

## Patient-Centered Outcomes Research Institute

### Conflict of Interest Rules for Research Funding

Approved by Board of Governors June 19, 2012

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The primary goal of the Patient-Centered Outcomes Research Institute (PCORI) Conflict of Interest (COI) policy is to safeguard the integrity and public trust in the process for funding patient-centered outcomes research (PCOR). The PCORI Board of Governors (Board) shall take all necessary actions to ensure that the grant review and award process protects the interests of patients, other stakeholders, and the public. To the greatest extent possible, the Board shall adopt policies and procedures to ensure that the grant review and award process is fair and does not adversely affect the quality of the research produced. The peer review and scoring of applications for funding, by independent peer review committees; the adherence to national priorities and a Board-approved research agenda; and the Board's final funding authority provide assurance that only the most responsive research proposals will be identified and funded.

An additional, important goal is to create policy and practice that allow researchers who are current or future members of PCORI's Methodology Committee (MC) and who wish to be eligible to compete for PCORI funding to do so, while ensuring that they have no knowledge obtained during their PCORI service that could advantage them unfairly in the competition. It serves the interests of PCORI and the public for MC members to participate in the competitive process so that the United States benefits from these individuals' research talent.

### Conflict of Interest Rules for PCORI Research Funding

- Members of the Board are ineligible to compete for PCORI research funding.
- Close relatives of Board members, including spouses/domestic partners/children, are ineligible to compete for PCORI research funding.
- The MC will be organized into two subcommittees:
  - A Methodology PCORI Funding Announcements (PFAs) Development Subcommittee (Board liaisons and others selecting to serve voluntarily) will be formed to work with the Board, the Executive Director, and the PCORI staff in developing research priorities and a research agenda. This work will include participation in preparation of funding announcements, statements of work for contract solicitations, and other methodological consultation as needed. This subcommittee will be excluded from eligibility to compete

for PCORI research funding.

- A Methodology Advisory Subcommittee will be formed to provide high-level advice to the Board, the Executive Director, and the PCORI staff with respect to methodological matters (i.e., input). This group will be prohibited from participating in creating funding announcements, statements of work for prospective PFA contracts, peer review of extramural proposals, etc. (i.e., involvement).
- The names of these two subcommittees and the use of the term “subcommittee” may subsequently be changed to reflect how the two groups actually function and relate to one another. The important feature is that there will be two distinct groups: one eligible to apply for PCORI funding and the other not eligible. Once established, “firewall” protections will be put into effect that prevent the eligible group from obtaining access to any information that would constitute an unfair advantage. MC members will be permitted to change subcommittees on a permanent basis if the situation changes.
- Firewall policies and procedures will be established between the two subcommittees and between the Advisory Subcommittee and other elements of PCORI.
- PCORI staff assigned to the two subcommittees shall adhere to all firewall policies and procedures.
- Members serving on the Advisory Subcommittee will be allowed to compete for PCORI funding.
- Current and future members of the MC will declare which sub-committee they will join.
- Advisory Subcommittee members are declared ineligible for the round of PFAs released in May 2012.
- Advisory Subcommittee members are eligible for all future PFAs as long as they do not breach the firewalls or are deemed by the PCORI Board of Governors to have been involved in the activities pursuant to a specific PFA.
- The Methodology PFA Development Subcommittee includes the Chair and Vice Chair of the MC; National Institutes of Health (NIH) and Agency for Healthcare Research and Quality (AHRQ) employees serving on the MC and who, at times, stand in for their NIH and AHRQ member of the PCORI Board of Governors; and others on the MC who voluntarily agree to serve on the Methodology PFA Development Subcommittee.
- Close relatives (spouses, significant others, dependents) of Board, MC members, or PCORI staff are excluded from competing for PCORI funding to the same extent as their respective Board, MC, or PCORI staff member.

- All Board members, MC members serving on either the PFA Development Subcommittee or the Advisory Subcommittee, and PCORI staff are expected to adhere to strict confidentiality agreements, keeping any information obtained solely during closed meetings of Board, MC, or with PCORI staff members confidential at all times.
- MC members and Board members, in their roles as teachers and mentors, may continue to provide scientific advice in framing research questions; preparing research proposals; and forming research teams to respond to research funding opportunities, including PCORI funding opportunities, provided they limit their mentoring to publicly available information in accordance with their confidentiality agreement(s). Board members, members of the Methodology PFA Development Subcommittee, and PCORI staff may not be listed as co-investigators, advisors, or consultants in grant applications at any time. Members of the Methodology Advisory Subcommittee are precluded from serving in these roles for the round of PFAs released in May 2012, as well as for any future PFA on which they are determined by the Standing Committee on Conflict of Interest (SCCOI) and Board to be conflicted. Such applications shall be subject to disqualification.
- Members of the PCORI community—Board, staff, and NC—will have restrictions on eligibility for funding after they resign from their PCORI roles. The policy distinguishes between two types of funding opportunities: broad funding announcements that address the full range of a national priority and targeted funding opportunities that are narrower.
- In situations where PCORI Board members, staff members, or MC members were directly involved in developing a targeted PFA (i.e., involvement beyond voting to release it, including, but not limited to, the drafting of language and development of evaluation criteria), they will be ineligible to compete for all releases of such targeted PFA for the PFA’s lifetime.
- PCORI Board members, staff members, and MC PFA Development Subcommittee members will be ineligible to compete for general (broad) PCORI funding announcements for one year from the effective date of their resignation.

Notes:

- Note that MC members who are eligible for PCORI funding during their service (and are appropriately firewalled) will also be eligible after they resign.
- The rules that apply to Board members, staff members, and MC members also apply to their close relatives.
- For each forthcoming PFA, Staff (Chief Scientific Officer) will be required to designate whether the PFA is considered “targeted” or “general” for purpose of determining future eligibility of members of the PCORI community.

- No waivers to this policy will be allowed; in the event that there are no qualified responses to funding announcements, the staff will take steps (e.g., hold educational training workshops) to increase the quality of future proposals.

## Elements to Be Included in a Formal PCORI Conflict of Interest Policy

The PCORI SCCOI is responsible for providing the Board with additional recommendations concerning formal COI policies, future changes to the waiver policy, firewall protection policies, and procedures to implement such protections.

The COI policy must identify the balance between eligibility and restrictions on eligibility for PCORI funding that assures the highest quality of research to best serve the interests of patients and the public. In finding this balance, the policy seeks to allow PCORI MC members to be eligible to apply for PCORI research funding only when they would not have an unfair advantage in competition for such funding as a consequence of their activities on the MC.

An unfair advantage may result from: (a) MC members' *involvement* in the development of PCORI priorities, research agenda, or funding announcements; (b) MC members' *involvement* in identifying gaps in methodological standards and/or comparative clinical effectiveness knowledge and/or outcomes research that subsequently become PCORI research funding opportunities; and (c) MC members' *involvement* in recommendation of methodological standards in the conduct of PCOR.

**“Involvement”** is defined as participation during closed meeting sessions of the Board, MC, or PCORI staff during which final decision making or preparation of research priorities, a research agenda, or specific PCORI funding announcements occur. **“Involvement”** implies advance knowledge of these deliverables prior to their public release.

**“Input”** is defined as providing information, suggestions, or recommendations, given in closed or open meeting sessions of the Board, MC, or to staff in response to requests for expert opinion or advice in the development of research priorities, a research agenda, or specific funding announcements. **“Input”** may be sought from MC members, from non-MC member experts in various disciplines, as well as from many stakeholder groups via engagement efforts and solicitations for public comment.

Examples of unfair advantage associated with **“involvement”** are largely overcome by: (a) transparency of process and deliberations; (b) sufficient intervals between public release of MC recommendations and members' submission of grant applications so as to allow enough time for all applicants to benefit equally from public knowledge; (c) exclusion of MC members from PCORI deliberations and venues where they might obtain information or exercise undue influence in the development of policy that could favor their applications for funding; (d) disclosure of possible conflicts of interest and recusal from Committee voting in areas of possible conflict; and (e) disqualification of individual MC members from applying for funding

in response to specific funding announcements in which the individual MC member has had involvement in the development of that specific funding announcement—such disqualification shall be for all funding cycles of that specific PFA.

### **MC-Specific Elements to be Included in a Formal COI Policy**

1. As soon as practical for current PCORI MC members, and at time of appointment for future MC members, each member shall be asked to declare in writing whether or not he or she wishes to be eligible to apply for PCORI funding opportunities and/or eligible to assist others in submitting applications in response to PFAs.
2. MC members who forego eligibility to apply for or to participate in responses to PFAs shall be considered the same as MC Board liaisons for purposes of being involved in the preparation of PFAs. These members will serve on the Methodology PFA Development Subcommittee of the MC.
3. MC members who declare a desire to maintain eligibility for PCORI funding opportunities shall have restricted access to closed meeting sessions of the PCORI Board and closed meeting sessions of PCORI staff. Such MC members may provide input (as defined above), but may not be involved in the development of any PFA for which they intend to make application and, further, shall be required to disqualify themselves from votes of the MC as they pertain to recommendations to the Board concerning PCORI's national priorities, research agenda, and/or funding announcements. Staff will develop and implement a comprehensive firewall policy. These members will serve on the Methodology Advisory Subcommittee of the MC.
4. All MC members may continue to be full voting participants in the recommendation of methodological standards for the conduct of PCOR and in the processes of recommending improvements to those standards over time. To the extent that new or improved standards are recommended for adoption by the PCORI Board, MC members who maintain eligibility to apply for PCORI research funding shall be expected to disclose to the Board their intent to apply for PCORI funding of research that will utilize the new standards. Under that circumstance, the Board, at its sole discretion, may suspend an MC member's eligibility for the first funding cycle utilizing the new standards.
5. Current MC members who desire eligibility to apply for PCORI funding opportunities, and who satisfy the firewall provisions of Item #3 above, shall become eligible to apply for PCORI funding announcements after the round of PFAs released in May 2012. For PFAs released after May 2012, MC members shall only be precluded from submitting applications for funding in response to those PFAs wherein they have been involved in development of said PFA. In that circumstance, the disqualification shall be for all funding cycles of that specific PFA. In the event MC members who are *not* members of the MC PFA Development Subcommittee are willing to permanently forego eligibility to targeted PFAs, they can be involved in development of one (or more) targeted PFAs. Their ineligibility applies only to those targeted PFAs which they are directly involved in

developing. Whenever an MC member who is not a member of the MC PFA Development Subcommittee is engaged to help develop a targeted PFA, such engagement shall be communicated to the Chair of the SCCOI. This member's participation and ineligibility for all funding cycles of that PFA shall be presented at the next regularly scheduled meeting of the SCCOI and included in the minutes of that meeting.