

Patient-Centered Outcomes Research Institute

Board of Governors
Teleconference and Webinar

June 19, 2012



Call to Order and Welcome

Eugene Washington, MD, MSc, Board Chair
Joe V. Selby, MD, MPH, Executive Director

PCORI Board of Governors Teleconference and Webinar
Tuesday, June 19, 2012



Presentation of Draft Conflict of Interest Rules for Research Funding

Larry Becker, PCORI Board Member
Chair, PCORI Standing Committee on Conflict of Interest

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Conflict of Interest Policy Goal

- Safeguard the integrity and public trust in the process for funding patient-centered outcomes research
- Create policy and practice that allows researchers who are current or future members of PCORI's Methodology Committee 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.

Standing Committee on Conflict of Interest (SCCOI)

- Will present today for the Board's consideration specific rules to govern eligibility for PCORI funding.
- Materials discussed today are available in document form on the PCORI website:

www.pcori.org/meetings-events/event/special-board-meeting-webinar

- This slide presentation is a reference for discussion and is not a substitute for the documents provided on the PCORI website.

Proposed PCORI Conflict of Interest Rules for PCORI Research Funding

- Members of the Board of Governors (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.

Proposed PCORI Conflict of Interest Rules for Research Funding

- The Methodology Committee will be organized into two subcommittees:
 - A Methodology **Executive Sub-committee** (Board liaisons and others selecting to voluntarily serve) 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 Sub-committee** 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 contracts, peer review of extramural proposals, etc. (i.e., involvement).
 - The names of these two sub-committees, and the use of the term “sub-committee,” 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. Methodology Committee members will be permitted to change sub-committees on a permanent basis if their situation changes.

Proposed PCORI Conflict of Interest Rules for Research Funding

- Firewall policies and procedures will be established between the two subcommittees, and between the Advisory Sub-committee and other elements of PCORI.
- PCORI Staff assigned to the two sub-committees shall adhere to all firewall policies and procedures.
- Members serving on the Advisory Sub-committee will be allowed to compete for PCORI funding.
- Current and future members of the Methodology Committee will declare which subcommittee they will join.
- Advisory Sub-committee members are declared ineligible for the round of PCORI Funding Announcements (PFAs) released in May 2012.

Proposed PCORI Conflict of Interest Rules for Research Funding

- Advisory Sub-committee members are eligible for all future PFAs so 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 Executive Sub-committee includes the Chair and Vice Chair of the Methodology Committee, NIH and AHRQ employees serving on the Methodology Committee and who at times stand in for their NIH and AHRQ member of the PCORI Board of Governors, and others on the Methodology Committee who voluntarily agree to serve on the Methodology Executive Sub-committee.

Proposed PCORI Conflict of Interest Rules for Research Funding

- Close relatives (spouses, significant others, dependents) of Board, Methodology Committee members, or PCORI staff are excluded from competing for PCORI funding to the same extent as their respective Board, Methodology Committee, or PCORI staff member.
- All Board members, Methodology Committee members serving on either the Executive or the Advisory sub-committees, and PCORI staff are expected to adhere to strict confidentiality agreements, keeping any information obtained solely during closed meetings of the Board, Methodology Committee, or with PCORI staff members confidential at all times.

Proposed PCORI Conflict of Interest Rules for Research Funding

- Methodology Committee 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 Executive 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 PCORI Funding Announcements (PFA) released in May 2012, as well as for any future PFA on which they are determined by the SCCOI and Board to be conflicted. Such applications shall be subject to disqualification.

Proposed PCORI Conflict of Interest Rules for Research Funding

- If a Board member or PCORI staff member resigns from their PCORI role, they and their respective close relatives are ineligible to compete for PCORI funding for one year from the effective date of their resignation.
- If a Methodology Committee member resigns, they shall not be eligible any sooner than a similarly situated Methodology Committee member who is eligible to compete for PCORI funding.
- 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.

Board Discussion of Draft Conflict of Interest Rules for Research Funding

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Proposed Action

The PCORI Board of Governors adopts
the rules proposed today
by the Standing Committee on Conflict of Interest
to govern eligibility for PCORI research funding.

Board Vote on Draft Conflict of Interest Rules for Research Funding

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Board Discussion of Additional Conflict of Interest Policy Issues

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Wrap-Up and Adjournment

Eugene Washington, MD, MSc, Board Chair
Joe V. Selby, MD, MPH, Executive Director

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