PEDSnet Policies
Version 6

LAST UPDATED: MARCH 2023

Version Date	Version and Modifications
November 2015	Version 1
June 2016	Version 2: major modifications and additions
January 2018	Version 3: addition of publication policy
March 2019	Version 4: significantly modified to reflect transition off PCORI contract funding and addition of new members
May 2020	Version 5: modified to update the database policies and transition to interim governance during the PEDsnet-CHA integration discussions
March 2023	Version 6: major modifications from the new governance committees.

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1　　　MISSION

Mission: To improve child and health system outcomes through the nation's leading network for multi-center pediatric research.

To accomplish this purpose, PEDSnet has created a collaborative infrastructure that makes multi-center pediatric clinical research easier and less expensive. It engages stakeholders in the research process, and generates new knowledge that informs the decisions that patients, families, clinicians, and health system leaders make each day to improve the health and healthcare of children and adolescents and the systems that serve their health needs.

PEDSnet has adopted the learning health system model for improving outcomes and is contributing to the formation of a national-scale pediatric learning health system. The essential attributes of a learning health system are:

1. **Communities** of children, families, front-line clinicians, researchers, and health system leaders who collaborate to produce and use pediatric health care data;
2. Access to extensive real-world clinical and administrative **data** from patients, families, electronic health records and other sources;
3. **Research** done in routine clinical care and community settings; and,
4. Quality **improvement** at the point of care brought about by the integration of relevant new knowledge generated through research or ascertainment of best practices.

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.

2   VISION

Vision Statement: We will change child healthcare by becoming the premier national resource for multi-center pediatric research and learning health systems science.

Vision Summary: We imagine a future in which PEDSnet has become a national public utility (i.e., available to the entire nation) for multi-center research, learning health systems science, and implementation science-oriented research. Several accomplishments will be necessary over the next five years to realize this vision.

- Families and children, especially those with rare disorders are involved in governance, data collection and outcomes reporting.
- The PEDSnet database will include over 15% of the nation's children, including diverse communities of persons usually underrepresented in research;
- >15 pediatric medical centers will be members of PEDSnet;
- Research funding will comprise a diverse portfolio of public and private sector sponsorship;
- PEDSnet is active in projects with multiple other research networks and will continue to expand in this area;
- Project leadership will be distributed across the network with a central coordinating center setting standards, but multiple institutions serving as study-specific coordinating centers; and,
- Long-term financial sustainability of the PEDSnet infrastructure will have been secured, including for improvement activities related to quality of care delivered over participating sites.

3   ORGANIZATION

This section reflects the current organizational structure of PEDSnet that is designed to support participatory decision-making regarding overall network governance (Steering Committee), data governance (Data Network Committee), and research project governance (Research Committee).

3.1   STEERING COMMITTEE

3.1.1 Steering Committee Responsibilities

The Steering Committee serves as the overall governing body for PEDSnet. It ensures that PEDSnet adheres to its mission, pursues its vision, and develops strategies as new opportunities, trends, and challenges present themselves. The Steering Committee will oversee network governance, policy, and strategy. This includes management of strategic partnerships, both with external funding partners as well as internal institutional member relationships. The Steering Committee will also oversee all network research and financial activities, including oversight of other PEDSnet committees and workgroups, member participation, and network communications.

Responsibilities include:

- Monitor Research Committee activities with monthly reports from Chair
- Monitor Data Network Committee activities with monthly reports from Chair
- Monitor Engagement activities with monthly reports from Network Engagement Lead
- Update PEDSnet policies annually and on an ad hoc basis
- Institutional research project participation voting process
- Dataset release voting process
- Monitor network finances
- New and existing institutional membership management
- Manage relationship with external partners (such as PCORnet, NESTcc)
- Oversight of Center Without Walls program
- Oversight of Network Data Governance
- Set and monitor strategic goals for the network
- Develop (every 3 years) and manage a strategic plan
- Develop and partnering with subspecialty networks

3.1.2 Steering Committee Membership

The PEDSnet Steering Committee has 2 members per institution. Each institution has 1 vote when decisions need to be made. The PEDSnet Site PI is the default voting member of the Steering Committee, but may delegate this responsibility to their Informatics Lead at their discretion. The Committee will also have 1 parent representative for every 3 institutional members. Institutions nominate their representatives, and current members approve these individuals.

3.1.3 Steering Committee Chair

A Chair from among the voting members will lead the PEDSnet Steering Committee. The term of the Chair will be one year with a second year served as the past-Chair. The Steering Committee Chair position will rotate between the previous year's Research Committee and Data Network Committee Chairs. The voting members of the Steering Committee will vote to approve the new chair on an annual basis.

3.1.4 Steering Committee Meetings
The PEDSnet Steering Committee Chair will lead these meetings, and they will be supported by the Coordinating Center. Meetings will be held via teleconference, videoconference, or in-person. In the Chair's absence, the Coordinating Center may lead the meetings. One meeting each year will be held face-to-face.

3.2   EXECUTIVE COMMITTEE

3.2.1 Executive Committee Responsibilities
The Executive Committee will provide oversight for the day-to-day operations of the network. Responsibilities include:

- Overseeing Coordinating Center activities;
- Developing the Steering Committee meeting agendas;
- Reviewing requests for Network Collaborations; and,
- Providing day-to-day oversight of ongoing research, network metrics, the PEDSnet database, and the project management office.

3.2.2 Executive Committee Composition
The Executive Committee members include the Steering, Data, and Research Committee Chairs and Co-Chairs and the past Steering Committee chair. The Coordinating Center will serve as staff to the Executive Committee.

3.3   DATA NETWORK COMMITTEE

3.3.1 Data Network Committee Responsibilities
The Data Network Committee will provide oversight of the data network and data governance. Responsibilities include:

- Institutional data submission timeliness and completeness
- Variable dictionary (in collaboration with Research Committee)
- Data quality
  - o   Minimum standards for production data
  - o   Data quality reports fed back to the sites
  - o   Data quality metrics made publicly available on the web site

- o   Study-specific data quality metrics and feedback to institutions
- Policies and procedures related to the data network and its regulatory environment
- Oversee PEDSnet query fulfillment
- Oversight of data access to full database and to self-service tools
- Strategic plan for the evolution of data network (latency, automating ETL processes, movement to the cloud, etc.)
- PEDSnet Common Data Model expansions
  - o   Set technical priorities; annual process; review Research Committee priorities
- Data science (research) priorities

3.3.2 Data Network Committee Membership

The PEDSnet Data Network Committee has 1 member per institution. The PEDSnet Site Informatics Lead is the voting member of the Data Network Committee. The Committee will also have 1 parent representative for every 3 institutional members.

3.3.3 Data Network Committee Chair

A Chair from among the PEDSnet Site Co-PIs will lead the PEDSnet Data Network Committee. The term of the Chair will be one year with a second year served as the past-Chair. In alternate years, the past-Chair of the Data Network Committee will become the Chair of the Steering Committee.

3.3.4 Data Network Committee Meetings

The PEDSnet Data Network Committee Chair will lead these meetings, and they will be supported by the Coordinating Center. Meetings will be held via teleconference, videoconference, or in-person. In the Chair's absence, the Coordinating Center may lead the meetings.

3.4 RESEARCH COMMITTEE

3.4.1 Research Committee Responsibilities

The Research Committee will oversee PEDSnet research project governance. Responsibilities include:

- Research intake process
- Grant submissions
  - o   Review process, clarify CC services, consider training sites on the PEDSnet standards for grant submission, consider setting up a repository of resources for grant submissions
- Research projects
  - o   What types of information are needed for committee oversight of research projects?
  - o   What should the content be for teams to report to the Committee activities for their research studies?

- Dissemination products: publications, presentations, and reports
  - o Review and revise as needed publication policy
  - o Consider a metric that evaluates the number of unique authors on manuscripts by month
- Variable dictionary (in collaboration with Data Committee)
- Research concept approval (by vote)
- Research priorities
  - o Develop and propose to Steering Committee annually
- PEDSnet Common Data Model expansions
  - o Set scientific priorities--Data Committee reviews for feasibility; and, the Steering Committee approves; annual process

3.4.2 Research Committee Membership
The PEDSnet Research Committee has 1 voting member per institution. The representative may be the Site PI or Informatics Lead. The Committee will also have 1 parent representative for every 3 institutional members.

3.4.3 Research Committee Chair
A Chair from among the voting members will lead the PEDSnet Research Committee. The term of the Chair will be one year with a second year served as the past-Chair. In alternate years, the past-Chair of the Research Committee will become the Chair of the Steering Committee.

3.4.4 Research Committee Meetings
The PEDSnet Research Committee Chair will lead these meetings, and they will be supported by the Coordinating Center. Meetings will be held via teleconference, videoconference, or in-person. In the Chair's absence, the Coordinating Center may lead the meetings.

3.5   SUBCOMMITTEES, WORKGROUPS AND RESEARCH CORES

3.5.1 Forming Workgroups and Subcommittees
The Steering Committee may create workgroups and subcommittees to accomplish specific tasks. In general, ad hoc workgroups will be time-limited; however, standing Workgroups or Subcommittees can be established as needed at the discretion of the Steering Committee.

3.5.2 Engagement Core
The role of the Engagement Core is to develop and oversee engagement of individual patients, parents/caregivers, clinicians, and health system leaders in PEDSnet research, and to promote coproduction of research and health system implementation strategies between these stakeholders and researchers. The Core's responsibilities include:

- Develop and oversee PEDSnet's research study engagement model;
- Develop and oversee PEDSnet engagement services for research studies; and,
- Provide recommendations to the Research Committee for Study Proposals.

3.5.2.1 Engagement Core Lead
The Engagement Core will be led by an institutional team based outside the Coordinating Center.

3.5.2.2 Engagement Council Membership
The Engagement Core will lead the Family Advisory Council (FAC) and Youth Advisory Council (YAC). Each institution will have two members on each council. The Director of Engagement or designated project manager will serve as staff to the Workgroup.

3.5.2.3 Payment for Parents and Youth
Parents and Youth will be compensated for the time they spend on engagement Council activities.

3.5.3 Data Models Workgroup
This Workgroup will develop guidance on Extract-Transform-Load algorithms to implement the PEDSnet common data model, create conventions for the PEDSnet CDM, assess potential changes to the common data model or content, and develop consensus policies for data provenance.

3.5.3.1 Data Models Workgroup Lead
The Coordinating Center will serve as the Data Models Workgroup lead.

3.5.3.2 Data Models Workgroup Membership
Each institution will have at least one member of this workgroup.

3.5.4 Communications Workgroup
The Communications Workgroup will oversee the PEDSnet website and monthly PEDSnet newsletter. It will manage communications with investigators on use of PEDSnet data and policies on reporting and publishing PEDSnet study results. The Workgroup will report up to the PEDSnet Steering Committee.

3.5.4.1 Communications Workgroup Lead
The workgroup lead will be selected from among the PEDSnet member sites, and will serve in the position for a 1 year term.

3.5.4.2 Communications Workgroup Membership
Each site will participate in at least two workgroups (in addition to the Regulatory Workgroup). There will be approximately 4-8 members per workgroup; members may include PEDSnet PIs, Informatics Leads, site investigators nominated by the Site PI, Parent Partners, and staff. The Coordinating Center will support the workgroup.

3.5.5 Finance, Membership, and External Relations Workgroup
The Finance, Membership & External Relations Workgroup will monitor and oversee network finances and make recommendations for improvement to the Steering Committee. It will

evaluate new institutional member applications, oversee the onboarding process of new institutional members, and conduct ongoing evaluations of existing members. The Workgroup will report up to the PEDSnet Steering Committee.

3.5.5.1 Finance, Membership, and External Relations Workgroup Lead
The workgroup lead will be selected from among the PEDSnet member sites, and will serve in the position for a 1 year term.

3.5.5.2 Finance, Membership, and External Relations Workgroup Membership
Each site will participate in at least two workgroups (in addition to the Regulatory Workgroup). There will be approximately 4-8 members per workgroup; members may include PEDSnet PIs, Informatics Leads, site investigators nominated by the Site PI, Parent Partners, and staff. The Coordinating Center will support the workgroup.

3.5.6 Regulatory Workgroup
The Regulatory Workgroup will oversee network regulatory policies and arrangements, such as data storage systems, small cell size policies, network IRBs, and network data-sharing legal agreements. The Workgroup will report up the the Steering Committee.

3.5.6.1 Regulatory Workgroup Lead
The workgroup lead will be selected from among the PEDSnet Coordinating Center or member sites, and will serve in the position for at least a 1 year term.

3.5.6.2 Regulatory Workgroup Membership
Each site will have at least 1 representative on the Regulatory Workgroup. Representatives may include IRB chairs or senior leaders, Privacy Office leaders, and senior legal representatives. The Coordinating Center will support the workgroup.

3.5.7 Strategic Planning Workgroup
The Strategic Planning Workgroup will assess the current and future strategic directions of the network. It will manage relationships with external partners as well as internal institutional member relationships and oversee resource and training needs. The Workgroup will report up to the PEDSnet Steering Committee.

3.5.7.1 Strategic Planning Workgroup Lead
The workgroup lead will be selected from among the PEDSnet Coordinating Center or member sites, and will serve in the position for a 1 year term.

3.5.7.2 Strategic Planning Workgroup Membership
Each site will participate in at least two workgroups (in addition to the Regulatory Workgroup). There will be approximately 4-8 members per workgroup; members may include PEDSnet PIs, Informatics Leads, site investigators nominated by the Site PI, and Parent Partners. The Coordinating Center will support the workgroup.

3.6   COORDINATING CENTER

3.6.1 Project Management Office
The PEDSnet Project Management Office includes Coordinating Center Project Managers and Institutional Project Managers. Its role is to provide logistical and project management support to Network operations and research projects. Responsibilities include:

- Communication within the Network;
- Management of the PEDSnet website, newsletter, and access to PEDSnet resources;
- Project management for research projects; start-up and monitoring of PEDSnet research studies, including obtaining relevant study governance approvals;
- Tracking and dissemination of network metrics to PEDSnet institutional teams;
- Management of network regulatory agreements (Master Protocol, Network Participation & Data Use Agreement);
- Logistical support to the Steering Committee, Data Committee, and Research Committee, and Working Groups; and,
- Management of PEDSnet Finances.

3.6.2 Data Network Coordinating Center
The Data Network Coordinating Center Center consists of two primary functional areas, Data Pipeline and Data Science Analytics.

The Data Pipeline team develops, maintains, and operates the PEDSnet Database. Responsibilities include:

- Implement the PEDSnet data sharing infrastructure;
- Maintain PEDSnet data standards;
- Manage submission of data extracts;
- Manage additional computation to generate final content;
- Perform data quality assessments;
- Ensure data security;
- Perform data linkages with external data sources;
- Provisioning, access, and archiving of study-specific data extracts;
- Track data metrics and report back to institutional teams;
- Document procedures; and,
- Develop reusable tools for management and use of the database.

The Data Science Analytics team provides data and statistical analysis support for research studies that use the database. The Data Science Analytics Team includes all certified PEDSnet data users, based at the Coordinating Center or institutions. Use of a certified PEDSnet Data Science Analyst is required for each study using the PEDSnet database. Responsibilities include:

- Maintain and continuously update a data dictionary with the specifications for study variables;
- Develop detailed analysis plans for research projects;
- Conduct study-specific data quality analyses;
- Conduct statistical analyses based on analysis plans;
- Develop and maintain analytic standards and best practices;
- Produce reports and manuscripts based on study results; and,
- Communicate results back to institutional teams.

3.7 ORGANIZATIONAL CHART
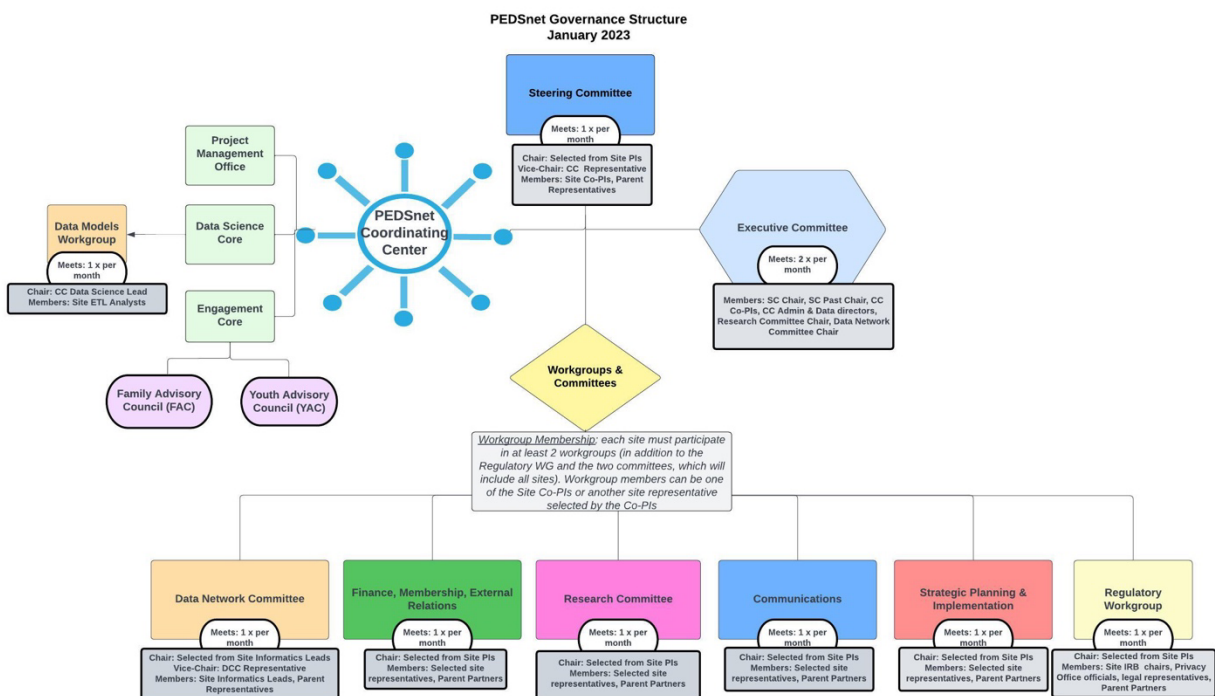
3.8 INSTITUTIONAL TEAMS

Each PEDSnet Member Institution will maintain a PEDSnet Institutional Team. These individuals will represent the Institution in various PEDSnet Committees and Workgroups, and will conduct the business of PEDSnet within their own institution. The composition of Institutional Teams and the role of team members is described below.

3.8.1 Site Principal Investigator

This individual acts as a PEDSnet champion for Executive Leadership in the individual's institution, oversees PEDSnet activities within his or her Institution, serves as the primary scientific resource for institutional investigators who wish to work with PEDSnet, approves requests for their institution to participate in PEDSnet research studies, and serves as a voting member on the Steering Committee.

3.8.2 Site Informatics Lead

This individual oversees institutional data extraction, transformation, and loading into the PEDSnet Common Data Model, submission of data extracts to the Coordinating Center, and provides informatics leadership within their institution and to PEDSnet. The Site Informatics lead is a member of the Data Network Committee and should be a senior informatics leader within their institution.

3.8.3 Committee and Workgroup Representatives

Each site will have a representative on the PEDSnet Research Committee, and in addition will participate in at least two workgroups. The Site Co-PIs will serve as the Research Committee representative. The workgroup representatives may be the Site PI or Informatics Lead, or can be another representative from the institution selected by the Site PI.

3.8.4 Data Pipeline Informatics Staff

These individuals include programmers and other informatics staff necessary to perform institutional PEDSnet data operations. They perform the data extraction, transformation, and loading of institutional source data into PEDSnet Common Data Model and submit data extracts to the Coordinating Center. In addition, Informatics Staff will maintain a local PEDSnet data mart, manage re-identification of patients for PEDSnet research studies, and provide informatics support for PEDSnet research at their institution. One or more members of the informatics staff will serve on the Data Models Workgroup.

3.8.5 Data and Statistical Analysis Informatics Staff

These individuals are those who have completed the PEDSnet Data Science Training(s) and are certified to execute PEDSnet research studies. This may include 1) Analysts certified to conduct analyses on study-specific datasets, 2) Analysts certified to both conduct analyses on study-specific datasets and also access the full database to extract a study dataset, and 3) certified clinical informatics staff and faculty.

3.8.6 Parent and Youth Partners

Each member institution will identify two parents to serve on the PEDSnet Family Advisory Council and two youth to serve on the Youth Advisory Councils. Sites will also identify parents to participate in additional workgroups, committees, and initiatives as needed.

3.8.7 Project Manager

This individual provides administrative and project management support to the Institutional Team, and serves as the institutional representative to Project Management Office. They will also manage site-led PEDSnet research projects (including tracking of project activity and

deliverables in the centralized data and PMO systems for reporting back to the network), maintain local PEDSnet regulatory approvals (both network and study-specific), and participate in monthly network Project Manager meetings.

3.8.8 IRB Specialist
This individual will serve as an institutional representative on ad hoc Workgroups that address human subjects policies, processes, and procedures.

3.8.9 Legal Representative
This individual will serve as an institutional representative on ad hoc Workgroups that address legal matters.

3.8.10 Sponsored Project Office Representative/s
This individual(s) will participate in ad hoc Workgroups related to contracting, grant preparation and management, and contractual processes to increase the efficiency of PEDSnet administrative operations.

4   DECISION MAKING

The same policy will be used for decision-making and voting in the Committees and Workgroups.

- All governance entities will seek to reach decisions through consensus;
- When voting is necessary, an 80% majority of voting members will be required to approve an Action; requests for site participation will still remain at each institution's discretion to approve.
- 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 >66% of total members in the governing entity.
- An 80% majority among member institutions is required for changes to any policy.

5 INSTITUTIONAL MEMBERSHIP

5.1 NEW MEMBERS

5.1.1 Notification of Interest
Pediatric institutions wishing to become members of PEDSnet start this process by notifying the Coordinating Center of their interest in writing. Altenatively, PEDSnet may identify an institution with special populations or services and seek out their participation through this same process. Once contacted, the Coordinating Center will explore their interests and share the expectations and benefits of PEDSnet membership. After this initial contact, interested institutions will submit a PEDSnet membership application.

5.1.2 Committee Review and Approval
The Coordinating Center will submit to the Finance, Membership, and External Relations Workgroup membership applications for pediatric institutions willing to meet expectations of membership. The Workgroup will conduct an initial assessment of the application, and present their recommendation to the Steering Committee. The Steering Committee will vote to approve the membership application.

5.1.3 Administrative Requirements
Once approved by the Steering Committee, candidate Institutional members will be required to:

- agree to PEDSnet policies;
- sign the PEDSnet Participation and Data Use Agreement;
- sign on to the SMART Institutional Review Board agreement; and,
- Submit a data goverance process and procedures for reviewing and approving release of institutional data.

Once all these documents have been submitted to the Coordinating Center and are fully executed, the new member may begin participation in PEDSnet governance and research.

5.2 MEMBERSHIP TERMINATION

5.2.1 Institutional Termination
An institutional member can terminate their membership at any time by notifying the Steering Committee Chair.

5.2.2 Steering Committee Termination
The Steering Committee can vote to terminate an institution's membership if it deems that the expectations of membership are not being fulfilled. An 80% majority vote is required for termination.

6   DATA NETWORK

In order to support a learning health system, PEDSnet fosters the use of data from real-world clinical settings for research, quality measurement, and improvement of child health. Use of these data make it possible to reach conclusions that more accurately reflect actual health and medical care than simulated or idealized data. It is equally important to use these data in a way that minimizes risk to the privacy of the persons represented in the data. The PEDSnet data network employs a number of methods in its data standardization and analyses to reduce privacy risk.

6.1   SUBMISSION OF INSTITUTIONAL DATA

6.1.1. Frequency of Data Submission
Institutions will submit data to the Coordinating Center for inclusion into the database. The frequency of these submissions is quarterly. Additional submissions may be requested on a study-specific basis if needed, for those sites participating in said study.

6.1.2. Data Remediation
In response to findings from data characterization assessments done by the Coordinating Center, institutions will conduct up to one remediation per quarter. Study-specific data quality problems will typically be addressed during the next data cycle.

6.2   LIMITED DATA SET

The Core Database meets the HIPAA definition of a limited data set (includes dates of birth and service, zip code, privacy-preserving record linkage (PPRL) hashes, and census block group).

Additional data elements beyond a Limited Data Set may be collected from time to time on a study-specific basis (examples include unstructured text data, survey data, chart review data). These additional data elements will be stored separately from the Core Database, and only incorporated into the core data once converted into a Limited Data Set.

6.3   DEFINITION OF PATIENT

For the purposes of inclusion in the PEDSnet database, 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.

6.4   COORDINATING CENTER RESPONSIBILITY FOR DATA SUBMISSIONS

Once data are received, the Coordinating Center will:

- Destroy any data extract that includes non-incidental protected health information, other than indirect identifiers as defined by HIPAA[1]; and except as specified in study analysis plans
- 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 database procedures;
- Transform PEDSnet data into PCORnet CDM and respond to queries on behalf of sites
- Load the data extract into the PEDSnet Database once the data meet acceptable levels of data quality; and,
- Mediate access to the data for usage approved by the PEDSnet Steering Committee.

6.5   DATA QUALITY ASSESSMENTS

The Coordinating Center will submit data reports for each data submission to the Data Network Committee that summarizes time of submission and data quality assessments. The report will provide a clear assessment of the quality of PEDSnet data for research and will provide both overall and institution-specific results.

6.6   COMMON DATA MODEL

6.6.1 PEDSnet Common Data Model
The Coordinating Center will maintain a pediatric-specific Common Data Model (PEDSnet CDM) for storage of PEDSnet data. The PEDSnet CDM will be expanded on an annual basis, with changes proposed by the Data Network and Research Committees and final approval made by the Steering Committee.

6.6.2 PCORnet Common Data Model
The PEDSnet Coordinating Center will also support research done using the PCORnet Common Data Model, and will maintain a translation between the PEDSnet and the PCORnet Common Data Models. As per PCORnet policy, the PCORnet Common Data Model will be modified on an annual basis.

6.7   PATIENT REIDENTIFICATION

6.7.1. Retention of Direct Patient Identifiers

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[1] https://www.hhs.gov/hipaa/for-professionals/privacy/index.html

Institutions contributing data to the PEDSnet Database will retain direct patient identifiers within each institution and will not share this information with the Coordinating Center except in defined study contexts. Patients will be assigned a site-level Patient Identifier that has no external meaning. Institutions will retain the mapping between the site-level Patient Identifier and local identifiers (such as a medical record number) to enable reidentification at the local institution.

6.7.2 Reidentification

All studies requiring reidentification will have Institutional Review Board oversight. Patient reidentification will be done by providing institutions with the site-level patient identifiers of interest, and the institutions will perform the reidentification.

6.7.3 Network-wide Identifiers

The Coordinating Center will maintain a unique network-wide PEDSnet Patient Identifier, which will not be disclosed to sites outside defined study context, in order to maintain an honest broker role.

6.8   AUTHORIZED USERS

The Coordinating Center will develop and maintain a process and procedures for staff members at member institutions to become authorized users of the PEDSnet database applications. The Data Network Committee will review and approve the process and procedures. On an annual basis the Coordinating Center will provide a list of authorized users to the Institutional Site Principal Investigators. The Coordinating Center will also conduct an annual assessment of current authorized users and remove those who should no longer have access.

6.9   RECORD LINKAGES

6.9.1 Engagement in Record Linkage

PEDSnet will execute or participate in record linkage across data sources when there is scientific benefit to be realized, and there are adequate methods available to mitigate risk of improper disclosure or reuse of linked data. PEDSnet will use Privacy-Preserving Record Linkage methods for linkage efforts beyond institution-level patient reidentification, unless study participants or the overseeing IRB have authorized use of clear text linkage.

6.9.2 Record Linkage Process

Procedures for Privacy-Preserving Record Linkage implementation will be maintained by the Coordinating Center, which will serve as an honest broker for linkage, and will incorporate best practices in encryption, accuracy, and risk reduction. With approval of the Steering Committee, PEDSnet may engage in Privacy-Preserving Record Linkage with another entity as honest broker, in which case the Coordinating Center will define additional procedures as appropriate to minimize risk for disclosure of protected patient or institutional information.

6.9.3 Deduplication

The Coordinating Center will maintain a Master Patient Index for PEDSnet generated by Privacy-Preserving Record Linkage, to be updated annually. The Master Patient Index will not be disclosed to member institutions or to external users. The Coordinating Center will conduct appropriate deduplication when indicated, in accordance with the network deduplication policy.

6.10   REQUESTS FOR DATA

6.10.1 Conduct of Data Analysis Using Database

In general, research using the database will be done within the secure PEDSnet database environment that is managed by the Coordinating Center. This approach generally precludes the need to share patient-level data outside the secure PEDSnet network environment. Investigators, data analysts, and statisticians who need to access the database will first apply to be an authorized user. For approved PEDSnet studies, a certified user either at the Coordinating Center or PEDSnet institution will set up a workspace within the PEDSnet database environment and transfer the minimum necessary data for the research project to the workspace. The workspace will support database and statistical applications allowing the team to conduct data analyses.

6.10.2 Requests for Datasets

Investigators who would like to have a de-identified or limited (as defined by HIPAA) patient-level dataset transferred to their institution make this request at the time of seeking PEDSnet Study Approval. Each institution that supplies data for the dataset must affirm its approval during the Steering Committee voting process. At each site's discretion, either the PEDSnet Site PI or Site Informatics Lead may approve dataset release votes, obtaining approval from appropriate institutional officials as needed. Approved requests will be processed by the Coordinating Center, which will provide the minimum data necessary to answer study questions. The Coordinating Center will maintain procedures to reduce risk of individual patient reidentification from datasets released to investigators. Data provided by PEDSnet can be used only for the purposes specified and approved by the Steering Committee.

6.11   REMOVAL OF DATA FROM THE DATABASE

Institutions at any time can request that data originating from their institution stored in the PEDSnet Database be removed. These requests must be made in writing and submitted to the Coordinating Center. Data will be destroyed within 3 months of receipt of this request from active studies and databases. Data that is archived will be destroyed within 6 months of receipt of this request. Data that have been released to a study will not be destroyed, but will be retained according to the study's retention policy. Reasonable effort will be made to destroy as well any copies of data that are known to exist, such as archived data submissions and intermediates in pipeline processing or analytic datasets still under construction. Long-term backups maintained by data center infrastructure cannot be destroyed, but data will not be restored from these backups, or will be removed immediately if restored as part of a larger dataset, once removed from the active database.

The Coordinating Center will retain core data for a 5-year period. Study data will be retained for a term specified in the study plan, or for 10 years if not specified. Exceptions to these retention periods may be requested as needed.

6.12   RESPONSE TO BREACH

If there is a breach or any use or disclosure of data that is not permitted under the relevant network or study-specific agreements of which the Coordinating Center, or any authorized data user at an institutional site, becomes aware, the Coordinating Center and institutional site team will comply with the steps outlined in the associated network or study-specific agreements.

6.13   DATA SECURITY

The Coordinating Center implements a broad set of security and reliability controls targeting the National Institute of Standards and Technology (NIST) 800-53 (current version), which are widely recognized security controls for a data center. Individual PEDSnet institutions implement their own information security policies to safeguard the data that is held locally.

All PEDSnet analytic datasets are subject to the following:

1. Extraction of the minimum data necessary to perform the analysis
2. Data must be stored on secure computer systems with access limited to authorized individuals, and mechanisms in place to enforce that access.
3. Data must be transmitted using methods that ensure adequate encryption and delivery to the intended recipient.
4. All use of data must be limited to the approved purposes, and consistent with the data usage agreements entered into for the analysis.
5. In addition to appropriate data use agreements, all individuals accessing or using the data will be required to sign the PEDSnet Responsible Use of Data agreement
6. Data must not be redisclosed to persons outside the study team for any purpose without permission of PEDSnet.

In addition, datasets containing any person-level records that are not synthetic, or have a k-anonymity of ≤11, (*i.e.* have any records that are identical for 5 or fewer persons), are subject to the following, unless specifically waived during the PEDSnet review process:

7. Replacement of stable identifiers with study-specific identifiers.
8. Shifting of dates within a one-year window centered on the actual date.
9. Replacement of free-text fields and sensitive values (*e.g.* site names) with single-use labels.
10. Replacement of geographic information with single-use labels.

11. Removal of data relating to testing or care for HIV, pregnancy, and mental health, excluding educational performance.

Each recipient is responsible for securing all copies of the data in their possession, and for requiring anyone to whom they distribute the data to provide assurance of compliance, but neither the PEDSnet CC nor intermediate recipients can guarantee security of data that have left their control.

6.14   DATA RETENTION AND DISCLOSURE

PEDSnet's goal is to support reproducible science, while limiting the risk to individual privacy that may result from ungoverned reuse or linkage of data.

1. The PEDSnet Coordinating Center will retain all derived datasets for a period of 10 years to allow for appropriate reuse. Alternatively, the Coordinating Center may maintain the algorithm by which the data were derived and a copy of the base network data, to allow for rederivation when needed.
2. Datasets released by PEDSnet may be retained by the recipient for the period mandated by the study sponsor, or by the publisher of results based on the data.
3. No dataset containing PEDSnet data may be deposited with a public database, journal, or institutional repository, whether or not access is limited, either alone or in combination with other data, without permission from each PEDSnet institution that has contributed data.
4. A copy of any derived analytic datasets and the code used to generate the dataset used in a published analysis will be deposited with the PEDSnet Coordinating Center, and will be retained along with the study dataset (see (1) above).

6.15   DATA DESTRUCTION

When all analyses using a dataset have been completed, and results have been disseminated in their final form, or a decision has been made not to pursue further dissemination, then data provided by PEDSnet outside the Coordinating Center secure environment must be destroyed following these requirements. Unless otherwise specified by the grant sponsor, datasets may only be retained for a period of 2 years after they are released to the investigator and study team; requests for additional annual renewals beyond this 2 year period must approved by the Steering Committee. Data destruction requirements can be applied at any time if the time for retention specified in a data usage agreement has lapsed, regardless of the state of analyses, unless an extension is granted by PEDSnet, or immediately if requested by PEDSnet in response to a data breach or other discovered risk to individual privacy.

1. All copies of data received from PEDSnet and derived data describing ≤11 individuals must be destroyed.
2. Destruction must ensure that the content of the data cannot be retrieved, and not merely that the files are inaccessible. The "delete" operation on most computers is not sufficient for this purpose; a "secure erase" or "overwrite" tool must be used. The process must conform to an accepted secure data destruction standard (*e.g.* NIST 800-88 for whole-disk sanitization or a DoD 5220.22-consistent multi-pass erasure for the data).

3. All copies of data that are reasonably known to exist must be destroyed, including replicates held by other members of the analytic team, and copies committed to version control repositories.

4. In the case that archived data cannot feasibly be destroyed (*e.g.* offline backups), the recipient must agree to 1) not restore the data for further use, 2) immediately destroy any copies restored as part of a larger dataset, and 3) maintain security of the data until destruction is feasible.

5. The recipient will notify the PEDSnet Coordinating Center of compliance with this requirement when destruction has been completed. This must include the data destruction standard used.

6. Each recipient is responsible for destroying all copies of the data in their possession, and for obtaining from anyone to whom they have distributed the data assurance of compliance. The same applies to the PEDSnet Coordinating Center.

6.16 SMALL CELL SIZES

This section will be added once the final small cell size policy is approved by the Steering Committee. For now, the current <11 threshold remains in place.

7   RESEARCH STUDIES

7.1   STUDY CONCEPT APPROVAL

Investigators or sponsors that would like to conduct a study within PEDSnet will complete a request form and submit that to the Coordinating Center. The Coordinating Center will ensure that the request is complete. The Research Committee will vote on study concepts. Approval allows the Coordinating Center to assist the requestor in the development of study proposals.

7.2   STUDY PROPOSAL APPROVAL

Before research can begin on a PEDSnet study (a project is considered a PEDSnet study if using data or other PEDSnet resources from 2 or more member sites), all necessary regulatory and governance approvals must be in place. Either the protocol (if a prospective study) or analysis plan (if a retrospective study), will be circulated to the PEDSnet committees once available for their review.

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

- A sponsoring PEDSnet member institution is part of the application;
- At least one investigator is from a PEDSnet institution;
- Research using existing PEDSnet data and/or data collected from PEDSnet clinical care sites at >1 PEDSnet institution;
- Appropriate engagement of stakeholders in the research;
- The study aims should align with the PEDSnet mission;
- The study requests includes clear information about how the work will be funded;
- The study request includes clear information on the data expectations from PEDSnet and is feasible to conduct the study within the PEDSnet network; and,
- The study aims are impactful to patients and families or the health systems that serve them.

The following priorities will also be given consideration when reviewing new requests for PEDSnet Study Approval:

- Priority should be given to requests for those studies that are 1) led by a PEDSnet member site, 2) collaborations with external consortium (such as AllofUs or other PCORnet networks), and 3) requests received directly from a sponsoring agency, such as the FDA, CDC, or industry sponsors.
- Priority will be given to requests that include sufficient funding resources to carry out the proposed study aims
- PEDSnet encourages support of project requests from junior investigators at PEDSnet institutions; however, given the limited funding typically available for training grants,

the local PEDSnet institution would likely need to be certified to conduct the data work for training grant projects submitted by their institution's investigators.

- PEDSnet is supportive of offering additional work on a pro bono basis when appropriate. Efforts needed to support pro bono projects should be distributed equitably across the network.

The requirements of PEDSnet Studies include:

- Registration with ClinicalTrials.gov for all interventional studies and strongly encouraged for observational studies;
- Quarterly reports made to the Coordinating Center on study progress. Reporting will continue until the primary manuscript or report is submitted (for reports) or published (manuscripts);
- Tracking of project activity in the designated PEDSnet data and project management systems, for incorporation into network metrics;
- Submission of a final report within six months of either completion of data analysis with the a certified PEDSnet data analyst or 12 months of receipt of a dataset;
- Permission to allow the Coordinating Center to publish a summary of research once the report is received;
- Submission of a data package to the Coordinating Center within 12 months from the completion of the final analysis including:
  - o Study protocol, including original version and all amendments
  - o Analysis files used to generate the published reports
  - o Statistical code used to generate the analysis files.
  - o 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.

7.3   ELECTIVE PARTICIPATION IN STUDIES

Participation by an Institution in a particular PEDSnet study is voluntary. An affirmation is required by the Site Principal Investigator for all studies. However, the expectation is that participating institutions allow their data to be used for retrospective observational studies that do not require contact with human subjects unless there is a compelling reason to not participate.

8   PATIENT AND STAKEHOLDER ENGAGEMENT

8.1   INCLUSION OF PARENTS AND/OR PATIENTS

In general, PEDSnet studies engage parents and/or pediatric patients in 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.

8.2   FINANCIAL RECOGNITION

Parents and patients who participate in PEDSnet studies or governance are compensated for their time.

9   REASSESSMENT AND MODIFICATION OF PEDSNET POLICIES

The PEDSnet Steering Committee will review PEDSnet policies on at least an annual basis. Alterations to PEDSnet policies will require an 80% majority of Steering Committee members to ratify the change(s).

10 CONFLICT OF INTEREST

All members of the Steering, Research, and Data Network Committees and Workgroups shall abide by their Institutional Conflict of Interest Policies and disclose any potential conflicts of interest annually to the Steering Committee.

The Steering Committee will be responsible for identifying potential conflicts and working with the individual to develop an appropriate conflict of interest mitigation plan.

If known that multiple PEDSnet institutions have an interest in applying to the same grant funding announcement, the Steering Committee will make a recommendation based on its review of the competing proposals.

11   SINGLE INSTITUTIONAL REVIEW BOARD

All PEDSnet institutional members are required to endorse the PEDSnet Single IRB policy by becoming a participating institution of the NCATS sponsored SMART IRB Agreement. Participation in these agreements 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.

12   PUBLICATION

12.1   PUBLICATION PRINCIPLES

PEDSnet expects that studies endorsed by the network will result in publishable reports in scientific journals or similar widely-available media. Each publication increases the dissemination of credible and innovative research generated within the network, and advances the PEDSnet mission to improve the quality of care by applying relevant new knowledge generated through research. The principles that PEDSnet studies will adhere to include:

- A commitment to equitable opportunities for participation and co-authorship among PEDSnet sites and investigators on approved PEDSnet studies;
- Encouragement of study teams and institutions to include authorship for junior investigators;
- Effective management of the logistics of large writing groups;
- Adherence to ICMJE authorship criteria;
- Adherence to the NIH Open Access Policy (for NIH funded studies) and strong encouragement (for non-NIH funded studies) to be submitted to journals that allow open access; and,
- Flexibility for study teams to develop publication procedures that accommodate the specific study context.

12.2   AUTHORSHIP

Authors must fulfill current ICMJE criteria, and should be offered the opportunity for authorship early in the planning process when significant contributions are possible. For manuscripts using PEDSnet existing or prospectively collected data, authorship should be offered to each institution that contributes data. All members of the group who are named as authors should fully meet the criteria for authorship. Group members who do not meet these criteria should be acknowledged, with their permission, elsewhere.

12.3   ACKNOWLEDGEMENTS

All publications for PEDSnet endorsed studies should include the following statement in the Acknowledgments:

"The research reported in this [work, publication, article, report, presentation, etc.] was conducted using PEDSnet, A Pediatric Clinical Research Network. PEDSnet has been developed with funding from the Patient-Centered Outcomes Research Institute (PCORI); PEDSnet's participation in PCORnet is funded through PCORI award RI-CHOP-01-PS1. This [work, publication, article, report, presentation, etc] includes data from the following PEDSnet institutions: [List all participating institutions]."

All articles related to PEDSnet studies or data are required to list "PEDSnet" as a keyword.

12.4   PEDSNET LOGO

When Study Principal Investigators or other team members present PEDSnet data at scientific or public meetings, all presentations (oral and poster) must use the PEDSnet logo and acknowledge the grant and data contributors using the appropriate acknowledgement statement.

The PEDSnet logo and template slides are available upon request at pedsnet@chop.edu.