



## **INFORMATION FOR PCORI MERIT REVIEWERS ON**

### **CONFIDENTIALITY, CONFLICT OF INTEREST, AND RATING EXPERTISE**

(February 2, 2015)

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
<b><i>High</i></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 Merit Review Officer.

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