Critique Writing

### Overview

Written critiques will be included in the final summary statements and will be used by several audiences during the Merit Review process:

- By applicants to inform possible resubmissions
- By you to prepare your oral presentation of your critique at the In-Person Panel Review
- By other Reviews to help prepare for their participation in the In-Person Panel discussion
- By PCORI staff as they build funding slates and manage projects

The goal of the critique is to ensure that applicants, other reviewers, and PCORI staff understand the strengths and weaknesses of each application, based on the merit review criteria. This helps PCORI identify the most meritorious applications and helps applicants understand the strengths and weaknesses of their application, which can inform how they strengthen subsequent submissions.

### Offline Critique Template

PCORI provides an offline critique template to all reviewers each cycle to ensure that guidance is consistent and incorporates any changes for that cycle. This document is a helpful tool that you should use to write your critiques. Each criterion will have its own section where perceived strengths and weaknesses can be organized, and scores can be provided.

#### Guidelines for Writing Critique Strengths and Weaknesses

##### **Write critiques, not summaries**

- ✓ A critique provides a detailed analysis and assessment of the application, not a summary of the content of the application.

##### **Provide details**

- ✓ Provide an explanation of why a specific point is a weakness or a strength.
- ✓ Provide constructive criticism and be specific.
- ✓ Do not use direct quotes from the application, but provide page numbers, when possible, when referring to specific sections.

##### **Be objective**

- ✓ Refrain from discussing your own personal experiences. Generalize your experiences to other patients with different conditions and experiences.
- ✓ Write your critique from the perspective of your specific stake in the healthcare process.

##### **Judge on application's merit**

- ✓ Evaluate each application as submitted. Your score and critique should be based on the application as-is, not the application's potential.
- ✓ Do not make assumptions about the principal investigator's intent. If information seems to be left out of an application, consider whether or not that is a weakness.
- ✓ Applications should not be compared to one another. For example, if you are assigned two applications focused on the same disease or condition or that propose similar dissemination strategies, be careful to not let the review of one affect the review of the other.



## Major and Minor Strengths and Weaknesses

Using modifiers—major, moderate, and minor—to describe strengths and weaknesses of your assigned applications can help you determine scores for each Merit Review criterion. The modifiers also help others who read your critiques to understand which points are more important to you and drove your score.

### Definitions of Strength and Weakness Modifiers:

<b>Major Strength</b>	is likely to lead to increased.....	use, implementation, and impact of PCOR among targeted populations of patients, caregivers, healthcare providers, policy makers, and/or other relevant stakeholders
<b>Moderate Strength</b>	would probably lead to increased.....	
<b>Minor Strength</b>	could lead to increased.....	
<b>Minor Weakness</b>	is easily addressable and does not substantially lessen the project's ability to increase the.....	
<b>Moderate Weakness</b>	would lessen the project's ability to increase the.....	
<b>Major Weakness</b>	would seriously limit the project's ability to increase the.....	

- ✓ The scoring chart below provides additional guidance and characteristics to help you determine a score for each criterion based on major and minor strengths and weaknesses.
- ✓ Feel free to copy/paste our wording for these modifiers in your critiques. For example, "The limited role of patient partners **would seriously limit the project's ability to increase use, implementation, and impact of PCOR** because \_\_\_\_\_."

## Merit Review Scores

Once you have finished describing the strengths and weaknesses for each criterion, you will provide a score for that criterion. The scoring range for the overall application and for the individual criteria consists of a nine-point scale, with lower numbers indicating higher quality. Numerically low scores (such as 1-3) reflect applications that have major strengths in a criterion area, while numerically higher scores (such as scores of 7-9) are associated with applications that are very weak in that criterion area.

The number and magnitude of strengths and weaknesses for each criterion should reflect the criterion score. For example, a score of 1 would correlate with an exceptionally strong application with essentially no weaknesses. An application with an overall score of 4 might have a mix of moderate strengths and moderate weaknesses, with strengths outweighing weaknesses. A score of 7 or 8 might indicate major

weaknesses and minor strengths. The scores will depend on the individual reviewer. You should feel free to ask your Merit Review Officer for guidance on scoring.

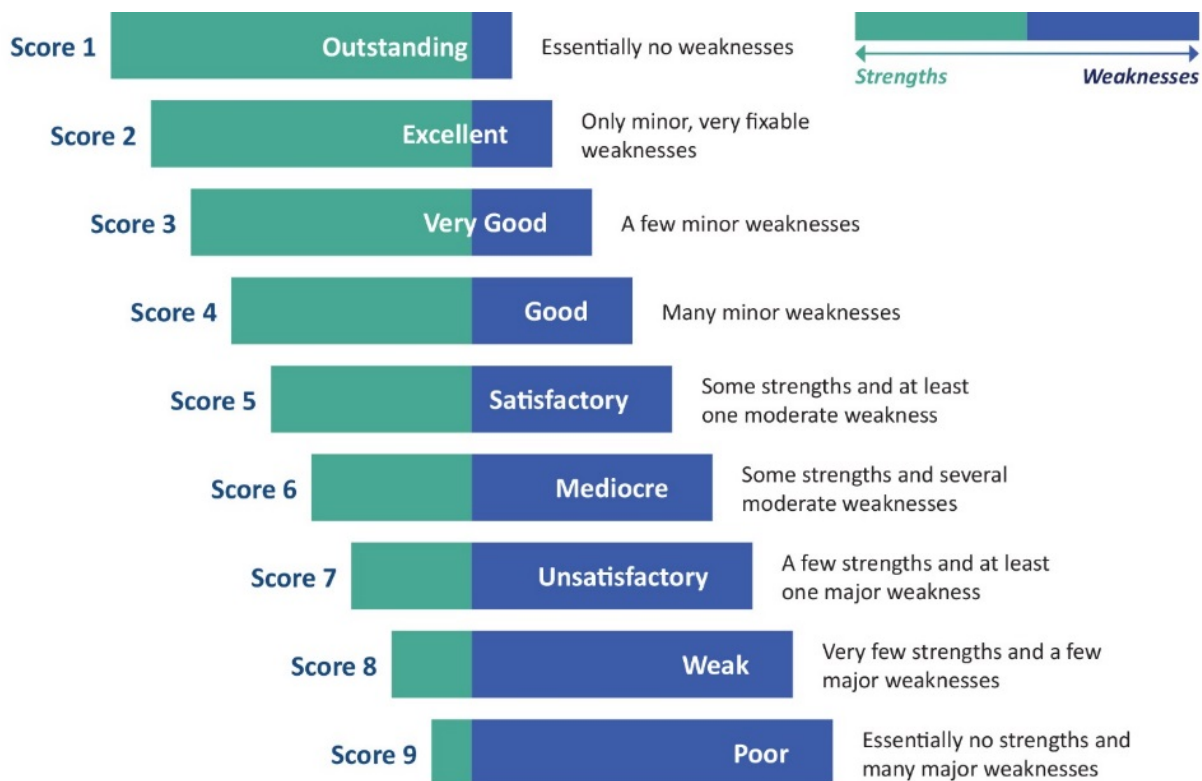
### Align scores to critiques

- If you assign a poor score, be clear about the weaknesses of the application (and vice versa).
- Text and score alignment will help other reviewers, staff, and the applicant understand your perspective when they read your reviews.
- The use of modifiers like major, moderate, and minor to describe strengths and weaknesses helps the reader understand what drove your scores.



The modifiers (major, moderate, minor) should help you determine a score for each criterion. When determining your score, consider how many strengths versus weaknesses you've identified. Also consider how the gravity of those strengths or weaknesses balance each other.

### Merit Review Scoring Chart: Criterion Scores



## Knowledge Check

**Instructions:** Take a moment to read the sample critique below and decide which score best aligns with the written critique. Select the best answer.

### Sample Critique 1:

#### **Criterion 6: Patient and Stakeholder Engagement**

##### *Strengths:*

- *The research team will assemble often to reformulate study questions and assess progress. There will be an internet listserv to facilitate discussion. Procedures are in place to make changes if needed based on the opinions of the designated individual stakeholders. This is a moderate strength.*

##### *Weaknesses:*

- *There is an extensive list of stakeholders with advanced degrees engaged in all aspects of the study; however, there is an absence of patient or caregiver input. For example, patients/caregivers with the common cold were not consulted on the design or implementation of the study nor are they involved in monitoring its progress. Also if patients/caregivers were involved in the design of the study we would have a better idea if the technique of sending letters to invite patients to participate in the study would be their preferred method of engagement. The exclusion of these very important stakeholders in the study design is a major weakness of this study.*
- *More specific details and commitments and/or plans for dissemination by stakeholders other than the PI/research team are needed to strengthen evidence of stakeholder engagement.*
- *There is no plan for patient/caregiver/advocate dissemination of the results. This is a major weakness of the study because patients with the common cold are characteristically disengaged and may not be reached through the medical community. Plans to engage and disseminate into the patient community by outreach measures would strengthen this project.*

**A. Score 3 – Very good, a few minor weaknesses**

**B. Score 8 – Weak, very few strengths and a few major weaknesses**

**Answer: The correct answer is B.** A criterion score of 8 would best align with the sample written critique because there are several major weaknesses listed, but only a few strengths. A score of 3 would not align with the written critique because there are too many major weaknesses listed for this application to be scored as excellent for this criterion.



## Sample Critique 2:

### Criterion 6: Patient and Stakeholder Engagement

#### Strengths:

- A major strength is that multiple stakeholder and patient groups are proposed to assist with the conduct of the study.
- Specific dissemination groups are discussed, including regional stakeholders and national dissemination advisers. This is a major strength.
- Patients and stakeholders were identified through interest and their involvement with the ABC Patient Advisory Council. This is a moderate strength.

#### Weaknesses:

- The initial formulation of research questions relied on national leaders, and less on regional stakeholders and patients, a minor weakness.

**A. Score 7 – Unsatisfactory, a few strengths and at least one major weakness**

**B. Score 2 – Excellent, only minor, very fixable weaknesses**

**Answer: The correct answer is B.** A criterion score of 2 would best align with the sample written critique because there are several solid strengths listed and only one minor weakness. A criterion score of 7 would not align with the written critique because the reviewer has only listed one minor weakness (the formulation of research questions did involve stakeholder input, just not at the regional level). The applicant has worked with a patient advisory council and lists specific groups that will collaborate on dissemination; these are solid strengths.

## Writing an Overall Narrative

The overall narrative should provide a high-level summary of the strengths and weaknesses of the application as a whole. The overall summary should be in paragraph format, instead of in a bulleted list, and should describe the likelihood that the project would exert a sustained, powerful influence on healthcare and patient-centered outcomes.

The overall narrative is a great place to give general feedback to the applicant. Keep in mind that your comments under each criterion should not simply be repeated in this section, because this would not be useful for the applicant. We want reviewers to provide a narrative about how the various strengths and weaknesses affect their overall evaluation of the application.



One way to think of writing the overall narrative is to consider it as an “elevator brief.” If you had to cover the most salient points on the merits of the application in the time it would take to ride an elevator 10 floors, what would you say?

## Assigning an Overall Score

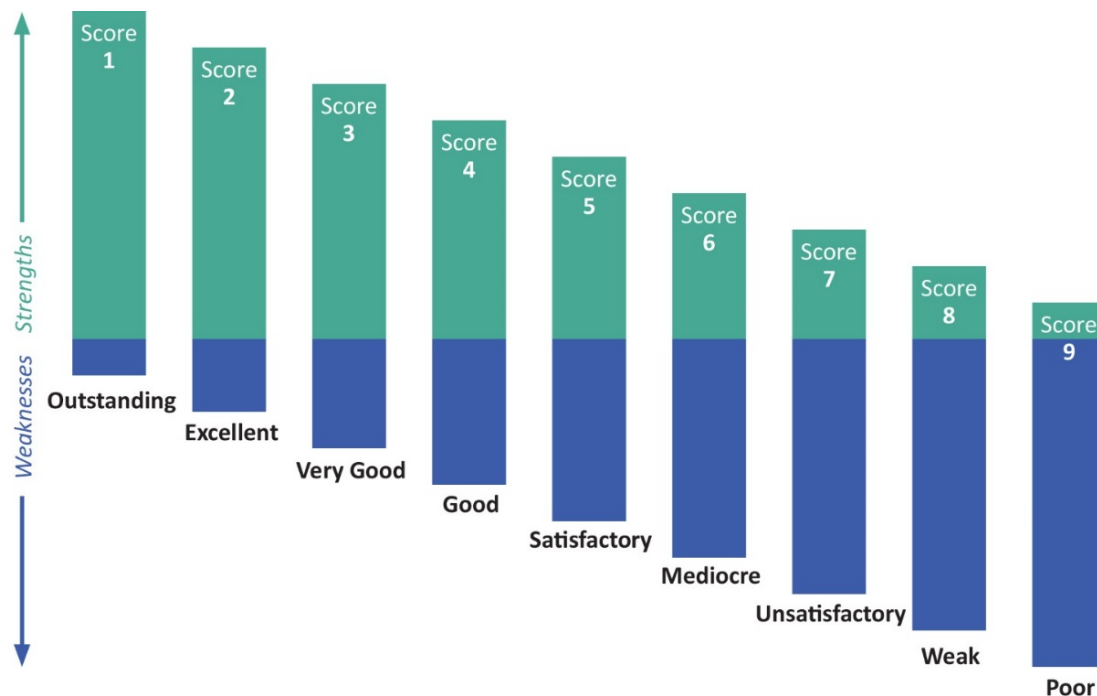
The overall score:

- Takes into consideration the entire application's strengths and weaknesses
- Accounts for all of the criteria you considered but is not an average of individual criterion scores
- Should not fall outside of the range of scores given for each criterion (for example, if you rated the criteria 3-8, do not assign an overall score of 9)



To assign an overall score, use the same 1 to 9 scale you used to score each individual criterion where 1 is the best possible score, and 9 is the worst possible score.

## Merit Review Scoring Chart: Overall Score



## Revising and Resubmitting a Critique

Almost every reviewer, no matter how experienced, will receive guidance and feedback from his or her Merit Review Officer for how to clarify comments in his or her critiques, especially for the first critique.

When revising and resubmitting a critique, please ensure that you:

- Thoroughly review the feedback provided by your MRO
- Pay close attention to all feedback to ensure that you address all questions and concerns
- Ask questions to ensure that you have a clear understanding of the specific areas of needed improvement

Prior to the In-Person Panel Review, MROs will review all critiques. This is a critical step in our review process.

## Chapter 5. In-person Panel Meeting

### Overview

The In-Person Panel Review provides an opportunity for reviewers to discuss the strengths and weaknesses of the applications selected for discussion after the Preliminary Review phase. The full panel has an opportunity to ask questions and fully discuss each application, with facilitation by the Chair. This discussion helps reviewers provide scores for the applications that they were not assigned to review.

- Reviewers receive a brief orientation to the panel process and group rules.
- The Panel Chair introduces each application.
- Reviewers assigned to each application make individual oral presentations, describing the strengths and weaknesses that drove their scores of the application.
- Members of the full panel ask questions and discuss the application.
- The Chair records an oral summary of the panel discussion.
- Each panel reviewer provides a final overall score for the application.

### Preparing for the In-Person Panel Review

Before the In-Person Panel Review:

- ☐ Review the list of applications that will be discussed at the In-Person Panel Review. Your Merit Review Officer will send you this list in discussion order before the panel meeting.
- ☐ Review all of the written critiques and preliminary scores for all of your assigned applications
- ☐ Prepare your brief oral presentation using main strengths and weaknesses from your written critique.
- ☐ Review the abstracts and written critiques for the other applications on the discussion order.



Becoming familiar with all of the applications and their critiques will help you understand and participate in the discussion, as well as score the applications after each discussion.

### Panel and Reviewer Roles

The following people will be in the room during the In-Person Panel Review

#### **Panel Reviewers** (not PCORI Staff members)

- About half of the panel reviewers will be scientists and the other half will be patients and stakeholders

#### **Merit Reviewer Officer (MRO)** (PCORI staff member)

- Serves as main PCORI point of contact for reviewers
- Provides guidance to reviewers on PCORI process and policy
- Presents brief orientation to panel proceedings
- Answers panel members' questions about PCORI and the review process

<ul style="list-style-type: none"> <li>Records notes of the panel discussion, which are also incorporated into the final summary statement</li> </ul>
<b>Panel Manager</b> (PCORI staff member) <ul style="list-style-type: none"> <li>Serves as administrative point of contact for reviewers</li> <li>Provides support for reviewers in the online scoring system and other technical needs</li> </ul>
<b>Panel Chair</b> (not a PCORI staff member; usually an experienced senior-level scientist) <ul style="list-style-type: none"> <li>Introduces and facilitates discussion of each application               <ul style="list-style-type: none"> <li>Helps clarify key strengths and weaknesses of applications</li> <li>Ensures that scores and verbal critiques align</li> <li>Clarifies points of scoring disparities among reviewers</li> </ul> </li> <li>Records an oral summary of the discussion of each application</li> </ul>
<b>Observers</b> <ul style="list-style-type: none"> <li>PCORI program staff members often attend the in-person meeting so they can better understand the projects they will recommend for funding</li> <li>Mentors are available on-site to provide support for patient and other stakeholder reviewers if needed</li> </ul>

## Inside the In-Person Panel Review

Click [HERE](#) or below on the embedded video to watch a simulation of an in-person panel review:





## Preparing Panel Presentations of your Assigned Critiques

Panel discussion gives reviewers an opportunity to participate in a thoughtful discussion about the strengths and weaknesses of the selected applications. Reviewers should familiarize themselves with all applications on the discussion list in advance, even if they were not assigned to review them. Your presentation should cover the main strengths and weaknesses of the applications you reviewed.

- Start by thinking about what other reviewers will need to know about the strengths and weaknesses of each application, based on your evaluation, in order to score the application.
- Review the written critiques that were submitted by the other three reviewers on your assigned applications. This will help you identify topics that are likely to be discussed in the panel.

Remember, you have about **two (2) minutes** to present. Be clear and to the point. Do not summarize the application, but you can add key details that the Chair may not have covered in his or her introduction or that have not been provided by the reviewers who have already presented.

## Panel Review Discussion Tips

Making sure that the In-Person Panel is a welcoming, safe, and open environment requires more than coming prepared to discuss your critique—it also requires being a thoughtful, respectful, and engaged participant. Here are some tips that can help you manifest these qualities in this stage of the process.

### Avoid Repetition

Avoid repetition of points made by previous reviewers. This will keep the discussion moving and allow adequate time to review each application on the schedule.

- If you agree with a reviewer's perspective, you can summarize why you agree:
  - "I agree with the previous reviewer about..."
- If you disagree with the reviewer's viewpoint, be sure to voice your views and disagree with the idea, not the person:
  - "I view this differently because..."
  - "I would like to add these important strengths/weaknesses that haven't been mentioned..."

### Maintain a Productive Discussion

A critical part of the In-Person Panel Review is a productive discussion. As a panel reviewer, you can help maintain a productive discussion by:

- Respecting all viewpoints
- Engaging in active listening
- Asking good questions
- Using words such as good, bad, better, or worse to describe scores, instead of high or low; this is to avoid confusion since low numerical scores indicate high quality
- Minimizing the use of acronyms and jargon
- Being culturally aware/sensitive

### Respect all Viewpoints

Although you may not agree with what other panel reviewers say, it is important that you:



- Listen to what others have to say before expressing your viewpoint
- Refrain from insulting, name-calling, criticizing, or putting down a panel member
- Build on one another's comments
- Work towards shared understanding
- Be mindful of cultural differences and the needs of different patient populations
- Be respectful of the different constituencies around the table; each person brings a valuable viewpoint that helps PCORI identify and fund the best research and projects to improve patient outcomes

### Practice Active Listening

A successful panel member uses active listening in order to check assumptions, clarify his or her thoughts, and understand others.

Here are a few active listening strategies that you can use during the In-Person Panel Review:

- Mentally commit to listening
- Avoid distractions
  - Turn off mobile devices
  - Avoid answering email and visiting web sites not related to the applications
  - Refrain from side conversations
- Take notes while you listen
- Jot down questions that you would like to ask
- Face the person who is speaking

### Ask Thoughtful Questions

Thoughtful questions are the key to a productive discussion. Questions can be used to probe for deeper analysis, get clarifications or examples, explore implications, or respectfully challenge opinions or ideas.

Examples of common In-Person Panel Review questions include:

- Can you tell me more about the engagement plan?
- Are end-users engaged and willing to disseminate the research findings?
- Can a clinician or clinical administrator in the room talk about how well this intervention could be implemented in clinical practice?

### Use Strength and Weakness Modifiers

Communicating the magnitude of the strengths and weaknesses you found in an application will provide useful context to the discussion. Use the major-moderate-minor modifiers from your critiques to indicate whether weaknesses, in particular, are fixable or not.



## Appendix 1. COI/Expertise

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### **INFORMATION FOR PCORI MERIT REVIEWERS ON CONFIDENTIALITY, CONFLICT OF INTEREST, AND RATING EXPERTISE**

(February 2, 2015)

[Click here to access PCORI's guidance on conflict of interest and rating expertise online.](#)

The Patient-Centered Outcomes Research Institute (PCORI) welcomes a broad array of stakeholder reviewers to participate in the evaluation of research applications ("Reviewers"). Reviewers are essential to helping PCORI fulfill its mission and to fund research that is both scientifically rigorous and truly patient centered. Given the important role of Reviewers in PCORI's application selection process, PCORI requires Reviewers to abide by a number of policies and commitments that support a fair and objective merit review process. This document provides information about three important obligations of any Reviewers participating in PCORI's merit review process: A) Confidentiality and Non-Disclosure; B) Conflict of Interest; and C) Rating Expertise.

#### **A. CONFIDENTIALITY AND NONDISCLOSURE**

Maintenance of confidentiality is a critical component of merit review. All Reviewers are required to agree to the terms of a PCORI Non-Disclosure Agreement ("NDA") before they participate in merit review activities. By agreeing to the NDA, Reviewers confirm that they will preserve and not disclose confidential information and that they will not use any confidential information except as required to perform the responsibilities of merit review.

In the context of preserving the confidentiality of the merit review, it is important that materials reviewed before or during the merit review meeting as well as discussion content of the merit review meeting not be disclosed to anyone at any time before, during, or after the merit review meeting except as part of the application evaluations during the actual meeting. Confidential information includes any information that has not been made public, such as information about applications, number of applications discussed, research topics, negative or positive outcomes of the meeting, and any personal information about other reviewers disclosed as part of the merit review process.

In order to maintain the integrity of the review process, Reviewers must not contact any applicants for whom they have access to application material. Merit assessments of applications must be completed using only the information provided by the applicant at the time of submission. Reviewers must not request additional information from applicants once the application has been submitted. If Reviewers need assistance in reviewing applications, he or she may contact their Merit Review Officer (MRO) for help or clarification.

Reviewers must not use social media or other electronic media tools during merit review panel discussions or activities. Reviewers must not discuss the review with other reviewers absenting themselves from the room for conflict of interest (COI) reasons, or with reviewers of any other panel. If a Reviewer is asked to disclose information about the contents of an application or about the nature of review discussions, he or she must inform the person making the request that merit review participants





may not disclose such information and must inform the panel MRO that he or she has been contacted directly.

It is the responsibility of each Reviewer to safeguard the confidentiality of review material while it is in his or her possession, not to share the material with other persons, and to properly dispose of both hard copy and electronic materials at the conclusion of the panel meeting or when directed to do so.

The actions outlined above are among the steps that a Reviewer should take to fulfill his/her obligations under the Non-Disclosure Agreement.

## **B. CONFLICT OF INTEREST (COI)**

PCORI's Board of Governors has adopted a Conflict of Interest Policy that applies to all PCORI activities, including merit review of applications for research funding. A copy of the PCORI Conflict of Interest Policy is provided to all Reviewers and is available on PCORI's website. The information here is intended to help Reviewers understand how PCORI implements and interprets the Conflict of Interest Policy in the context of merit review activities, including how conflicts of interest should be disclosed and addressed.

PCORI requires each Reviewer to disclose conflicts of interest as a condition of participating (or being considered for participation) in merit review. PCORI relies on the professionalism and integrity of each Reviewer to identify any financial or personal associations that have the potential to bias or have the appearance of biasing the Reviewer's activities and decisions in merit review. The *appearance or perception* of bias can be enough to undermine the public trust. All efforts should be made to identify all associations that may give rise to a conflict of interest. **It is important that each Reviewer submit COI disclosures by the requested deadline so that application assignments can be made to the full panel in a timely manner.**

A COI in merit review exists when a Reviewer or a close relative or professional associate of the Reviewer has a financial or personal association related to an application, including the applicant and investigators, which may bias the evaluation of the application or create the perception of bias. The term "close relative" includes a parent, spouse, domestic partner, or child. Depending upon factors like financial dependency, cohabitation, and family history, sometimes other relatives could also be considered "close relatives." Reviewers should use their best judgment in determining when a familial relationship is close enough that the relative's associations could bias or appear to bias their decision making.

Financial associations often involve relationships or interests that may cause a Reviewer to have a financial stake in whether certain applications are selected for PCORI funding. Regardless of the level of financial involvement or other interest, if a Reviewer feels, or may be perceived as being, unable to provide an objective evaluation, he or she may not participate in the review of the application. Personal associations can be either professional or non-professional relationships with the applicant, the investigator(s), or a person or organization whose interests would be affected by the project under review.

For COI purposes, applicant and investigators include the roles listed below.

- **Applicant:** Principal Investigator (PI) listed in the application
- **Investigator:** All active participants (PI, co-PI, research partner, collaborator, consultant, subcontractor, and other senior/key personnel) listed in the application





Based on the nature of the COI, it may be handled at either the PFA or application level. Please review the following examples of COI and how to handle them at each level. While the following are provided as general examples, PCORI reserves the right to address conflicts of interest on a case-by-case basis.

### **1. PCORI Funding Announcement (PFA) Level COI**

Certain conflicts of interest can be viewed as involving such powerful influences or deeply-felt relationships that they have the potential to bias (or appear to bias) a Reviewer's evaluation of *all of the applications* submitted in response to a PFA. For example, a Reviewer might hold so large a financial interest in one application that it would not reasonably appear the Reviewer could impartially evaluate competing applications that have been submitted in response to the same PFA.

If any of the following types of conditions apply, the Reviewer cannot serve on panel reviewing applications received in response to a particular PFA.

- The Reviewer is an investigator in an application on a PFA reviewed by the panel.
- The Reviewer has a close relative who is an investigator on an application reviewed by the panel.

There may be other circumstances, in addition to those identified above, in which a Reviewer feels unable to serve impartially on a panel evaluating applications submitted in response to a specific PFA, or in which it might appear that the Reviewer cannot do so. The Reviewer should report such conflicts to the panel's MRO or the Associate Director, Merit Review and self-recuse from participating on the panel for applications related to the specific PFA.

### **2. Application Level COI**

In contrast to PFA-level conflicts of interest, the potential for bias created by other types of conflicts may be confined to the review of a particular application. If any of the following types of conditions apply, the Reviewer can serve on the panel but must recuse himself or herself from the discussion and scoring of the application. The Reviewer will not have access to that application or participate in the discussion or scoring of the application, and the recusal will be documented.

- The Reviewer or his/her close relative currently receives, or within the past 12 months has received, medical care from the applicant entity, principal investigator, or other individuals identified in the application as key personnel.
- The Reviewer or his/her close relative currently has a significant personal or professional relationship with the applicant entity, principal investigator, or other key personnel. (Note that sometimes negative relationships – for example, a professional rivalry – can be a significant personal or professional relationship.)
- The Reviewer or his/her close relative provides, or within the past 12 months has provided, technical assistance to the applicant entity, principal investigator, or other key personnel in any of the following ways:
  - Assistance with preparing or submitting the application.

- Providing the applicant entity, principal investigator, or other key personnel with resources for the application that are not freely available to others in the research community -- e.g., specialized data analysis, service, or confidential material.

Note that providing resources that are freely available to anyone in the scientific community (e.g., letter of support, service, equipment, data, or other material) would not be considered a conflict of interest.

- The Reviewer or his/her close relative is employed at the applicant entity.
  - For multi-campus State institutions, a Reviewer who is primarily employed at one campus of the institution is not considered to have a conflict of interest with respect to an application submitted by another campus of the same institution provided that the reviewer has no institutional responsibilities that would significantly affect the other campus.
  - For private institutions and affiliates, a Reviewer who is primarily employed at one affiliate of the institution is not considered to have a conflict of interest with respect to an application submitted by another affiliate of the same institution provided that the reviewer does not have institutional responsibilities that would significantly affect the other affiliate.
- The Reviewer or his/her close relative is actively negotiating, or has an agreement about future employment at the applicant entity.
- The Reviewer or his/her close relative has a professional relationship other than employment with an applicant entity – e.g., consulting or other vendor contract, service on board of directors, service on advisory committee.
- The Reviewer or his/her close relative could receive professional gain or advancement (e.g., publications, scientific prizes, or academic appointments) as the direct result of the application funding decision.
- The Reviewer or his/her close relative could receive a financial benefit exceeding \$10,000 per year from individuals or companies that own or manufacture medical treatments, services, or items that the application proposes to study.

### **C. RATING EXPERTISE**

PCORI merit review is designed to incorporate the perspective of scientists, patients, and other healthcare stakeholders, including having merit review panels that incorporate appropriate areas and levels of expertise. To support appropriate composition of merit review panels, Reviewers will be notified when application abstracts and lists of key personnel are available and accessible in PCORI Online. When reading the application title and abstracts, Reviewers should indicate for each application whether their expertise matches with the content of the application and whether that content match is *high, medium, low, or none*.



For Scientific reviewers, PCORI expects reviewer rating of expertise for specific applications to be made on the basis of the individual's research expertise and science training. Please note that expertise is an indication of the extent of the reviewer's subject-matter expertise and is not a reflection of his or her willingness to review an application.

It is not necessary for any patient or stakeholder reviewer to indicate high, medium, or low expertise on applications. Patients and stakeholders provide critical and important perspectives during the review process, independent of technical expertise. If patient or stakeholder reviewers do have specific disease expertise, however, it is appropriate to indicate this in the system. Please also note that the ratings are used to match applications to reviewers and are not a reflection of the relative importance of any reviewer on the panel.

Please use the following descriptors to indicate Rating Expertise:

Rating	Description For Scientists
<b>High</b>	The Reviewer is able to evaluate the application with little or no need to make use of background material or the relevant literature. The Reviewer has likely published in areas closely related to the science presented in the application.
<b>Medium</b>	The Reviewer has most of the knowledge to evaluate the application but will require some review of relevant literature to fill in details or increase familiarity with the system employed. The Reviewer may employ similar methodologies in his or her own work but may need to review the literature for recent data relevant to the application.
<b>Low</b>	The Reviewer understands the broad concepts but is unfamiliar with the specific methodology or other details, and reviewing the application would require considerable preparation.
<b>None</b>	The Reviewer has only superficial or no familiarity with the concepts and methodology described in the application.

**It is important that each Reviewer submit the expertise information by the requested deadline so that application assignments can be made to the full panel in a timely manner.**

#### **D. ENFORCEMENT AND CONCLUSION**

If a Reviewer violates his or her obligations as a reviewer, including relating to Confidentiality, Conflicts of Interest, or Rating Expertise, PCORI may implement sanctions or corrective measures, as appropriate. These sanctions may include: removing the Reviewer from the panel; notifying other panel members of the violation; initiating an internal investigation of the Reviewer's conduct and its consequences; and disqualifying the Reviewer, indefinitely or for a specified period, from participating as a PCORI reviewer.

If any Reviewer has any questions about the information outlined in this document on Confidentiality and Non-Disclosure, Conflicts of Interest, or Rating Expertise, please contact your panel's MRO or the Associate Director, Merit Review ([tafari@pcori.org](mailto:tafari@pcori.org)).

PCORI is grateful for the important contributions that Reviewers make to PCORI's application selection process.

## Appendix 2. Human Subjects Checklist

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### How to Evaluate Human Subjects Protections

January, 2015

[Click here to access detailed guidance for evaluating Human Subjects Protections online.](#)

PCORI requires that research involving human subjects include adequate safeguards. Institutional Review Boards selected by awardees have authority for ensuring the protection of human subjects. PCORI asks merit reviewers to assist with identifying any issues with protection of human subjects that PCORI staff should review with potential funding awardees.

Human subjects protections concerns should not be factored into the application's score, but they should be flagged for PCORI staff by checking the appropriate box and providing written comments in PCORI Online.

The four bullets below provide guidelines that may be helpful to merit reviewers in identifying concerns that PCORI staff should be aware of for any potential awardee. Please note any concerns regarding human subjects protections in your review.

- **Risks to Human Subjects**

Does the application adequately describe human subjects involvement, characteristics, and design; sources of material; and potential risk, including:

- Description and justification for the proposed involvement of human subjects
- Characteristics of subject population (number, age range, and health status, e.g., physical and cognitive functioning)
- Inclusion/exclusion criteria
- Rationale for involvement of vulnerable populations (e.g., fetuses, pregnant women, children, prisoners, institutionalized individuals)
- Role of collaborating sites where research will be performed
- Description and justification of research procedures (including dosage and frequency of intervention)
- Description of what research material, data, and information will be collected
- Access to personally identifiable information collected and retained
- Management and protection of materials and information
- All potential risks to subjects (e.g., physical, psychological, financial, legal) including likelihood and seriousness
- Any alternative treatments or procedures available to subjects in lieu of participation

- **Adequacy of Protection against Risks**

Does the application adequately describe recruitment, informed consent, and protections against risk, including:

- How subjects will be recruited
- Description of informed consent and parental permission and assent
- Waiver for any elements of consent



- How risks described previously, including privacy and confidentiality, will be minimized
  - Additional protections for vulnerable populations
  - Ensuring necessary medical/professional intervention for adverse events
- **Potential Benefits of the Proposed Research to Human Subjects and Others**
  - Does the application adequately describe how potential risks to subjects appear reasonable in relation to anticipated benefits?
- **Importance of the Knowledge to Be Gained**
  - Does the application adequately describe how potential risks to subjects appear reasonable in relation to the importance of the knowledge that may result from the study?