Governance Policies for PCORnet, the National Patient-Centered Clinical Research Network

1.0 Leadership and Decision-Making
When reading this document it is important to note that there are several categories of documents that will govern PCORnet activities, duties, and responsibilities. These include but may not be limited to: (1) PCORnet Governance Policies; (2) Standard Operating Procedures; and, (3) Committee charters. It is natural that differences in phrasing may occur among them. If there is any perceived inconsistency among (1), (2), and (3), this document governs. Additionally, PCORI has contractual agreements with certain Networks and the Coordinating Center that establish responsibilities relating to PCORnet.

1.1 Organizational Structure
PCORnet is comprised of Networks (both Clinical Data Research Networks and Patient-Powered Research Networks), a Coordinating Center, and PCORI. PCORnet's governance consists of a PCORnet Council and its Committees, which include the Executive Committee, Data Committee, Engagement Committee, Research Committee, and Nominating Committee, and such ad hoc Committees as are set up by the PCORnet Council from time to time, together with inclusive working groups, established with PCORnet Council approval. PCORnet recognizes that governance continues at the Clinical Data Research Networks and Patient-Powered Research Networks levels through the individually-adopted governance structures and processes of each network, and together the two levels of governance must function to assure and enhance the inclusion and participation of the networks' constituent entities.

1.1.1 Networks
There are two types of Networks in PCORnet: Clinical Data Research Networks (composed of health systems) and Patient-Powered Research Networks (composed of patient or participant communities). Patients play prominent leadership roles in all networks. In each Patient-Powered Research Network, a patient serves as principal investigator or co-principal investigator. In each Clinical Data Research Network, patients serve as representatives in local governance, representing patient interests at the Network and PCORnet level. One representative of each Network serves as a voting member of the PCORnet Council.

1.1.2 PCORnet Council
The PCORnet Council is the main governing body of PCORnet. The PCORnet Council will be responsible for the oversight of PCORnet's research agenda, for commissioning and approving PCORnet's strategic plan and for achieving its strategic goals as a premier national clinical and patient-centered outcomes research network. In this role, the PCORnet Council will ratify all proposed PCORnet policies. The PCORnet Council will review and approve documents and work products prepared by its Committees. The PCORnet Council will oversee the Executive Committee and ratify or revise its decisions. Minutes of PCORnet Council meetings will be produced by the Coordinating Center and approved by the PCORnet Council. Once approved, the PCORnet Council meeting minutes will be made publicly available. The PCORnet Council will be composed of one voting representative from each Network, one voting representative from the Coordinating Center, and one voting representative from PCORI. An elected Chair will lead the PCORnet Council. PCORI will designate the PCORnet Program Director, who will serve as the Vice Chair of the PCORnet Council and will be the PCORI voting representative. The Executive Director of PCORI will serve as an ex-officio non-voting member of the PCORnet Council.
1.1.2.1 Nominating Committee
The PCORnet Council will form a Nominating Committee composed of two CDRN principal investigators, two PPRN principal investigators, one patient leader, and one representative from PCORI. At least one of the principal investigators must be a patient principal investigator or co-investigator. One individual will be elected by the PCORnet Council to chair the Committee. The Nominating Committee will convene before the PCORnet Council schedules the annual leadership elections and on an as-needed basis, when vacancies occur and nominations are required. The Nominating Committee will develop a list of candidates for open leadership positions, which includes the Chairs of the PCORnet Council and its Committees and the four at-large representatives on the Executive Committee. The list of candidates will be submitted to the PCORnet Council before the leadership elections.

1.1.2.2 PCORnet Council and Committee Chairs
The Chairs of the PCORnet Council and its Committees will be elected by the PCORnet Council. The Chairs will serve two-year terms, renewable for one additional term.

1.1.3 PCORnet Advisory Group
The PCORnet Advisory Group’s purpose is to help PCORnet establish relationships between research funders and PCORnet and to ensure coordination with federal and private sector health data and research initiatives that affect PCORnet. It will include one representative from each of the following federal agencies and offices: the Agency for Healthcare Research and Quality, the Assistant Secretary for Planning and Evaluation, the Centers for Disease Control and Prevention, the Center for Medicare and Medicaid Services, the Food and Drug Administration, National Institutes of Health, and the Office of the National Coordinator for Health Information Technology, and five representatives from non-federal organizations, including the life sciences industry, health research foundations, educational institutions, and others. In addition to the representatives identified above, the Executive Committee may add members to the Advisory Group, as it deems necessary to meet the purpose of the Advisory Group. This Advisory Group will elect a Chair and Vice-Chair and will be responsible for setting priorities and agendas for the group in collaboration with the Executive Committee. The Advisory Group will meet at least quarterly, and will meet quarterly with the PCORnet Executive Committee.

1.1.4 Executive Committee
The Vice Chair of the PCORnet Council will serve as the Chair of the Executive Committee. There will be 7 voting members of this Committee. They include: the PCORnet Council Chair; PCORnet Council Vice Chair; one member of the Coordinating Center; two elected at-large PPRN Network principal investigators elected by PPRN Network representatives, one of whom will be a patient principal investigator or co-investigator; and two elected at-large CDRN principal investigators elected by CDRN Network representatives. The Executive Director of PCORI, as well as the Chairs of the Engagement, Data and Research Committees, will serve as ex-officio non-voting members of the Executive Committee. The Executive Committee will act on behalf of the PCORnet Council in between convened meetings of the PCORnet Council, and its actions will be subject to review and revision at the next convened PCORnet Council meeting. The Executive Committee will develop PCORnet’s strategic plan under the PCORnet Council’s oversight, develop operational plans for executing the PCORnet Council’s agenda for PCORnet, soliciting input by those affected by PCORnet policies, and ensuring the network’s performance is optimized for quality and efficiency. The Nominating, Data, Research, and Engagement Committee Chairs will select representatives from the Networks for their respective committees that represent a diversity of experiences within PCORnet. These lists will be submitted to the Executive Committee for approval. The Executive Committee may request changes to the proposed
lists to ensure appropriate representation of different perspectives on the Committees. The PCORnet Council will approve the final lists.

1.1.5 Engagement Committee
The Engagement Committee’s purpose is to design, continuously improve, and oversee PCORnet’s system of engagement of patients, clinicians, research, health system leaders, industry, regulators, and other stakeholders. The Engagement Committee will review and make recommendations to the PCORnet Council for approval of Network engagement policies and standard operating procedures. This Committee of the PCORnet Council will be composed of a Chair and up to 10 members drawn from the voting members of the PCORnet Council, or their designees. Three members will be patients. Other stakeholders will also be represented.

1.1.6 Data Committee
The Data Committee’s purpose is to oversee PCORnet’s data network, which is managed by the Coordinating Center. It will also be charged to stimulate informatics and research data innovations that advance the goals of PCORnet. This Committee of the PCORnet Council will be composed of a Chair and up to 10 members drawn from the voting members of the PCORnet Council, or their designees. At least two members will be patients.

1.1.7 Research Committee
The Committee’s purpose is to design, continuously improve, and oversee PCORnet's research activities, which includes such topics as generating and prioritizing research concepts, ensuring research quality, and developing research partnerships, and assigning PCORnet study designation to individual projects when principal investigators request such designation. This Committee of the PCORnet Council will be composed of a Chair and up to 10 members drawn from the voting members of the PCORnet Council, or their designees. At least two members will be patients.

1.1.8 Coordinating Center
The Coordinating Center is responsible for overall coordination of PCORnet within strategic and operational plans developed and approved by the PCORnet Council. In this role, it furnishes logistical support to the PCORnet Council, the Committees, and the Work Groups. The Coordinating Center is responsible for implementing PCORnet’s engagement, technical, and scientific standards and operating procedures. It develops and operates PCORnet’s data infrastructure with guidance from the PCORnet Council and its Committees. It assists the PCORnet Council in identifying opportunities for PCORnet research. It also supports many of the PCORnet multi-site research studies. The Executive Committee will oversee Coordinating Center activities. One member of the Coordinating Center serves as a voting member of the Executive Committee and of the PCORnet Council, except on matters implicating its actions and oversight, from which it must recuse itself from deliberations and vote because of its conflict of interest. Other Coordinating Center members join and support the different committee activities as non-voting members.

1.1.9 Role of PCORI
PCORI will continue to fund selected Clinical Data Research Networks, Patient-Powered Research Networks, and the Coordinating Center throughout Phase II (September 2015 to August 2018) of PCORnet to advance PCORnet’s capability and capacity. PCORI, with the oversight of the PCORI Board of Governors, will continue to provide leadership and stewardship over PCORnet during this period. Consistent with this role, all PCORnet policies are subject to approval by PCORI.
1.2 Decision-Making
All PCORnet Committees will seek to reach decisions through consensus. When voting is necessary, a simple majority of the entire Committee will be required to approve an action. In the case of the PCORnet Council only, in addition to a simple majority of the entire committee, a simple majority of all the Clinical Data Research Networks (CDRNs) and a simple majority of all the Patient-Powered Research Networks (PPRNs) will be required to approve an action. The PCORnet Council will approve all PCORnet policies. The PCORnet Council will approve Committee documents, work products, and decisions.

1.3 Policy Development and Review Process
The Executive Committee is responsible for creating and managing a policy development process. The PCORnet Council must review and approve the process. As needed, the Executive Committee will review the policy development process and seek input on its adequacy and fairness from those it affects to ensure that it is functioning effectively, and if not, suggest changes to the PCORnet Council. Subsequent to its approval, policies can be amended, and new policies can be developed on an ongoing basis.

1.4 Forming New Committees and Work Groups
Additional Committees can be developed and chartered by the PCORnet Council. The Executive, Data, Research, and Engagement Committees may form Work Groups designed to promote inclusion of Network constituents in analyzing challenges and developing alternative solutions for Executive Committee and PCORnet Council consideration. Work Groups shall therefore be tasked with developing or reviewing policies, documents, Standard Operating Procedures, and other work products. In general, Work Groups will have a time-limited engagement. The composition of each Work Group will reflect at least the diversity of the PCORnet Council and is at the discretion of the Committee Chair in the first instance, subject to the approval of the Executive Committee and revision by the PCORnet Council. Similarly, the PCORnet Council will have the authority to dissolve and end the work of a Committee or Work Group.

2.0 Patient Engagement

2.1 Requirement for Patient Engagement Policy
Networks within PCORnet must have an Engagement Policy and associated Standard Operating Procedures that meet the following requirements and that describe how the requirements are achieved:

- Patients are partners in the research process.
- Patients are involved in network leadership positions.
- Patients are involved in decision-making about network participation in proposed studies.
- Patients are involved in: formulating research questions; defining essential characteristics of study participants, comparators, and outcomes; identifying and selecting outcomes that the population of interest notices and cares about (e.g., survival, function, symptoms, health-related quality of life) and that inform decision making relevant to the research topic; monitoring study conduct and progress; and, designing and suggesting plans for dissemination and implementation activities.
- Patients who contribute to PCORnet at large and to Network leadership roles are compensated.
3.0 PCORnet Data Network

3.1 PCORnet Data Network Architecture
The PCORnet data network will use a distributed architecture in which there is no central data repository. Rather, Networks must collect and maintain data using the Common Data Model and the PCORnet Query Tool to respond to network-wide queries in a standardized way.

3.2 PCORnet Common Data Model
The PCORnet Common Data Model will be maintained and managed by the Coordinating Center. Each Network will arrange or store its data in an instance of the PCORnet Common Data Model. The PCORnet Council, based on recommendations from the Data Committee in consultation with the Coordinating Center, will approve expansions and modifications of the Common Data Model.

3.3 PCORnet Query Tool Portal
The PCORnet Query Tool provides access to the PCORnet Data Network. The Coordinating Center will entertain requests to execute a query using the PCORnet Query Tool to access PCORnet across multiple networks. Nothing in this section shall be construed as affecting the right of each institution to agree or decline to execute queries using that or any other tool with respect to its own data, or the authority of a Network to execute queries using that or any tool or queries within its own Network.

3.4 Monitoring Use of the PCORnet Query Tool
The Data Committee will establish requirements, which will be approved by the PCORnet Council, for monitoring the use of the PCORnet Query Tool. The Coordinating Center with Executive Committee oversight will be responsible for monitoring and reviewing all activity related to the PCORnet Query Tool.

3.5 Minimum Necessary Data
All investigations that use the PCORnet Query Tool will involve the use and disclosure of the minimum necessary data to fulfill each query. The Coordinating Center will consult with Networks and research teams, as necessary, to determine the minimum data necessary for a query response. The Data Committee will resolve differences in opinion, should they arise, between researchers, Networks, and the Coordinating Center regarding what constitutes minimum data for a specific query.

3.6 Minimum Bin Size
In order to reduce the risk of re-identification of individuals within a dataset, PCORnet uses a conservative minimum cell size threshold of 11 for all PCORnet data queries unless superseded by commitments made to participants with respect to use of their information, or unless authorized by the research protocol and any Institutional Review Board(s) approving the query. Alternative approaches to protect patient privacy and prevent re-identification may be employed within PCORnet (for example to conduct a research study in a rare disease that results in a cell size of ≤ 10), if considered to provide appropriate protection of privacy.

3.7 Sharing of Patient-Level Data
Datasets at the patient-level may be necessary for answering certain research questions. These datasets are created only as part of a study-specific protocol, which will have appropriate regulatory review to protect patient privacy.
4.0 Participating In and Using PCORnet

4.1 Elective Participation in Queries
Participation by a Network in any particular query is not compulsory. Networks (and the sites within Networks) have discretion to elect to participate or not participate in all PCORnet queries.

4.2 Compliance with Laws and PCORnet Policies
As a condition of participating in PCORnet and/or using the PCORnet Data Network, all Networks, the Coordinating Center, and researchers are required to comply with all PCORnet Policies and Standard Operating Procedures, as well as all applicable laws regarding the conduct of research and data-related activities, including obtaining any necessary patient consents or waivers. Failure to comply with the PCORnet Policies, Standard Operating Procedures, and/or applicable laws is grounds for being excluded from participation in PCORnet and/or being denied access to the PCORnet Data Network.

5.0 PCORnet Studies
A principal investigator of a research activity may apply to the Research Committee of PCORnet to be considered for a “PCORnet Study” designation. The PCORnet study designation may be desirable to reflect the PCORnet brand and its association with high quality, efficient, and timely patient-centered outcomes research. The Research Committee may also prioritize and approve the use of Coordinating Center resources for preparatory to research activities that are intended to lead to PCORnet studies, subject to available capacity.

5.1 Requirements for PCORnet Studies
To qualify for PCORnet Study designation, a study must:
1. Be patient-centered¹.
2. Include at least 1 PCORnet Network.
3. Use quality-checked data standardized to the PCORnet Common Data Model format for those variables that are available in the Common Data Model.
4. Use as many of the following PCORnet resources as possible, when appropriate for the study design:
   a. PCORnet query tool
   b. PCORnet Single IRB Agreement
   c. PCORnet Data Sharing Agreement
   d. PCORnet Master Services Agreement
   e. Coordinating Center project management resources
   f. Other resources to be defined by the PCORnet Council or its designee
5. Demonstrate how patients are engaged in the design, conduct, analysis, or dissemination of the research.

5.2 Sale of PCORnet Study Data
PCORnet does not sell source data developed as part of PCORnet studies to third parties unless they are being shared for a PCORnet-approved use.

5.3 Application for PCORnet Study Status
PCORnet study status will not be given to cost-effectiveness studies. The Research Committee will evaluate and make decisions on applications for the PCORnet study designation.

¹ A research activity is Patient-Centered if it pursues a question that is important to patients, measures outcomes that are noticeable and meaningful to them, and produces results that help them weigh the value of healthcare options given their personal circumstances, conditions, and preferences.

5.4 Additional Requirements for PCORnet Studies

Studies that receive the PCORnet study designation must meet the following obligations:

1. Registration with ClinicalTrials.gov for all eligible studies, including clinical trials and observational outcome studies; and posting the proposed protocol on PCORnet.org.
2. Submission to the Coordinating Center within 18 months from the completion of the final analysis, the final protocol; and two abstracts of no more than 500 words, one for medical professionals and one for a lay audience, to be posted on the public PCORnet website.
3. Acknowledgment of the study’s status as PCORnet study in all websites, reports, presentations, and manuscripts.
4. Submission to the Coordinating Center, within 18 months from the completion of the final analysis files, a report on lessons learned from successes and failures, which will be deposited in the PCORnet Commons.
5. PCORnet studies are not required to seek approval for publications or presentations from the PCORnet Council or any of its standing Committees.
6. PCORnet studies should offer the possibility of authorship (a minimum of one author per network) to all PCORnet Clinical Data Research Networks and Patient-Powered Research Networks contributing data to a study. This, however, is not a guarantee of authorship. Authors must meet International Committee of Medical Journal Editors (ICMJE) criteria.

6.0 Reassessment of PCORnet Policies

The PCORnet Council will review PCORnet policies on at least an annual basis.

7.0 Open Science

PCORnet is highly committed to Open Science and recognizes that this is a complex area that will require thoughtful implementation. The implementation of Open Science policies is a high priority for PCORnet and should be adhered to when possible.