



**PEDS**net  
A Pediatric Learning Health System

## **PEDSnet Governance Policies**

### **Version 2**

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The initial and subsequent versions of the PEDSnet governance policies have been reviewed and approved by the PEDSnet Steering Board.

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## 1 INTRODUCTION

### 1.1 PURPOSE OF THIS DOCUMENT

PEDSnet ([pedsnet.org](http://pedsnet.org)) is a network of pediatric institutions and their scientific investigators, patients, parents, clinicians, and health system leaders who collaborate to produce research that improves children's health and healthcare. This document describes the policies that govern actions of individual and institutional collaborators who participate in the creation, development, dissemination, and implementation of PEDSnet and its products.

### 1.2 WHY PEDSNET WAS FORMED

In its current state, the pediatric clinical research system generates evidence too slowly and at too high a cost. Pediatric care often relies on *hand-me-down* evidence from adult studies. Because many health conditions in childhood are uncommon, no single institution has a sufficient number of patients to produce generalizable research that can inform shared clinical decisions that are made by parents, children, and their clinicians for all pediatric health conditions. A persistent challenge is the lack of a national interconnected, multi-institutional infrastructure that can produce the volume of research that is needed to improve children's healthcare. ***PEDSnet was formed to address these challenges.***

The concept for PEDSnet was spawned at a 2009 IOM-sponsored meeting when 25 children's hospital health systems met to discuss advancing children's healthcare through a national learning health system innovation collaborative. As a proof-of-principle, an obesity [study](#) was done using 6 pediatric institutions' EHR data. Data were extracted, mapped to common data standards, and aggregated for analysis. This project paved the way toward the development of a prototype learning health system. In collaboration with the ImproveCareNow network for children with inflammatory bowel disease, PEDSnet secured a grant from the Agency for Healthcare Research and Quality (AHRQ) to build a learning network. The journey from concept to prototype to national scaling was detailed in a 2014 [article](#) published in Health Affairs.

The scaling of PEDSnet is being made possible by two [clinical data research network](#) (CDRN) infrastructure grants from the Patient Centered Outcomes Research Institute (PCORI). The CDRN program has provided PEDSnet with resources to: **(1) build effective leadership and governance** that emphasizes fiscal stewardship, patients' perspectives, and seamless sharing, and creates **policies and procedures** including a **Single Institutional Review Board model** that supports cooperation across institutions for research; **(2) create a community of engaged** patients, families, clinicians, scientists, and health system leaders involved in co-producing knowledge and know-how; **(3) standardize interoperable data** on millions of children that enables data sharing, cohort identification, and research (from proposal concept

to completed studies); **(4)** develop the **capacity to conduct** observational studies and clinical trials rapidly and efficiently using the PEDSnet infrastructure; and, **(5)** design a **sustainability model** that makes PEDSnet highly attractive to funders because of the availability of a range of standardized clinical data, longitudinal data capture, large pediatric populations, and reliable inter-operability with other research networks.

As a CDRN, PEDSnet is a member of [PCORnet](#), which is a consortium of [CDRNs](#), including PEDSnet, and [Patient-Powered Research Networks](#). These Networks are working together to create a national clinical and health services research resource. PEDSnet is the only CDRN within PCORnet focused exclusively on children.

### 1.3 WHAT PEDSNET DOES

#### 1.3.1. MISSION

**Mission Statement:** PEDSnet conducts multi-institutional pediatric research that informs clinical care and contributes to a national learning health system that enhances health for all children.

To accomplish this purpose, PEDSnet makes multi-institutional pediatric clinical research faster and less expensive, engages multiple stakeholders in the research process, and generates new knowledge that informs the decisions that patients, clinicians, and health system leaders make each day to improve the health and healthcare of children and adolescents.

PEDSnet has adopted the learning health system (LHS) model for improving health and healthcare. The essential attributes are:

1. Clinical **communities** of patients, families, front-line clinicians, researchers, and health system leaders who collaborate to produce and use pediatric health care data;
2. Access to extensive electronic health and health care **data**;
3. Observational **research** and clinical trials done in routine clinical care settings; and
4. Quality **improvement** at the point of care brought about by the integration of relevant new knowledge generated through research.

The learning health system is dependent on the active collaboration of all its members, and success is defined by its impact on the health and lives of patients. PEDSnet's focus is on facilitating the conduct of efficient multi-institutional pediatric research, and on research that evaluates alternative approaches for implementing evidence at the point of care.

### 1.3.2 VISION


**2018 Vision Statement:** To be the premier multi-specialty national pediatric clinical network for conducting research in routine healthcare settings.

**2018 Vision Summary:** By the end of 2018, PEDSnet will be recognized as the premier multi-specialty national pediatric clinical network for conducting research in routine care settings. It will be able to access health and healthcare data for several million of the nation's children. Having completed or launched interventional and observational research studies, PEDSnet will have secured a diverse portfolio of federal and private sector funding. It will have created a variety of governance, technical, scientific, and engagement resources that many investigators and institutions have used to conduct efficient pediatric clinical and health services research. PEDSnet will have forged relationships with strategic partners, including several PCORnet Clinical Data Research Networks and Patient-Powered Research Networks that have organized to catalyze the formation of a distributed, national pediatric learning health system. PEDSnet will have transitioned from sole support from the Patient Centered Outcomes Research Institute to a sustainable business model that ensures its long-term sustainability.

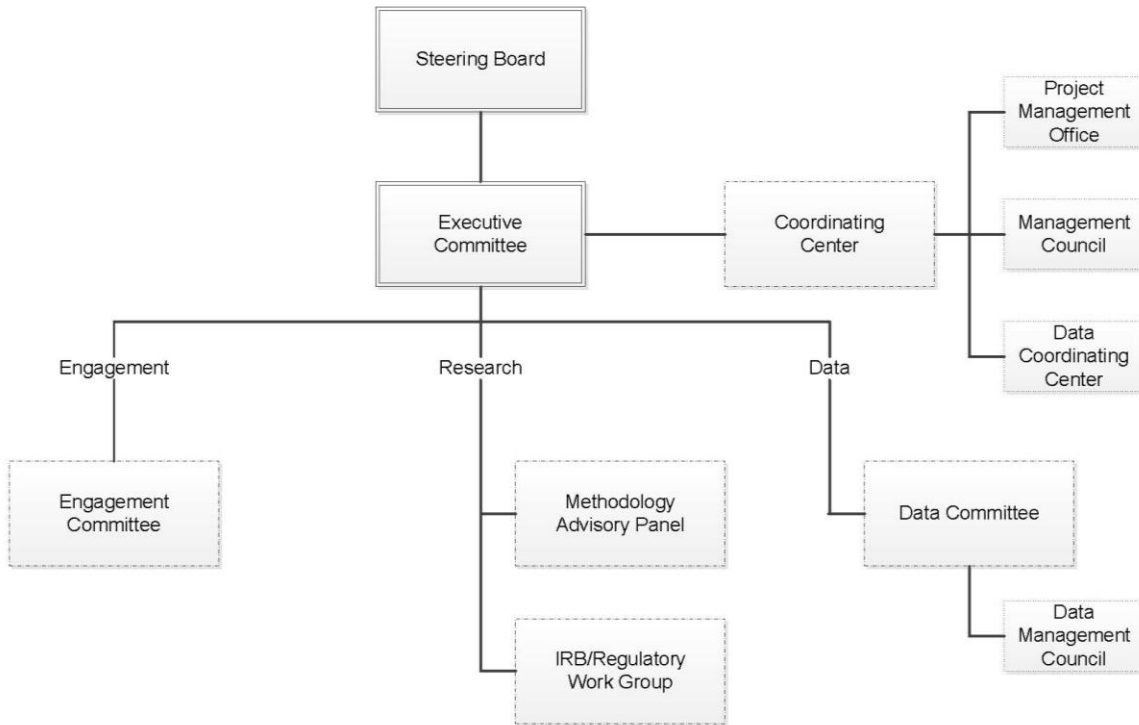
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### 1.3.3 STRATEGIC GOALS

PEDSnet will realize its 2018 vision by pursuing five strategic goals, which the PEDSnet Steering Board adopted in November 2015.

1. Develop the most comprehensive and complete pediatric data network in the US;
  2. Become a highly efficient and high throughput pediatric clinical and health services research network;
  3. Attain financial sustainability without additional infrastructure funding from PCORI;
  4. Accelerate the development of an emerging national-scale pediatric learning health system; and
  5. Provide training opportunities for investigators interested in the science of learning health systems.
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**2 PEDSNET ORGANIZATIONAL ARCHITECTURE**



PEDSnet is composed of Member Institutions, a Steering Board, an Executive Committee, three subcommittees (Data, Engagement, and the Methodology Advisory Panel), Work Groups, and a Coordinating Center.

**2.1 FOUNDING MEMBER INSTITUTIONS**

Eight Founding Member Institutions established PEDSnet, as it is currently configured, in 2014. As Founders, these institutions established PEDSnet’s governance, data network, scientific, technical, methodologic, engagement, and organizational expertise. Representatives of the Founding Institutions participate in the Steering Board, Committees, and work groups.

The 8 Founders are:

- Boston Children’s Hospital
- Children’s Hospital Colorado
- Children’s Hospital of Philadelphia
- Cincinnati Children’s Hospital Medical Center
- Nationwide Children’s Hospital



- Nemours Children's Health System
- St. Louis Children's Hospital
- Seattle Children's Hospital

These institutions are academic health centers that provide inpatient, specialty outpatient, emergency, and primary care services and programs and support large research infrastructures. With regional catchment areas extending across 11 states, and a national and international specialty referral base, PEDSnet Founding Member Institutions annually provide care for >2.1 million unique patients, about 3% of all children in the U.S., from diverse demographic, geographic, and socioeconomic backgrounds.

### 2.2 STEERING BOARD

The Steering Board serves as the overall governing body for PEDSnet. It ensures that PEDSnet is true to its mission, pursues its vision and strategic goals, and update vision as new opportunities, trends, and challenges present themselves. Responsibilities include:

- Oversight of PEDSnet's network, data, research, and engagement operations;
- Commissioning and approving PEDSnet's strategic plans;
- Defining new strategic directions;
- Ratifying policies; and,
- Providing institutional leadership in support of PEDSnet's mission and vision.

#### *Steering Board Membership*

The PEDSnet Steering Board has 10 voting members, one institutional leader who represents their Institution, and 2 parents. Each Founding Member Institution also has an Alternate Board Member. Voting members may choose to delegate voting authority to their Alternate if they are unable to vote, because of travel, illness, or other circumstances. Each institution is allowed one vote. Members and Alternates serve two-year terms, which can be renewed at the discretion of their Institution. Each institution identifies its Steering Board Member and an Alternate. Both individuals attend Steering Board meetings, receive Steering Board meeting materials, and attend PEDSnet face-to-face meetings. The institutional PEDSnet Site Principal Investigator, who also serves as a representative to the Executive Committee, will submit nominees from their Institution to the Chair and Vice Chair of the Steering Board. Addition of new members to the PEDSnet Steering Board will require a two-thirds majority of voting members to approve the nomination. Members may resign by providing written notice to the Chair of the Steering Board.

### *Steering Board Chair and Vice Chair*

An elected Chair from among the 10 voting members will lead the PEDSnet Steering Board. The Chair will serve a two-year term, renewable for one additional term. The PEDSnet Executive Director will serve as the Vice Chair of the PEDSnet Steering Board, and in this role, will provide managerial support to the Chair of the Steering Board and will be a non-voting member.

### *Steering Board Meetings*

The PEDSnet Steering Board Chair will chair these meetings. In his or her absence, the Vice Chair will lead the meeting. In cases when both individuals are absent, the Vice Chair will appoint a member of the PEDSnet Executive Committee to serve in this role. In general, meetings will be held via teleconference and webinar. One meeting each year will be held face-to-face. The Steering Board will approve summaries of Steering Board meetings within 45 days of a meeting. Once approved, the summaries will be made publicly available on the PEDSnet web site.

## 2.3 EXECUTIVE COMMITTEE

The Executive Committee (EC) will oversee PEDSnet research, data, engagement, and network operations, and will provide a forum for member institutions to communicate with one another. Responsibilities include:

- Ensure efficient and effective operations of the Network;
- Oversee the Coordinating Center, Data, Engagement, and Methods Advisory Panel Committees;
- Develop policies for ratification by the Steering Board;
- Approve changes to the Common Data Model;
- Approve requests for PEDSnet collaboration; and,
- Approve requests for PEDSnet Study Approval.

### *Executive Committee Members*

There will be 8 voting members of the Executive Committee. Each Founding Institution will appoint one individual to serve as the Institutional PEDSnet Site Principal Investigator, and these 8 individuals will be the voting members of the Executive Committee. The PEDSnet Executive Director will serve as the Chair of the Executive Committee. The Director of the Data Coordinating Center and the Director of PEDSnet Operations, both in the Coordinating Center, will serve as non-voting members. EC members will serve two-year terms, which can be renewed at the discretion of their institution. Members may resign by providing written notice to the Chair of the Executive Committee.

### *Strategic Planning*

At the discretion of the Steering Board, the Executive Committee will develop and submit for Steering Board review and ratification a PEDSnet strategic plan. Once the Steering Board ratifies this, the Executive Committee will develop operational plans for executing the strategic plan, monitoring and reporting on progress towards achieving strategic goals and objectives, and ensuring the network's performance is optimized for quality and efficiency.

### *Executive Committee Meetings*

The Executive Committee will meet on a biweekly to weekly basis, depending on the volume of activity it must handle. The PEDSnet Executive Director will chair meetings. In his or her absence, another member of the PEDSnet Executive Committee will be designated to serve in this role. In general, meetings will be held via teleconference and webinar. Summaries of Executive Committee meetings will be produced by the Coordinating Center and approved by the Executive Committee within 30 days of a meeting.

## 2.4 DATA COMMITTEE

The role of the Data Committee is to oversee PEDSnet's data network and to develop data governance policies. Responsibilities include:

- Develop policies for managing the Data Network;
- Develop data governance policies;
- Develop policies for responding to requests for data queries or data-sets;
- Stimulate informatics innovations that advance PEDSnet's mission and goals; and,
- Make recommendations to the EC regarding expansion of the PEDSnet Common Data Model.

### *Data Committee Members*

There will be 8 voting members of the Data Committee. Each Founding Member Institution will appoint one individual to serve as the PEDSnet Institutional Informatics Leader. These individuals will be the voting members of the Data Committee. The PEDSnet Director of the Data Coordinating Center will serve as the Chair of the Data Committee. Data Committee members will serve two-year terms, which can be renewed. Members may resign by providing written notice to the Chair of the Executive Committee.

### *Data Committee Meetings*

The Data Committee will meet on a frequency commensurate with the volume of activity it must handle. The PEDSnet Director of the Data Coordinating Center will chair meetings. In his or her absence, another member of the PEDSnet Data Committee will be designated to serve in this role. In general, meetings will be held via teleconference and webinar.

## 2.5 ENGAGEMENT COMMITTEE

The role of the Engagement Committee is to stimulate, strengthen, and oversee engagement of institutions, networks, and individuals in PEDSnet. Responsibilities include:

- Development and oversight of PEDSnet's membership model;
- Development and oversight of PEDSnet's approach to outreach;
- Identification and dissemination of effective patients, parent, and clinician engagement methods for research projects; and,
- Development and oversight of the PEDSnet engagement services.

### *Engagement Committee Members*

There will be 8 voting members of the Engagement Committee. Each Founding Member Institution will appoint one individual to serve on the Engagement Committee. The Executive Director will select an individual to chair the Engagement Committee. Engagement Committee members will serve two-year terms, which can be renewed. Committee members may resign by providing written notice to the Chair of the Executive Committee.

### *Engagement Committee Meetings*

The Engagement Committee will meet on a frequency commensurate with the volume of activity it must handle. The PEDSnet Engagement Committee chair will lead meetings. In his or her absence, another member of the PEDSnet Engagement Committee will be designated to serve in this role. In general, meetings will be held via teleconference and webinar.

## 2.6 METHODOLOGY ADVISORY PANEL (MAP)

The purpose of the MAP, a sub-committee of the Executive Committee, is to assist investigators in developing high quality protocols that will result in actionable results for health care providers and patients or changes in practice. Responsibilities include:

- Development and implementation of the PEDSnet Study Approval process
- Provision of constructive feedback to research proposals

### *MAP Membership*

The MAP members will be chosen so as to provide particular expertise in research designs and methods, such as those highlighted in the PCORI Methodology Report and Standards. In addition, some MAP members will have expertise in the use of patient-reported child health outcome measures. The MAP members will be nominated by Institutional Site Principal

Investigators and will be approved by the PEDSnet Director of Research. Each PEDSnet site will have, at minimum, one funded methodologist (generally doctoral-level statisticians, epidemiologists, clinical trial experts, and social scientists) on the MAP.

### *MAP Meetings*

The MAP will meet on a frequency commensurate with the volume of activity it must handle. The PEDSnet Director of Research will appoint a chair or co-chairs to lead the meetings. In general, meetings will be held via teleconference and webinar.

## 2.7 COORDINATING CENTER

The PEDSnet Executive Director leads the Coordinating Center (CC). The CC includes a PEDSnet Management Office (PMO), Data Coordinating Center (DCC), and a PEDSnet Management Council (PMC).

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### 2.7.1 PEDSNET EXECUTIVE DIRECTOR

Responsibilities for this individual include:

- Ensure successful execution of the PEDSnet strategic and operational plans;
- Provide leadership to the Coordinating Center; and,
- Serve in the following roles:
  - Network liaison to PCORnet;
  - Vice Chair of the PEDSnet Steering Board; and,
  - Chair of the PEDSnet Executive Committee.

The PEDSnet Executive Director is appointed by and reports to the Steering Board.

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### 2.7.2 PEDSNET MANAGEMENT OFFICE (PMO)

The PMO provides logistical and project management support to Network operations and research projects. Responsibilities include:

- Communication within the Network;
- Outreach activities under the direction of the Engagement Committee;
- Management of the PEDSnet web site and access to PEDSnet resources;
- Project management for research projects; and,
- Logistical support to the Steering Board, Committees, and Working Groups.

The PMO is led by the PEDSnet Director of Operations, who is appointed by and reports to the PEDSnet Executive Director.

### 2.7.3 DATA COORDINATING CENTER (DCC)

The DCC develops, maintains, and operates the PEDSnet data network under the guidance of the Data Committee. Responsibilities include:

- Implement the PEDSnet data sharing infrastructure;
- Maintain Network data standards;
- Manage submission of data extracts;
- Perform data quality assessments of the data network;
- Ensure the data security;
- Perform data linkages with external data sources;
- Document procedures;
- Provide monthly reports on uses of the data network;
- Develop reusable tools for management and use of the data network;
- Archive study data and results; and,
- Respond to data requests for queries and data sets to support research studies.

The DCC is led by the PEDSnet Informatics Director, who is appointed by and reports to the PEDSnet Executive Director.

### 2.7.4 PEDSNET MANAGEMENT COUNCIL (PMC)

The PMC will be responsible for overseeing the day-to-day operations of the Network. It will ensure that the operational plans approved by the Executive Committee are executed efficiently and effectively. It will produce standard processes for review and approval by the Executive Committee. The members of the PMC will include the PEDSnet Director of Operations, Informatics Director, Research Director, Engagement Director, and Executive Director.

#### *Research Director*

The Research Director will be responsible for developing policies, processes, and procedures that facilitate development of research projects and their implementation. The Research Director will promote research partnerships, oversee the assignment of PEDSnet Study Approval to individual projects, and oversee the development of policies for IRB oversight for PEDSnet studies. The Research Director may develop working groups to manage some of these activities, such as an IRB/Regulatory work group to develop and oversee a Single IRB framework for the Network. The Research Director will be appointed by and report to the Executive Director.

### *Engagement Director*

The Engagement Director will be responsible for designing, continuously improving, and overseeing the formation and engagement of PEDSnet's communities of patient, clinician, and network participants, management of the PEDSnet membership program, and the identification and development of engagement resources and tools for research projects. The Engagement Director may develop working groups to manage some of these activities. The Engagement Director will be appointed by and report to the Executive Director.

### *Informatics Director*

The Informatics Director will provide operational leadership for PEDSnet's data network and data governance, lead DCC operations, will chair the Data Committee, and stimulate informatics innovations that advance the goals of PEDSnet. The Informatics Director may develop working groups to manage some of these activities. The DCC Director will be appointed by the PEDSnet Principal Investigator.

### *PMC Meetings*

The PMC will meet on a weekly basis. Meetings will be chaired by the Director of Operations.

## 2.8 INSTITUTIONAL TEAMS

Each Founding Member Institution will assemble several individuals to form an Institutional Team. These individuals will represent the Institution in various PEDSnet Committees and Work Groups, and will conduct the business of PEDSnet within their own institution. The composition of Institutional Teams and the role of team members is as follows:

### *Steering Board Member*

Serves on the Steering Board as a voting member

### *Steering Board Alternate*

Serves on the Steering Board as a non-voting member

### *Site Principal Investigator*

Oversees PEDSnet activities within his or her Institution; serves as primary scientific liaison for institutional investigators who wish to work with PEDSnet; approve requests for their institution to serve as a PEDSnet sponsor institution; approves PEDSnet study concept submissions to the Methods Advisory Panel; serves on the PEDSnet Executive Committee;

### *Site Informatics Lead*

Oversees data extraction, transformation, and loading into data network; supervises informatics staff; and, serves on Data Committee

### *Informatics Staff*

Execute data extraction, transformation, and loading of data into data network; maintain local PEDSnet data mart; manage re-identification of patients for PEDSnet research studies; and, provide informatics support to conduct of PEDSnet research at their institution

### *Parent Partners*

Participate in PEDSnet Committees and work groups; participate in PEDSnet Studies as parent partners

### *Project Manager*

Provides administrative and project management support to Institutional Team; serves as institutional representative to PMO

### *IRB Representative*

Serves on the Regulatory Working Group, representing the institution's regulatory interests

### *Legal Representative*

Provides legal expertise to ad hoc PEDSnet working groups

### *Sponsored Project Office Representative/s (including Research Business/Finance)*

Participate in ad hoc working groups related to contracting, and grant preparation and management; implement streamlined grant preparation, management (including budget), and contractual processes to increase the efficiency of PEDSnet administrative operations



### 3 DECISION-MAKING AND VOTING

The same policy and procedures will be used for decision-making and voting in the Steering Board, Committees, and Work Groups:

- All governance entities will seek to reach decisions through consensus;
- When voting is necessary, a two-thirds majority of voting members will be required to approve an Action;
- One vote is allowed per PEDSnet member institution;
- Voting can be done up to one week following a call for a vote, and can be done electronically, in person, or via teleconference; and,
- A quorum will be defined as >75% of total members in the governing entity.

## 4 DATA NETWORK

### 4.1 INCLUSION OF DATA IN DATA NETWORK

Institutions may choose to submit data to the DCC for inclusion into the data network, or retain data locally and after appropriate data quality analyses are done, make their data available to the distributed Data Network under the conditions established by the PEDSnet governance and regulatory structures.

The core PEDSnet data resource meets the HIPAA definition of a limited data set (includes dates). For the purposes of inclusion in the PEDSnet data network, a patient is defined as an individual with at least one clinician face-to-face visit in any outpatient or inpatient setting and at least one diagnosis code recorded since January 1, 2009.

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#### 4.1.1 SUBMISSION OF DATA EXTRACTS TO DCC

Institutions that choose to submit data extracts to the DCC have the following responsibilities and expectations:

- Submit data on a quarterly basis;
- Under the guidance of the DCC, extract data from institutional data sources, transform those data according to the PEDSnet Extract-Transform-Load conventions maintained by the DCC, and securely upload the data extract to the DCC; and
- In response to findings based on DCC data quality assessments, remediate the ETL processes to address data quality issues as much as possible, and/or annotate issues that cannot be resolved and resubmit revised data to the DCC.

Once data are received, the DCC will:

- Destroy any data extract that includes protected health information, other than dates or zip codes, as defined by HIPAA;
- Run data characterization analyses to ensure acceptable levels of data quality;
- Communicate to institutions any problems detected in data quality, and institutions will remediate modifiable problems;
- Create any derived variables or data profiles required by data network procedures;
- Load the data extract into the PEDSnet Data Network once the data meet acceptable levels of data quality;
- Load the data extract into the PCORnet Data Network (via PopMedNet as dictated by PCORnet DCC); and,
- Mediate access to the data for usage approved by the PEDSnet Executive Committee and/or as required by PCORnet.

### 4.1.2 RETENTION OF DATA EXTRACTS WITHIN THE INSTITUTION

Institutions that choose to retain data extracts have the following responsibilities and expectations:

- Incorporate data extracts within the Institution on a quarterly basis;
- Under the guidance of the DCC, institutions that retain their data locally will extract data from institutional data sources, transform those data according to the PEDSnet Extract-Transform-Load conventions maintained by the DCC, and load the data extract to a local PEDSnet data mart staging area;
- The institutional informatics team is responsible for creating any derived variables or data profiles required by data network procedures, under the guidance of the DCC;
- Before loading the data extract into the PEDSnet data network, the institutional informatics team will run data characterization analyses, provided by the DCC, to ensure acceptable levels of data quality, and will report results to the DCC;
- Once the data meet acceptable levels of data quality, they will become part of the PEDSnet Data Network; and,
- Respond to data queries from PEDnet investigators and the PCORnet Data Coordinating Center in accordance with PEDSnet and PCORnet data governance and regulatory requirements.

## 4.2 DATA QUALITY

The Informatics Director will submit data quality reports on a quarterly basis to the Executive Committee. Once that Committee reviews and approves it, the report will be sent to the Steering Board. The report will provide a clear assessment of the quality of PEDSnet data for research. The DCC will communicate to institutions any problems detected in data quality, and institutions will remediate modifiable problems.

## 4.3 COMMON DATA MODEL

PEDSnet data will be stored in both the PEDSnet and PCORnet Common Data Model formats, either at the PEDSnet DCC for sites that provide data (Section 4.2.1) or at the local site for sites that elect to manage data access locally (Section 4.2.2).

### 4.3.1 PEDSNET COMMON DATA MODEL

The DCC will maintain a pediatric-specific Common Data Model (PEDSnet CDM) for storage of PEDSnet data. The PEDSnet CDM will be used for studies and data queries that are done in PEDSnet only. The PEDSnet CDM will be expanded on an annual basis, with expansions proposed by the Data Committee and approved by both the Executive Committee and Steering Board.

### 4.3.2 PCORNET COMMON DATA MODEL

The PEDSnet Data Network will also support the PCORnet Common Data Model. The PCORnet CDM will be used for PCORnet studies and data queries. As per PCORnet policy, the PCORnet CDM will be expanded on an annual basis.

## 4.4 PATIENT REIDENTIFICATION

All Institutions contributing data to the PEDSnet Data Network regardless of whether data are submitted to the PEDSnet DCC or kept locally will retain direct patient identifiers locally, within each institution, and will not share this information with the DCC. Patients will be assigned a PEDSnet Patient ID that has no internal meaning. Sites will retain the mapping between the PEDSnet Patient ID and local identifiers (such as a medical record number).

Certain research applications may require patients of interest to be identified in order to contact them for participation in study. All studies requiring reidentification will have IRB oversight. Patient reidentification will be done by providing institutions with the PEDSnet patient identifiers of interest, and the institutions will perform the reidentification.

## 4.5 AUTHORIZED USERS

The DCC will develop and maintain a process and procedures for staff members at member institutions to become authorized users of the PEDSnet data network applications. The Executive Committee will review and approve the process and procedures. The DCC will provide a list to the Executive Committee on a periodic basis of all individuals granted authorized user status during the reporting period.

## 4.6 REQUESTS FOR DATA

Requests for data will be made to the PEDSnet Coordinating Center, which will do an administrative review. Additional data and network governance oversight and review is dictated by the nature of the data request as outlined below.

### 4.6.1 FEASIBILITY AND DESCRIPTIVE ANALYSES

The Data Coordinating Center will provide a service to requesters who would like to obtain counts or cross-tabulations of patients or events in preparation for development of a research project proposal or use in a descriptive study.

These requests will generally not require Institutional Review Board oversight, because they are not considered human subjects research.

All requests will be approved by a Site Principal Investigator or the Executive Committee.

### 4.6.2 PATIENT-LEVEL DATA-SET REQUESTS

Investigators who require either a de-identified or limited (as defined by HIPAA) patient-level data-set will be required to obtain PEDSnet Study Approval (see Section 5.3.2 for definition of “PEDSnet Study”). Once the request is approved, the DCC will provide the minimum data necessary to answer study questions.

## 4.7 REMOVAL OF DATA FROM THE DATA NETWORK

Institutions at any time can request that data stored in either the PEDSnet or PCORnet CDM within the DCC be removed from the data network. These requests must be made in writing and submitted to the PEDSnet Executive Director. Data will be destroyed within 30 days of receipt of this request. Data previously released or archived as part of a research study is not included in the scope of this section.

## 5 ACCESSING PEDSNET RESOURCES

### 5.1 GUIDING PRINCIPLES FOR INQUIRIES REGARDING PEDSNET SCIENTIFIC RESOURCES

Many opportunities will come to PEDSnet from investigators, patient groups, health systems, and sponsors. PEDSnet will seek to prioritize studies that directly address clinical decision making among diagnostic or treatment alternatives available to parents, patients and providers or by health care delivery systems. A related goal is to engage patients and other stakeholders in all phases of research and dissemination of results.

It is expected that those proposing research ideas to PEDSnet will include teams led by experienced investigators with content and methodological expertise as well as more junior investigators. Teams may be local to one institution or incorporate individuals at several PEDSnet sites, or collaborators external to PEDSnet.

Some investigators may not have experience with the level of patient or clinician engagement expected by this network or some of the more non-traditional study design elements which may be useful in patient-centered research. The PEDSnet Engagement Committee will provide resources and services to support deeper engagement of patients, families and clinicians in research.

Investigators will also need guidance regarding the data resources available, optimal use of the infrastructure for collaborative research (e.g. Master Reliance Agreements among PEDSnet institutions), and support from the PEDSnet Data Coordinating Center.

In order to provide a systematic, transparent, and efficient approach for engaging in opportunities as a Network, PEDSnet will maintain a simple process for collecting, evaluating and triaging opportunities. This 'Front-Door' ensures potential research partners have a clear pathway for engaging PEDSnet and for PEDSnet members to participate equally.

### 5.2 FRONT DOOR UNIT

In order to ensure research study proposals leveraging PCORnet are consistently solicited, collected and evaluated, the following guiding principles for the Front Door of PEDSnet include:

- Relevant information regarding PEDSnet priorities, data and analytical resources, and policies should be freely and publicly available to potential investigators;
- Information regarding both the process for proposal submission and evaluation intake should be clear and succinct;
- The review process should be efficient, rapid and reproducible;
- Information gathered should enable initial decision-making by Institutions about participation by PEDSnet institutions; and,
- Confidentiality of requests and scientific ideas should be protected.

The Coordinating Center will maintain an administrative *Front Door Unit* that will process requests for scientific resources.

### 5.3 TYPES OF INQUIRIES

#### 5.3.1 FEASIBILITY OR DESCRIPTIVE ANALYSES

These requests may be related to early assessments of feasibility of a study or the preparation of a grant application. They may also be simple cross-tabulations that could result in a publication. In some cases, these requests can be satisfied by granting the requestor access to PEDSnet data network applications. In others, the DCC will perform a data analysis based on specifications provided by the requestor. Inquiries should clearly indicate at what aggregation level the results should be aggregated: overall for PEDSnet, by Institution, or some other unit. Aggregation units' identities will be masked when they are delivered to the requestor. These requests will be processed efficiently, and will not require prospective review by the Executive Committee. The Front Door Unit will provide a monthly report to the Executive Committee on all requests of this type made to PEDSnet and their disposition.

#### 5.3.2 REQUEST FOR PEDSNET COLLABORATORS

Investigators within or outside of PEDSnet can submit a study idea to PEDSnet, requesting approval to develop a PEDSnet proposal. The Front Door Unit will facilitate matching a request for technical or scientific expertise with available resources and expertise within the Institutions in domains such as: clinical, methodological, data, engagement, regulatory, and other. These requests will not require IRB or Executive Committee approval. The Front Door Unit will provide a monthly report to the Executive Committee on all requests of this type made to PEDSnet and their disposition.

#### 5.3.2 PEDSNET STUDY APPROVAL

A research team will be required to submit their study proposal to be considered for PEDSnet Study Approval. The Front Door Unit will perform administrative reviews of these applications. Both a technical and scientific review will be done, the former by the Data Committee and latter by the Methodology Advisory Panel. Results from these reviews will be presented to the Executive Committee, which will grant PEDSnet Study approval and will also approve the use of any requested Coordinating Center resources.

*The criteria for PEDSnet Study Approval will include at a minimum all of the following:*

- A sponsoring PEDSnet member institution;
- An investigator team with at least one investigator from a PEDSnet institution;
- Research using existing PEDSnet data and/or data collected from PEDSnet clinical care sites at >1 PEDSnet institution;
- Consideration of how to engage patients and clinicians in the research; and,
- Endorsement by the PEDSnet Executive Committee, informed by the PEDSnet MAP and family partner review process.

*The expectations of PEDSnet Studies include:*

- Registration with ClinicalTrials.gov, if appropriate;
- Use of PEDSnet's streamlined regulatory and contractual resources, when appropriate;
- Participation in the tracking of network efficiency metrics (e.g. regulatory- time to multi-site IRB approval);
- Posting of study summaries and updates on the public facing portion of the PEDSnet web site;
- Submission of a data package to the Coordinating Center within 12 months from the completion of the final analysis including:
  - Study protocol, including original version and all amendments
  - Analysis files used to generate the published reports
  - Statistical code used to generate the analysis files.
  - Data Quality Assessment for data domains and elements outside current CDM;
- Acknowledgment of the study's status as a PEDSnet study in all websites, reports, presentations, and manuscripts; and,
- Submission of a report on lessons learned from successes and failures to the Coordinating Center within 12 months from the completion of the final analysis, which will be deposited in the PEDSnet Commons.

### 5.4 ELECTIVE PARTICIPATION IN STUDIES

Participation by an Institution in a particular PEDSnet study is voluntary. However, the expectation is that participating institutions allow their data to be used for observational studies that do not require contact with human subjects (data-only studies) unless there is a compelling reason to not participate. For studies that require recruitment, additional data collection, or participation in a trial that intervenes at either the patient level or a clinical system (cluster designs), sites will need to affirmatively express willingness to participate.



## 6 PATIENT AND STAKEHOLDER ENGAGEMENT

Engaging participants is foundational to the work of PEDSnet and extends beyond patients and families to clinicians, researchers and health systems.

### 6.1 GUIDING PRINCIPLES

Guiding principles include:

- Patients and families are partners in all phases of the research process including: formulating research questions; defining essential characteristics of study participants, comparators, and outcomes; identifying and selecting outcomes for the population of interest, conducting and monitoring the research and disseminating and implementing the results;
- Patients are involved in network leadership positions; and,
- Patients are involved in decision-making about network participation in proposed studies.

### 6.2 FINANCIAL RECOGNITION

Many parent and stakeholder participants will be motivated by a desire to improve the research base and care processes that affect child health. How this is recognized is an important issue and in some cases, those engaged in a PEDSnet project will be recognized financially. Patients who contribute to PCORnet at large and to Network leadership roles are compensated if the participation requires sustained work effort.

### 6.3 ENGAGEMENT RESOURCES AND TRAINING

PEDSnet will develop the tools, training and support to enable patients, families, clinicians, researchers and health system leaders to interact throughout the research and implementation process. The initial focus of activities will be prioritizing resource development to support the needs of projects that are using PEDSnet resources. We anticipate that will include the research prioritization process, engagement design studios, training for patients and families in research, training for clinicians and researchers in co-production with patients and families, and training in community building to engage communities of individuals interested in PEDSnet.

## 7 REASSESSMENT AND MODIFICATION OF PEDSNET POLICIES

The PEDSnet Steering Board will review PEDSnet policies on at least an annual basis. Alterations to PEDSnet policies will require two-thirds of Steering Board members to ratify the change(s).

## 8 CONFLICT OF INTEREST

All members of the Steering Board and Committees shall abide by their institutional Conflict of Interest Policies and disclose any potential conflicts of interest annually to the Board. The PEDSnet Executive Committee will be responsible for identifying potential conflicts and working with the Board member to develop an appropriate conflict of interest mitigation plan.

## **9 INSTITUTIONAL REVIEW BOARD**

### **9.1 PARTICIPATION IN THE PEDSNET SINGLE IRB FRAMEWORK**

All PEDSnet institutional members are required to endorse the PEDSnet single IRB policy by becoming a participating institution of the Master Common Reciprocal Institutional Review Board Reliance Authorization Agreement (also referred to as the Master Reliance Agreement).

### **9.2 VOLUNTARINESS OF PARTICIPATION IN MASTER RELIANCE AGREEMENT**

Participation in the Master Reliance Agreement allows an institution to choose on a case-by-case protocol basis whether to participate in a ceded review, as a relying or reviewing institution, or perform its own IRB review. Given the network's underlying principle of collaboration, PEDSnet expects that IRB reliance opt-out will be a rare occurrence, and would require an appropriate justification.

## 10 PRIVACY AND DATA SECURITY

PEDSnet believes that the protection of privacy, confidentiality, and data security is essential to the existence and success of research. Equally essential is fostering an environment of trust among patients who are contributing to the data resource, and the entities who are stewards and users of the data. PEDSnet maintains a policy for the protection of patient privacy, data security, confidentiality of health data, and appropriate use of data.

### *Transparency and Communication*

PEDSnet will make its policies and practices on health information open and available for patients and other stakeholders. PEDSnet will clearly communicate with patients, their families, and all other stakeholders about how patient data are used in clinical research, the safeguards undertaken by the network to protect patient privacy and maintain data security, and will seek input from patients and other key stakeholders on how best to engage the PEDSnet community on these issues.

### *Legal Requirements*

Each PEDSnet healthcare organization adheres to all local policies regarding the use of healthcare data. All research practices in PEDSnet comply with current local and national, legal and regulatory requirements. PEDSnet institutions that collect and maintain personal information are subject to the federal Privacy Rule under the Health Insurance Portability and Accountability Act (HIPAA), which requires a description of institutional privacy practices on how the entity collects and maintains personal information, and patients' rights regarding their data.

### *Use Specification and Minimization*

The purposes for which health information are used should be specified at the time of study design (including reference to future use), and only the minimum necessary information for those purposes should be released. Common categories of data that will be made available to data requestors (who have undergone appropriate review and approval mechanisms) include: deidentified, aggregate data; deidentified, individual level results or small populations; non-readily identifiable patient level data ("limited data sets"); and, identifiable patient level data.

### *Response to Breach*

Data provided by PEDSnet must be used only for the purposes specified. If there is a breach of data that risks identification of individual patients, mechanisms for notification as outlined in PEDSnet policies will be activated. The level of action will be low if the risk of invasion of privacy and breach of confidentiality is minimal, and high if the risk of invasion of privacy and breach of confidentiality is significant.

### *Voluntariness and Local Control*

Decisions to participate in specific PEDSnet research projects that involve individual patient-level data will always be made voluntarily by each participating PEDSnet institution. Research using readily identifiable personal information will be done only with the consent of the individual families participating, or in rare cases when an Institutional Review Board decides

that the information is limited and there are safeguards in the study to insure that identifiable information will not be released.

### *Data Security*

PEDSnet adopts best practices for protection of patient data. The Data Coordinating Center implements a broad set of security and reliability controls targeting the Statements on Standards for Attestation Engagements No. 16 (SSAE16), which are widely recognized audit standards that verify the state of internal controls for a data center. Individual PEDSnet institutions implement their own information security policies to safeguard the data that is held locally. The PEDSnet Data Coordinating Center coordinates a significant number of administrative safeguards to minimize the risk of a breach involving protected health information.

