

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

CONFLICT OF INTEREST POLICY *

Article I Definitions

1. **Conflict of Interest.** The term “conflict of interest” means an association, including a financial, business, or personal association, that has the potential to bias or has the appearance of biasing an individual’s decisions in matters related to the Patient-Centered Outcomes Research Institute (PCORI) or the conduct of PCORI activities.

2. **Real Conflict of Interest.** The term “real conflict of interest” means any instance where a member of the PCORI Board of Governors, the PCORI Methodology Committee, a PCORI Advisory Panel, or the PCORI staff, or a “close relative” of such member, has received or could receive any of the following:

- a. A direct financial benefit of any amount deriving from the result or findings of a study conducted by PCORI;
- b. A financial benefit from individuals or companies that own or manufacture medical treatments, services, or items to be studied by PCORI that in the aggregate exceeds \$10,000 per year. For purposes of the preceding sentence, a financial benefit includes honoraria, fees, stock, or other financial benefit and the current value of the member or close relative’s already existing stock holdings, in addition to any direct financial benefit deriving from the results or findings of a study conducted by PCORI; or
- c. A direct financial benefit of any amount deriving from a transaction or arrangement entered into by PCORI.

3. **Close Relative.** The term “close relative” means a spouse, parent (including in-laws), child or sibling.

Article II Disclosure of Conflicts of Interest

1. Each individual who is a member of the PCORI Board of Governors, the PCORI Methodology Committee, a PCORI Advisory Panel, or the PCORI staff (each, a “Relevant Person”) shall disclose all conflicts of interest and real conflicts of interest not less frequently than annually.

2. Each Relevant Person shall submit to PCORI a Conflict of Interest Disclosure Form, in the form attached hereto as Appendix I, on at least an annual basis. Such Conflict of Interest Disclosure Forms shall be updated as necessary to ensure that such forms are complete and accurate at all times.

3. The PCORI Board of Governors may request that Relevant Persons provide additional information related to conflicts of interest and real conflicts of interest as deemed necessary or advisable by the PCORI Board of Governors.

4. PCORI shall publicly disclose conflicts of interest of Relevant Persons in the manner required by Part D of Title XI of the Social Security Act (42 U.S.C. 1301 et. seq.).

Article III Procedures

1. **Duty to Disclose.** In connection with any conflict of interest or real conflict of interest, a Relevant Person must disclose the existence of the conflict of interest or real conflict of interest and be given the opportunity to disclose all material facts to the PCORI Board of Governors, PCORI Methodology Committee or PCORI Advisory Panel, as applicable.

2. **Determining Whether a Conflict of Interest Exists.** After disclosure of the conflict of interest or real conflict of interest and all material facts, and after any discussion with the Relevant Person, he/she shall (a) have the opportunity to voluntarily recuse himself or herself with respect to the matter at issue, or (b) leave the meeting of the PCORI Board of Governors, PCORI Methodology Committee or PCORI Advisory Panel, as applicable, while the determination of a conflict of interest or real conflict of interest is discussed and voted upon. The remaining members of the PCORI Board of Governors, PCORI Methodology Committee or PCORI Advisory Panel, as applicable, shall determine whether the Relevant Person must recuse himself or herself with respect to the matter at issue. Such decisions shall be subject to review and confirmation or reversal by the PCORI Board of Governors.

3. **Violations of the Conflicts of Interest Policy.**

- a. If the PCORI Board of Governors, PCORI Methodology Committee or PCORI Advisory Panel has reasonable cause to believe a Relevant Person has failed to disclose a conflict of interest or real conflict of interest, it shall inform the Relevant Person of the basis for such belief and afford the Relevant Person an opportunity to explain the alleged failure to disclose.
- b. If, after hearing the Relevant Person's response and after making further investigation as warranted by the circumstances, the PCORI Board of Governors, PCORI Methodology Committee or PCORI Advisory Panel determines that the Relevant Person has failed to disclose a conflict of interest or real conflict of interest, it shall refer the matter to the Board of Governors to take appropriate action.

Article IV

Mandatory Recusal; Prohibition on Gifts

1. **Mandatory Recusal.** Members of the Board of Governors shall be recused from relevant PCORI activities in the case where the member (or a close relative of such member) has a real conflict of interest directly related to the research project or the matter that could affect or be affected by such participation. This means that a member of the Board of Governors cannot deliberate or vote with respect to PCORI activities described in the preceding sentence.

2. **Prohibition on Gifts.** PCORI, its Board of Governors and staff, shall be prohibited from accepting gifts, bequeaths, or donations of services or property when such acceptance could have the potential to bias or have the appearance of biasing its, his or her decisions in matters related to PCORI or the conduct of PCORI activities.

Article V

Records of Proceedings

The minutes of the PCORI Board of Governors, PCORI Methodology Committee or PCORI Advisory Panel shall contain:

- a. The names of the individuals who disclosed or otherwise were found to have a conflict of interest or real conflict of interest, the nature of the conflict of interest or real conflict of interest, any action taken to determine whether a conflict of interest or real conflict of interest was present, and the PCORI Board of Governors', PCORI Methodology Committee's or PCORI Advisory Panel's decision as to whether a conflict of interest or real conflict of interest in fact existed. The information disclosed shall include the type, nature, and magnitude of the interests of the individual involved, except to the extent that the individual recuses himself or herself from participating in the consideration of or any other activity with respect to the study or other PCORI related activity as to which the conflict exists.
- b. The names of the individuals who were present for discussions and votes relating to the matter, the content of the discussion, and a record of any votes taken.

Article VI

Periodic Reviews

To ensure that PCORI operates in a manner consistent with its purposes and does not engage in activities that are inconsistent with its duties and obligations prescribed by statute, periodic reviews shall be conducted. The periodic reviews shall, at a minimum, include the following subjects:

- a. Whether compensation arrangements and benefits are reasonable, based on competent survey information, and the result of arm's length bargaining.
- b. Whether partnerships, joint ventures, and arrangements with management organizations conform to PCORI's policies, are properly recorded, and reflect reasonable investment or payments for goods and services.

Article VII

Use of Outside Experts

When conducting the periodic reviews as provided for in Article VI, PCORI may, but need not, use outside advisors. If outside experts are used, their use shall not relieve the Board of Governors of its responsibility for ensuring periodic reviews are conducted.

Article VIII

Relation to Applicable Laws

Nothing in this Conflict of Interest Policy shall operate to alter the laws and other legal and policy requirements to which Relevant Persons are subject due to federal employment or any other reason.

* This version of PCORI's COI policy replaces an earlier version to correct language in Article IV, Section 2 regarding PCORI's prohibition on gifts to PCORI Board Members, Methodology Committee Members, and staff.