



Methodology Committee Charter

The Methodology Committee (“Committee”) shall make recommendations to the Board of Governors (“Board”) regarding methods for patient-centered outcomes research. This includes guidance about the appropriate use of methods in such research, methodological standards, as well as establishing priorities to address gaps in research methods or their application.

Membership

Committee Members. The Committee shall consist of up to 15 members who are appointed by the Board. In addition to the members appointed by the Board, the Directors of the Agency for Healthcare Research and Quality and of the National Institutes of Health (or their designees) shall also each be included as members of the Methodology Committee. Any member of the Committee may resign at any time by giving written notice to the Board Chairperson and the Executive Director. Vacancies shall be filled in the same manner as the original appointment.

Term and Term Limits. A member of the Committee shall serve for a term of six (6) years; except that for Committee members first appointed or for transition purposes relating to the initiation of the Board’s authority to appoint Committee members¹, Committee members shall be appointed to terms staggered evenly over two (2)-year increments to the extent necessary to implement and preserve evenly staggered terms of the Committee members. To the extent necessary to fulfill the functions of the Committee, the requirements of the authorizing law (including relating to composition requirements), and/or the needs of PCORI, the Board may appoint a Committee member to serve an additional six (6) year term. No Committee member shall be appointed for more than two (2) full consecutive six (6) year terms. Any Committee member appointed to fill a vacancy occurring before the expiration of the term for which the Committee member’s predecessor was appointed may be appointed for the remainder of that term and thereafter may be eligible for reappointment to a full term. A Committee member may serve after the expiration of that Committee member’s term until a successor has been appointed.

Chair and Vice Chair. The Chair and Vice Chair of the Committee shall be nominated by the Governance Committee from among the members of the Committee, upon consultation with the members of the Methodology Committee, and shall be appointed by the Board. The Chair and Vice Chair shall serve for a two (2) year term or until replaced by the Board and shall be eligible to serve no more than two (2) consecutive terms in such respective office, unless the Board extends the term upon the recommendation of the Governance Committee. The Chair and Vice Chair may be removed from such position at any time by a two-thirds (2/3) vote of the Board.

¹ Pursuant to the 2019 reauthorizing amendments to PCORI’s authorizing law, the authority to appoint Methodology Committee members was changed from the Comptroller General of the United States to the PCORI Board of Governors. See Title VI, Subtitle D, Sections 6301 [“Patient-Centered Outcomes Research”] and 10602 [“Clarifications to patient-centered outcomes research”] of the Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119, 727, 1005 (2010) as amended by Div. N, Sec. 104, Pub. L. 116-94, 133 Stat. 2534 (2019), codified at 42 U.S.C. 1320e, 42 U.S.C. 1320e-1, 42 U.S.C. 1320e-2, 42 U.S.C. 299b-37, 26 U.S.C. 501, 4375-4376, 9511.

Committee Operations

The Committee shall meet upon the call of the Committee Chair, upon the call of a majority of its members, or upon the call of the Board Chairperson, provided that reasonable notice has been provided to all Committee members. Meetings may be held in person, by teleconference, or by other electronic means that allow appropriate participation by all members. The Committee may meet periodically in executive session without management present. All meetings except executive sessions shall be open to members of the Board but only members of the Committee may participate in Committee votes. The Committee shall keep minutes of meetings, and shall report regularly to the Board. The Committee shall be staffed by research specialists and by such other staff as the Executive Director, with the counsel of the Committee, deems appropriate.

Quorum and Voting

The Committee shall vote on recommendations that will be formally presented to the Board and shall vote on other matters at the discretion of the Chair. A majority of the members of the Committee shall constitute a quorum. The act of a majority of the Committee members present at a meeting at which a quorum is present shall be the act of the Committee. Any action that may be taken at a meeting of the Committee may be taken without a meeting if a consent in writing, setting forth the action so taken, is approved by a majority of the members of the Committee and such approval is filed with the minutes of the Committee. Such consent shall have the same force and effect as a vote at a meeting.

Committee Responsibilities

The Committee shall have the responsibility of making recommendations to the Board of Governors and PCORI on the following matters, as well as any other responsibilities reasonably related to its purposes or assigned by the Chairperson of the Board or the Board of Governors.

- Develop and periodically update Methodological Standards for clinical comparative effectiveness research for recommendation to the Board, consistent with PCORI's authorizing law:
 - Identify gaps in patient-centered outcomes research methods (including design, statistical techniques, and reporting and dissemination strategies);
 - Recommend scientifically based methodological standards building on existing work on methodological standards including specific criteria for design, internal validity, generalizability, feasibility, timeliness of research, inclusion and evaluation of subpopulations, and risk adjustment for health outcome measures;
 - Such standards should also include methods by which new information, data, or advances in technology are considered and incorporated into ongoing research projects by the Institute, as appropriate; and,
 - Include the opportunity for input from relevant experts, stakeholders, and decision-makers, and the opportunity for public comment in the process for developing and updating Methodological Standards.
- Advise the Board of Governors and PCORI on matters related to increasing the quantity, quality, and timeliness of research information and speed implementation and use of evidence:

- Develop and recommend prioritized research topics that would address methodological gaps, filtering projects through the screens of patient-centeredness and scientific opportunity;
- Develop a translation table framework to serve as a guide to the Board and PCORI on appropriate methods and design for specific research questions;
- Make recommendations to the Board about any Advisory Panels or other methodological forums that should be established to provide input to the Methodology Committee;
- Provide methodological expertise on activities of the Board that pertain to the design, conduct, communication and dissemination of research studies; and,
- Advise the Board and PCORI on significant topics, designs, methods and outcomes for research that PCORI funds or is considering funding, and on implementation and dissemination of methodological standards.
- Additional Responsibilities:
 - Consult and contract with academic, non-profit, or other private and governmental entities with relevant expertise as well as with relevant stakeholders to carry out activities;
 - Submit reports to the Board on the Committee's performance of its functions, consistent with PCORI's authorizing law;
 - Advise the Board regarding potential areas of needed expertise and other characteristics that may benefit the Committee's effectiveness to inform the Board's appointment of new members of the Committee or potential reappointments of existing members of the Committee;
 - Report to the Chairperson of the Board and the Board on Committee activities; and,
 - Annually review the Committee Charter, the Committee's own performance, coordination with other Committees, and make appropriate recommendations to the Board.

History:

Approved by the PCORI Board of Governors 3/8/2011

Amended and approved by the PCORI Board of Governors 4/21/2015

Amended and approved by the PCORI Board of Governors 4/26/2016

Amended and approved by the PCORI Board of Governors 9/12/2017

Amended and approved by the PCORI Board of Governors 6/19/2018

Amended and approved by the PCORI Board of Governors 4/16/2019

Amended and approved by the PCORI Board of Governors 9/14/2020