

PCORnet[®] Steering Committee

Approved on: May 30th, 2025

PURPOSE

The PCORnet[®] Steering Committee (SC) will function as the primary governing group for PCORnet[®], representing the PCORnet[®] Network Partners (i.e., Clinical Research Networks, Patient Partners, and the Coordinating Center for PCORnet[®]). The SC will develop and review policies, programs, recommendations, and activities, and make decisions that are in alignment with the strategic priorities for PCORnet.^a The policies, operations, and products of the SC will support the PCORnet[®] Core Principles listed below. The SC will review and approve documents and work products prepared by its Committees and Workgroups. The SC will oversee the Executive Management Team and ratify or revise its decisions. The SC will operate under principles of shared responsibility, mutual respect, and trust fostering a shared commitment to the accomplishment of goals for PCORnet. Additionally, PCORI has contractual agreements with the Clinical Research Networks and Coordinating Center for PCORnet[®] that established responsibilities relating to PCORnet.

PCORNET[®] CORE PRINCIPLES

PCORI funded the development of PCORnet to improve the nation's capacity to conduct health research and to learn from the healthcare experiences of millions of Americans to allow for large-scale research to be conducted with enhanced accuracy and efficiency. The SC supports the governance of the Network in accordance with the PCORnet[®] Core Principles:

- Maintains governance and operational mechanisms for the meaningful engagement of patients and other partners, including community members, families, caregivers, clinicians, delivery systems, payors and researchers, in all phases of the research process;
- Implements the network through a distributed research network model that is committed to building a national resource that is accessible via a central gateway to researchers within and outside of the network;
- Committed to a network model that encourages and facilitates the sharing of resources and tools, including through an on-line "common" that is available to the networks and public;
- Uses a common data model that standardizes the definition, format, and content of data across participating data networks so that standardized applications, tools, and methods can be applied to advance quality and consistency;
- Uses streamlined and standardized mechanisms, including centralized IRB models (e.g., SMART IRB) and standardized data use agreements, for the efficient and rapid conduct of research in the network;

^a The Steering Committee has the authority to make decisions within the scope of PCORI infrastructure contracts and those that do not related to funding or research commitments.

- Advances a network model that advances the quality and availability of complete and comprehensive data sets, including through linkages of disparate sources of complementary data; and
- Complies with applicable laws, regulations, and legal requirements, including but not limited to those governing privacy, security, data, research, and human subjects.

APPOINTMENT AND MEMBERSHIP

The SC will consist of members representing the major collaborators in PCORnet. Patient or Health Community Partners will represent at least 40 percent of the SC voting ballots and will be fairly compensated for their contributions and time in accordance with the approved PCORnet Patient and Other Partner Compensation Policy.

The composition will be as follows:

- 8 Clinical Research Network (CRN) Principal Investigators (PIs), coupled with **either** a CRN Co-PI, or CRN Site Investigator (each CRN pair holds a single vote and each CRN is limited to a **pair**)^b
- 1 Chair, elected from amongst PCORnet leadership (i.e., CRN PI, CRN Dual PI, CRN Site Investigator, and Patient Partner Co-I)
- 1 Vice Chair, elected from amongst PCORnet leadership (i.e., CRN PI, CRN Dual PI, CRN Site Investigator, and Patient Partner Co-I)
- 8 Patient Partner Co-Is^c
- Coordinating Center (CC) PIs (the CC will hold a single rotating vote)
- PCORI representatives (PCORI holds a single vote)
- 16 Project Managers (2 from each CRN)^d
- 8 Research Readiness Coordinators (1 per CRN)^d

SC Chair

The Chair will be elected by SC members. The Chair will be responsible for calling meetings and establishing the Committee's agenda, in collaboration with the Executive Management Team. The Chair will serve a 1-year renewable term. Please note that the Chair must volunteer or be nominated and then be voted on before having a second term.

SC Vice Chair

^b the pair must be named in advance, no substitutions

^c Some Clinical Research Networks may elect to have both Patient Partner Co-Investigator (Phase 4) and Phase 3 elected Patient or Health Community Partner attend Steering Committee Meetings. In this event, the Patient Partner Co-I and Phase 3 elected Patient or Health Community Partner dyad holds a single vote. The Patient Partner Co-I is responsible for submitting the single vote.

^d indicates the attendees are listen only, non-voting members

The Vice Chair will be elected by SC members. The Vice Chair will serve as the alternate for the SC Chair as needed. The Vice Chair will also serve a 1-year renewable term. Please note that the Vice Chair must volunteer or be nominated and then be voted on before having a second term.

EXECUTIVE MANAGEMENT TEAM

The Executive Management Team (EMT) reports to the PCORnet[®] SC. The Executive Management Team will ensure timely decision-making, while balancing the need to engage the broader Network. The EMT operates to provide SC input into Network management decisions and insights into SC challenges and opportunities; triage and prepare issues for SC decisions; execute Network strategies; and generally, organize and prepare for SC meetings. The EMT is a collaborative management structure with the below:

- 1 SC Chair
- 1 SC Vice Chair
- 1 CRN representative (CRN PI, Co-PI, or CRN Site Investigator)
- 1 Coordinating Center representative
- 1 ex-officio member from the Administrative Core of the Coordinating Center (non-voting)
- 3 Patient Partner Co-Is
- PCORI representatives (non-voting)

The CRN, Coordinating Center, and Patient Partner Co-I on the EMT will be elected by the SC for staggered 2-year renewable terms to ensure continuity of knowledge.

COMMITTEES AND WORKGROUPS

The EMT may elect to establish standing committees and/or short term working groups to address specific network needs.

MEETING SCHEDULE AND FREQUENCY

The SC will meet a minimum of once every other week, but may meet more frequently. In addition to SC members, Coordinating Center staff may attend meetings. CRN PI, Co-PI, and Patient Partner Co-I should attend $\geq 80\%$ of meetings and have a recorded vote on $\geq 80\%$ of motions. Meeting support services will be provided by the Coordinating Center.

QUORUM AND VOTING

A quorum shall consist of a majority of the members of the Committee. The SC will document its decision making related to policies and key decisions through online voting. It should be noted that the Chair, as selected from among the membership, receives one vote and his/her institution does not receive an additional vote.

Because of the differential voting power of the constituencies participating in PCORnet, vote results will be reviewed to ensure that the Patient or Health Community partner voice is not

overpowered. Specifically, if all Patient or Health Community partners vote against the majority, the SC will re-discuss and determine if a new vote is required.

CONFLICT OF INTEREST

Members will be asked to disclose any potential conflicts prior to and upon joining the SC and will update disclosures when they change. The SC Chair or designee shall be responsible for identifying conflicts and determining what actions would be necessary to ensure that a member does not participate in matters in which such a conflict would or could exist. Only activities that conflict with the members ability to objectively make decisions in the best interest of PCORnet should be reported.

HISTORY

Approved by the SC on May 30th, 2025