



PEDSnet
A Pediatric Learning Health System

PEDSnet Policies

Version 4

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PEDSnet policies are approved by the PEDSnet Steering Board.

Version Date	Version and Modifications
November 2015	Version 1
June 2016	Version 2; major modifications and additions
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1 MISSION

Mission: To conduct multi-institutional pediatric research that improves patient and health system outcomes.

To accomplish this purpose, PEDSnet develops resources that make multi-institutional pediatric clinical research faster and less expensive, engages stakeholders in all parts of 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.

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. Clinical **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 electronic health records and other sources;
3. **Research** 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 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 AND STRATEGIC GOALS

2.1 VISION

Vision: We will be the nation's top multi-specialty pediatric clinical research network.

Vision Summary: We imagine a future in which PEDSnet is recognized as the premier multi-specialty national pediatric clinical network for conducting research. It will be able to access health and healthcare data for over 10% of the nation's children. Having completed or launched interventional and observational research studies, PEDSnet will have a diverse portfolio of public and private sector funding. It will have created a variety of governance, technical, scientific, and engagement resources that many investigators, specialty groups, and institutions have used to conduct efficient pediatric clinical and health services research. PEDSnet will have forged relationships with strategic partners that have organized to catalyze the formation of a distributed, national pediatric learning health system. PEDSnet will have a sustainable business model that ensures its long-term sustainability.

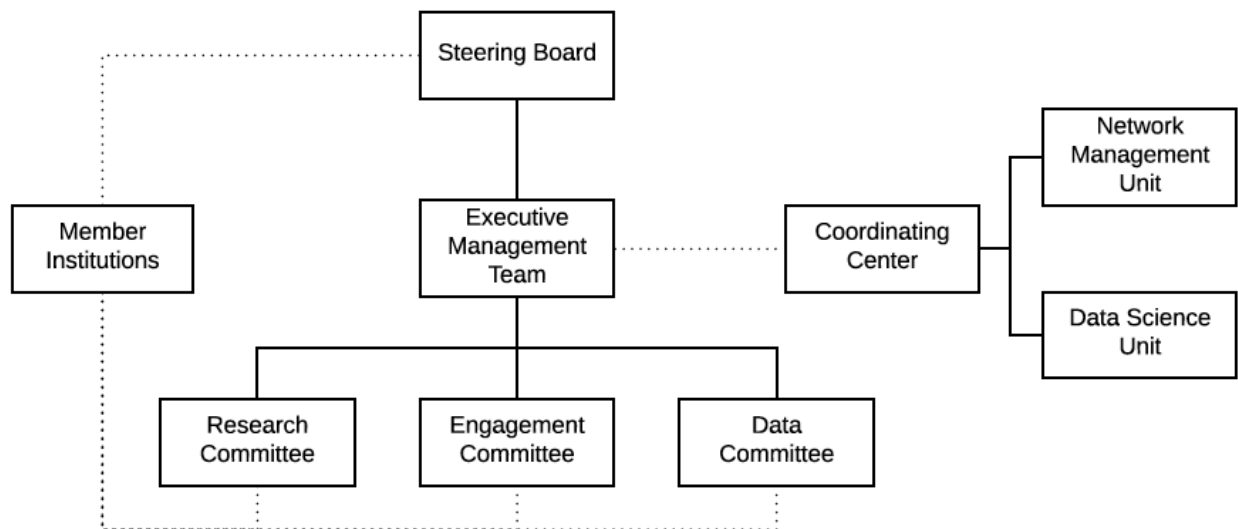
2.2 STRATEGIC GOALS

PEDSnet will pursue four strategic goals until 2021.

1. Grow the data network to include 10% of US children;
2. Reduce study start-up time to <60 days;
3. Attain financial sustainability; and,
4. Provide training opportunities in the science of pediatric learning health systems.

3 PEDSNET ORGANIZATION

3.1 ORGANIZATIONAL CHART



PEDSnet is composed of Member Institutions which have a representative on the Steering Board and each of the three Committees.

3.2 STEERING BOARD

3.2.1 Steering Board Responsibilities

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 updates the vision as new opportunities, trends, and challenges present themselves. Responsibilities include:

PEDSnet Policies

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

3.2.2 Steering Board Membership

The PEDSnet Steering Board has 1 voting member per PEDSnet member institution and 1 parent representative for every 5 institutional members. Voting members may choose to delegate voting authority to an Alternate if they are unable to vote, because of travel, illness, or other circumstances. Steering Board members are appointed by their institution.

3.2.3 Steering Board Chair and Vice Chair

An elected Chair from among the 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.

3.2.4 Steering Board Meetings

The PEDSnet Steering Board Chair or Vice Chair will chair these meetings. 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.

3.3 EXECUTIVE MANAGEMENT TEAM

3.3.1 Executive Management Team Responsibilities

The Executive Management Team (EMT) oversees PEDSnet Coordinating Center operations. Responsibilities include:

- Conduct efficient and effective operations of the Network;
- Lead and oversee data science operations;
- Ensure coordination across the different organizational entities of the Network;
- Develop the Steering Board meeting agendas for review and approval by the Board Chair;
- With input from the Committees, develop policies for ratification by the Steering Board; and,
- Ensure that requests for PEDSnet collaboration meet PEDSnet standards and are within scope.

3.3.2 Executive Management Team Composition

The Executive Management Team is led by the PEDSnet Executive Director and includes the Directors of Network Operations and Data Science.

3.4 RESEARCH COMMITTEE

3.4.1 Research Committee Study Concept Approval

Investigators within and outside PEDSnet as well as sponsors can submit a request to PEDSnet to conduct a study within the Network. The Coordinating Center will manage the administrative intake of these requests. Once the request has passed administrative review, the Research Committee will vote to approve or reject the study concept. Approval then enables the Coordinating Center to work with the requestor to develop a study proposal.

3.4.2 Research Committee Study Proposal Approval

The Research Committee approves all study proposal requests to ensure that the research requested is scientifically sound, leverages the unique resources within PEDSnet, and is likely to produce new knowledge that can improve patient or health system outcomes. The study proposal review is done with input from the Data and Engagement Committees. In addition to the review of scientific merit, the members of the Committee also choose whether their institution will opt in or out of the study.

3.4.3 Research Committee Membership

Members include all Site Principal Investigators. Each institution has one voting member of the Research Committee.

3.4.4 Research Committee Chair

The PEDSnet Executive Director will serve as the Chair of the Research Committee.

3.4.5 Research Committee Meetings

The Research Committee meets on a weekly to biweekly basis, depending on the volume of activity it must handle. Summaries of Research Committee meetings will be produced by the Coordinating Center and approved by the Research Committee within 14 days of a meeting.

3.5 ENGAGEMENT COMMITTEE

3.5.1 Engagement Committee Responsibilities

The role of the Engagement Committee 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 between these stakeholders and researchers. The Committee's responsibilities include:

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

3.5.2 Engagement Committee Study Proposal Review

The Engagement Committee reviews and makes recommendations on modifications and approval for all study proposal requests. The Committee's charge for these reviews is to ensure that the research requested appropriately engages stakeholders in the research process.

3.5.3 Engagement Committee Members

The Engagement Committee will be comprised of parents and youth who will be teamed with investigators; the latter will be appointed by the Executive Director. Each institution will have one voting member of the Engagement Committee. Institutions will select their Engagement Committee member, but generally this person will be a parent or older youth.

3.5.4 Payment for Parents and Youth

Parents and youth will be compensated for the time they spend on Engagement Committee activities.

3.5.5 Engagement Committee Chair

The Executive Director will appoint the Engagement Committee Chair.

3.5.6 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.

3.6 DATA COMMITTEE

3.6.1 Data Committee Responsibilities

The role of the Data Committee is to oversee PEDSnet's data network and data science activities. Responsibilities include:

- Develop policies for managing the Data Network;
- Approve data network processes and procedures developed by the Data Science Unit within the Coordinating Center;
- Develop data governance policies for approval by the Steering Board;
- Make recommendations to the Steering Board regarding changes to the PEDSnet Common Data Model and Data Network pipeline activities (e.g., latency of data refreshes); and,
- Provide recommendations to the Research Committee for Study Proposals.

3.6.2 Data Committee Study Proposal Approval

The Data Committee reviews and makes recommendations on modifications and approval for all study proposal requests. The Data Committee's charge for these reviews is to ensure that the data science methods proposed are appropriate.

3.6.3 Data Committee Members

Members will include Site Informatics Leads. Each member institution will have one voting member on the Data Committee.

3.6.4 Data Committee Chair

The Director of Data Science, appointed by the Executive Director, will chair the Data Committee.

3.6.5 Data Committee Meetings

The Data Committee will meet on a frequency commensurate with the volume of activity it must handle. In general, meetings will be held via teleconference and webinar. Summaries of Data Committee meetings will be produced by the Coordinating Center and forwarded by the Research Committee within 14 days of a meeting.

3.7 COORDINATING CENTER

3.7.1 PEDSnet Executive Director

The Executive Director will be a scientist or data scientist who will serve as the overall principal investigator for the Coordinating Center. Responsibilities include:

- Ensure successful execution of the PEDSnet strategic and operational plans;
- Ensure effective integration of all Coordinating Center activities; and,
- Serve in the following roles:
 - Network liaison to PCORnet and other strategic partnerships;
 - Member of the Executive Management Team;
 - Vice Chair of the PEDSnet Steering Board; and,
 - Chair of the PEDSnet Research Committee.

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

3.7.2 Network Management Unit

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

- Communication within the Network;
- Management of the PEDSnet web site and access to PEDSnet resources;
- Project management for research project start-up and monitoring; and,
- Logistical support to the Steering Board, Committees, and Working Groups.

The Network Management Unit is led by the PEDSnet Operations Director, who is appointed by and reports to the PEDSnet Executive Director.

The Network Management Unit will lead meetings with all the PEDSnet project managers to ensure effective communication across the network.

3.7.3 Data Science Unit

The Data Science Unit develops, maintains, and operates the PEDSnet Data Network.

Responsibilities include:

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

The Data Science Unit is led by the Data Science Director, who is appointed by and reports to the PEDSnet Executive Director.

3.8 INSTITUTIONAL TEAMS

Each PEDSnet Member will assemble a PEDSnet Institutional Team. These individuals will represent the Institution in various PEDSnet Committees, 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:

3.8.1 Steering Board Member

This individual serves on the Steering Board as a voting member and acts as a PEDSnet champion for Executive Leadership in the individual's institution.

3.8.2 Site Principal Investigator

This individual 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 Research Committee.

3.8.3 Site Informatics Lead

This individual oversees institutional data extraction, transformation, and loading into the PEDSnet Common Data Model and submission of data extracts to the Data Science Unit. The Site Informatics lead is a voting member on the Data Committee.

3.8.4 Informatics Staff

These individuals will include ETL analysts, programmers, and other informatics staff necessary to perform institutional PEDSnet operations. They perform the data extraction, transformation, and loading of institutional source data into PEDSnet Common Data Model and submit data extracts to the data science unit. 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

3.8.5 Parent and Youth Partner

Each member institution will identify a parent or youth patient to serve on the PEDSnet Engagement Committee.

3.8.6 Project Manager

This individual provides administrative and project management support to the Institutional Team, and serves as the institutional representative to Network Operations Unit.

3.8.7 IRB Specialist

This individual will serve as an institutional representative on ad hoc working groups that address human subjects policies, processes, and procedures.

3.8.8 Legal Representative

This individual will serve as an institutional representative on ad hoc working groups that address legal matters.

3.8.9 Sponsored Project Office Representative/s

This individual(s) will participate in ad hoc working groups related to contracting, grant preparation and management, and contractual processes to increase the efficiency of PEDSnet administrative operations

4 DECISION-MAKING

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 >66% of total members in the governing entity.

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 Executive Director of their interest in writing. Once contacted the Executive Director 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 to the Coordinating Center.

5.1.2 Steering Board Vote

The Executive Director will submit to the Steering Board membership applications for pediatric institutions willing to meet all expectations of membership. The Steering Board will vote to approve the membership application; two-thirds of voting members are required for approval.

5.1.3 On-boarding

Once approved by the Steering Board, the new institutional member will undergo a process for on-boarding their institutional PEDSnet team and integration of their source data into the PEDSnet data network.

5.2 MEMBER EXPECTATIONS

5.2.1 Administrative Requirements

All institutional members will need to approve the following:

- Steering Board member will approve and sign the PEDSnet policies;
- Institutional representative will sign the Participation and Data Use Agreement;
- Institutional representative will sign the PEDSnet Master Institutional Review Board agreement;
- Institutional representative will sign the SMART Institutional Review Board agreement;

5.2.3 Research Leadership

Institutions will provide leadership for no fewer than two research studies each year for which they serve as the contracting entity.

5.2.4 Data Network Participation

As described in Section 6, all members will adhere to the data network policies and their associated processes and procedures.

5.2.5 Membership Fees

On an annual basis the Steering Board will set the level of the institutional annual membership fee.

5.3 MEMBERSHIP TERMINATION

5.3.1 Institutional Termination

An institutional member can terminate their membership at any time in writing in a letter to the Executive Director. Membership fees cannot be recovered nor will they be prorated.

5.3.2 Steering Board Termination

The Steering Board can vote to terminate an institution's membership if it deems that the expectations of membership are not being fulfilled. A two-thirds majority vote is required for termination.

6 DATA NETWORK

6.1 SUBMISSION OF INSTITUTIONAL DATA

Institutions will submit data to the Data Science Unit for inclusion into the data network. The frequency of these submissions will be quarterly. In response to findings from data characterization assessments done by the Data Science Unit, institutions will conduct up to one remediation per quarterly data submission cycle. Study-specific data quality problems will be addressed during the next quarterly data remediation cycle.

6.2 LIMITED DATA-SET

The PEDSnet core data resource meets the HIPAA definition of a limited data set (includes dates of birth and service and zip code).

6.3 DEFINITION OF PATIENT

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.

6.4 DATA SCIENCE UNIT RESPONSIBILITY FOR QUARTERLY DATA SUBMISSIONS

Once data are received, the Data Science Unit will:

- Destroy any data extract that includes non-incidentally protected health information, other than indirect identifiers 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; and,
- Mediate access to the data for usage approved by the PEDSnet Research Committee.

6.5 DATA QUALITY ASSESSMENTS

The Data Science Unit Director will submit data quality reports on a quarterly basis to the Research Committee. The report will provide a clear assessment of the quality of PEDSnet data for research.

6.6 COMMON DATA MODEL

6.6.1 PEDSnet Common Data Model

The Data Science Unit 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 expansions proposed by the Data Committee and approved by the Research Committee.

6.6.2 PCORnet Common Data Model

The PEDSnet Data Science Unit will 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

Institutions contributing data to the PEDSnet Data Network will retain direct patient identifiers within each institution and will not share this information with the Data Science Unit except in defined study contexts. Patients will be assigned a site-level Patient Identifier that has no internal 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 Data Science Unit 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 Data Science Unit 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 Data Committee will review and approve the process and procedures. On an annual basis the Data Science Unit will provide a list of authorized users to the Institutional Site Principal Investigator Directors.

6.9 RECORD LINKAGE

6.9.1 Engagement in Record Linkage

PEDSnet will execute or participate in record linkage across data sources when there is significant 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 all linkage efforts beyond institution-level patient reidentification.

6.9.2 Record Linkage Process

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

6.9.3 Deduplication

The Data Science Unit will maintain a Master Patient Index for PEDSnet generated by Privacy-Preserving Record Linkage. The Master Patient Index will not be disclosed to member institutions or to external users. The Data Science Unit will maintain procedures for assessment risk due to patient duplication to the validity of PEDSnet studies, and for appropriate deduplication where indicated.

6.10 REQUESTS FOR DATA

6.10.1 Conduct of Data Analysis Using Data Network

In general, research using the data network will be done within the secure PEDSnet data network environment that is managed by the Data Science Unit's staff. This approach generally precludes the need for patient-level data to leave the secure PEDSnet network environment. Investigators, data scientists, and statisticians who need to access the data network will first apply to be an authorized user. For approved PEDSnet studies, the Data Science Unit will set up a workspace within the PEDSnet data network 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 Data-sets

Investigators who would like to have a de-identified or limited (as defined by HIPAA) patient-level data-set transferred to their institution make this request at the time of seeking PEDSnet Study Approval. These requests will be evaluated by the Research Committee, which will vote to approve or deny it. Each institution that supplies data for the data-set must affirm its approval during this voting process. Approved requests will be processed by the Data Science Unit, which will provide the minimum data necessary to answer study questions. The Data Science Unit will maintain procedures to reduce risk of individual patient reidentification from data-sets released to investigators.

6.11 REMOVAL OF DATA FROM THE DATA NETWORK

Institutions at any time can request that data stored in the PEDSnet Data Network be removed. 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.

6.12 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 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.

6.13 DATA SECURITY

PEDSnet adopts best practices for protection of patient data. The Data Science Unit implements a broad set of security and reliability controls targeting the Statements on Standards for Attestation Engagements No. 16 (SSAE16) SOC2, 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.

7 RESEARCH STUDIES

7.1 ACCESSING PEDSNET

The Coordinating Center will process requests for scientific resources, including:

- Requests for collaboration with PEDSnet;
- Requests for studies using the data network;
- Requests for the formation of patient or clinician study groups; and,
- Request to conduct a prospective clinical or health services research study.

7.2 PEDSNET 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 then vote on study concepts to either approval or reject. Approval allows the Coordinating Center to assist the requestor in the development of study proposals.

7.3 PEDSNET STUDY PROPOSAL APPROVAL

Before proposals are submitted to a sponsor for funding, the PEDSnet Research, Data, and Engagement Committees will conduct a review and provide feedback to the investigator team. In addition, all the reviews will be shared with the Research Committee which will vote to grant PEDSnet Study Approval.

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 from a PEDSnet institution;
- Research using existing PEDSnet data and/or data collected from PEDSnet clinical care sites at >1 PEDSnet institution;
- An Engagement Committee approved plan for how the project will engage patients and clinicians in the research; and,
- Endorsement by the PEDSnet Research Committee, informed by the PEDSnet Data and Engagement Committees' recommendations.

The expectations of PEDSnet Studies include:

- Registration with ClinicalTrials.gov for all interventional studies and strongly encouraged for observational studies;
- 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.

7.4 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 retrospective observational studies that do not require contact with human subjects unless there is a compelling reason to not participate. For studies that require prospective recruitment, additional data collection, or participation in a trial that intervenes at either the patient level or a clinical system (cluster designs), institutions will need to affirmatively express willingness to participate.

8 PATIENT AND STAKEHOLDER ENGAGEMENT

8.1 INCLUSION OF PARENTS AND/OR PATIENTS

PEDSnet studies engage parents and/or pediatric patients 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.

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 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).

10 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 Executive Director. The PEDSnet Research Committee will be responsible for identifying potential conflicts and working with the Board member to develop an appropriate conflict of interest mitigation plan.

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 Master Common Reciprocal Institutional Review Board Reliance Authorization Agreement and 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. 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, being offered the opportunity for authorship early in the planning process when significant contributions are possible. For manuscripts using PEDSnet 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 National Pediatric Learning Health System, and 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 PIs 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@email.chop.edu.