PCORnet Steering Committee
Approved on: 09.21.2022

PURPOSE
The Steering Committee (SC) for PCORnet will function as an advisory group to the PCORnet Network Partners (i.e., Clinical Research Networks, Patient Partners, and the Coordinating Center). The SC will develop and review policies, programs, recommendations, and activities, and make decisions. The policies, operations, and products of the SC will support the PCORnet core principles listed below. The PCORnet 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, trust, diversity, equity and inclusivity, fostering a shared commitment to the accomplishment of goals PCORnet. Additionally, PCORI has contractual agreements with the Clinical Research Networks and Coordinating Center that established responsibilities relating to PCORnet.

CORE PRINCIPLES
PCORI funded the development of PCORnet®, the National Patient-Centered Clinical Research Network 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 PCORnet SC works to ensure that the Network:

- Maintains governance and operational mechanisms for the meaningful engagement of patients and other stakeholders, 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 “knowledge repository” 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;
- Is committed to research that is patient-centered, and addresses issues related to diversity equity and inclusion
- Is committed to principles of open science and engagement of stakeholders for dissemination of results.
- 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 representatives will represent at least 20 percent of the SC votes and will be fairly compensated for their contributions and time in accordance with the approved PCORnet patient and stakeholder compensation policy. The Chair will be supported by a Vice Chair.

The composition will be as follows:

- 1 Chair, elected from amongst the members
- 1 Vice Chair, elected from amongst the members
- 8 Clinical Research Network (CRN) Principal Investigators (PIs) and Dual PIs (each CRN pair holds a single vote)
- Coordinating Center (CC) PIs (the CC will hold a single vote)
- PCORI representatives (PCORI holds a single vote)
- 16 Project Managers (2 from each CRN, non-voting)
- 8 stakeholder representatives (one vote per stakeholder)

**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, once renewable term.

**SC Vice Chair**

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, once renewable term.

**Patient Representatives**

The patient representatives will serve 2-year, once renewable terms to ensure the diversity of the patient voice is captured. Patient nominations will be sought from participating CRNs and the Stakeholder Core of the Coordinating Center selected by the Executive Management Team.

**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

The EMT is a collaborative management structure with the below:

- 1 SC Chair
- 1 SC Vice Chair
- 1 CRN representative
- 1 Coordinating Center representative
- 3 stakeholder representatives
- PCORI representatives

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

**COMMITTEES**

Three standing committees will advise the PCORnet SC on topics specific to Data, Engagement, and Research as described below. These standing committees will abide by the terms of their Charters. All products of the committees must be presented to the SC. If the product is a policy or recommendation for action, the SC will vote to accept or deny. All committees report to the EMT and the EMT makes a determination about when products, policies, and recommendations should be presented to the SC.

The Committees will be led by one Chair and one Vice Chair elected by the Committee. Nominations for committee members will be solicited from across the Network and members will be selected by the EMT. Committees will also include representation from the Coordinating Center and PCORI.

- **Research Committee** – The purpose of the Research Committee is to support the development of research programs that leverage PCORnet and are suitable for PCORnet Study Designation, and to help identify and address barriers to successful conduct of awarded research projects.

- **Engagement Committee** – The purpose of the Engagement Committee is to support the development of the science of engagement, and to promote and strengthen engagement within PCORnet governance and research.

- **Data Committee** – The purpose of the Data Committee is to identify and support data priorities for PCORnet to ensure efficient and high-quality research leveraging the PCORnet Common Data Model and querying capabilities.

**ad hoc STRATEGICALLY FOCUSED WORKGROUPS**

Strategically focused workgroups may also advise the PCORnet SC. Important topics may arise that would benefit from additional work from *ad hoc* strategically focused workgroups that may be requested either by the SC Chair, or another member of the SC. These strategically focused
workgroups shall advise the PCORnet SC. All requests for workgroups are made to the SC Chair, who may approve or disapprove. All workgroups are expected to provide updates to the SC upon request. All products of the workgroups must be presented to the SC. If the product is a policy or recommendation for action, the SC will vote to accept or deny.

All workgroups report to the EMT and the EMT makes a determination about when products, policies, and recommendations should be presented to the SC. Nominations for workgroup members will be solicited from across the Network Partners and members will be selected by the EMT. Ad hoc workgroups should have clear deliverables and timelines not to exceed six months.

**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, as may one project manager per CRN. All SC members are expected to participate in at least 90% of SC meetings. 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/stakeholder voice is not overpowered. Specifically, if all stakeholder representatives vote against the majority, the SC will re-discuss and determine if a new vote is required. The SC will also reconsider any topics that result in a vote where the majority and minority votes are fewer than three apart would trigger reconsideration.

**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.

**HISTORY**
Approved by the PCORnet SC on September 21st, 2022.

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1 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.