



PEDSnet
A Pediatric Learning Health System

PEDSnet Policies

Version 2020

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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

PEDSnet will explore the possibility of integrating its operations with the Children’s Hospital Association. The policies in this document are designed to provide guidance on the governance of the network during this transitional period.

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1 MISSION

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

To accomplish this purpose, PEDSnet has created an infrastructure that makes multi-center 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

Vision Statement: We will become the premier national resource for multi-center pediatric big data research using electronic health records and pragmatic clinical research.

- Big data: large volumes of patient data, linked across service settings and time, that are updated frequently, and assessed to be of the highest possible quality.
- Pragmatic research: clinical, translational, and health services research that has practical value, helping to improve health and healthcare decision-making and the design of policies and programs.

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. Several accomplishments will be necessary to realize this vision.

- The PEDSnet database will include over 10% of the nation's children;
- >25 pediatric medical centers will be members of PEDSnet;
- Research funding will comprise a diverse portfolio of public and private sector sponsorship;
- 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.

3 ORGANIZATION

This section reflects the interim governance structure of PEDSnet during this transitional period. PEDSnet will explore the possibility of integrating its operations with the Children's Hospital Association.

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.

Responsibilities include:

- Oversight of PEDSnet's network, data, research, and engagement operations;
- Management of PEDSnet membership;
- Developing and overseeing the implementation of PEDSnet's strategic goals;
- Ratifying policies; and,
- Providing institutional leadership in support of PEDSnet's mission and vision.

3.1.2 *Steering Committee Membership*

The PEDSnet Steering Committee has 1 voting member per member institution. Each institution also has an Alternate member. Voting members may delegate to the Alternate attendance at meetings and authority for voting. 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*

An elected Chair and Vice Chair from among the voting members will lead the PEDSnet Steering Committee. The term of the Chair and Vice Chair will be one year for each position. The Vice Chair will become Chair after their one year term. Both will serve on the Executive Management Team.

3.1.4 *Steering Committee Meetings*

The PEDSnet Steering Committee Chair will lead these meetings. Meetings will be held via teleconference or videoconference. In the Chair's absence, the Vice Chair will lead the meetings. One meeting each year will be held face-to-face with location determined by the Executive Management Team. The Executive Director will serve as staff to the Steering Committee.

3.2 EXECUTIVE MANAGEMENT TEAM

3.2.1 Executive Management Team Responsibilities

The Executive Management Team (EMT) 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, the PEDSnet database, and the project management office.

3.2.2 Executive Management Team Composition

The Executive Management Team is led by the Steering Committee Vice Chair. Additional members include the Steering Committee Chair, the Executive Director, the Technology Director, the Operations Director, the Finance Director, and Two Parents. The Operations Director will serve as staff to the Executive Management Team.

3.3 WORKGROUPS

3.3.1 Forming Workgroups

The Steering Committee may from time to time create ad hoc workgroups to accomplish specific tasks. Each workgroup will be chaired by a voting member of the Steering Committee. In general, ad hoc workgroups will be time-limited. Two are standing Workgroups: Engagement and Data Pipeline.

3.3.2 Engagement Workgroup

The role of the Engagement Workgroup 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 Workgroup'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 Steering Committee for Study Proposals.

3.3.2.1 Engagement Workgroup Lead

The Steering Committee will appoint an Engagement Workgroup lead for a term of two years, renewable one time.

3.3.2.2 Engagement Workgroup Membership

One parent from each institution will participate in the Engagemet Workgroup as a voting member. The Director of Engagement will serve as staff to the Workgroup.

3.3.2.3 Payment for Parents and Youth

Parents will be compensated for the time they spend on Engagement Workgroup activities.

3.3.3 Data Pipeline Workgroup

This Workgroup will provide oversight of the PEDSnet data pipeline, develop guidance on Extract-Transform-Load algorithms to implement the PEDSnet common data model, oversee data quality, oversee the PEDSnet data dictionary, and make recommendations to the Steering Committee for changes to the common data model.

3.3.3.1 Data Pipeline Workgroup Lead

The Steering Committee will appoint a Data Pipeline Workgroup lead for a term of two years, renewable one time. The Technology Director will serve as staff to the Workgroup.

3.3.3.2 Data Pipeline Workgroup Membership

The Informatics Lead for each institution will participate in the Workgroup as a voting member.

3.4 COORDINATING CENTER

3.4.1 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 web site and access to PEDSnet resources;
- Project management for research project start-up and monitoring;
- Logistical support to the Steering Committee and Working Groups; and,
- Management of PEDSnet Finances.

3.4.2 Database Management Center

The Database Management Center develops, maintains, and operates the PEDSnet Database. 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; and,
- Develop reusable tools for management and use of the database.

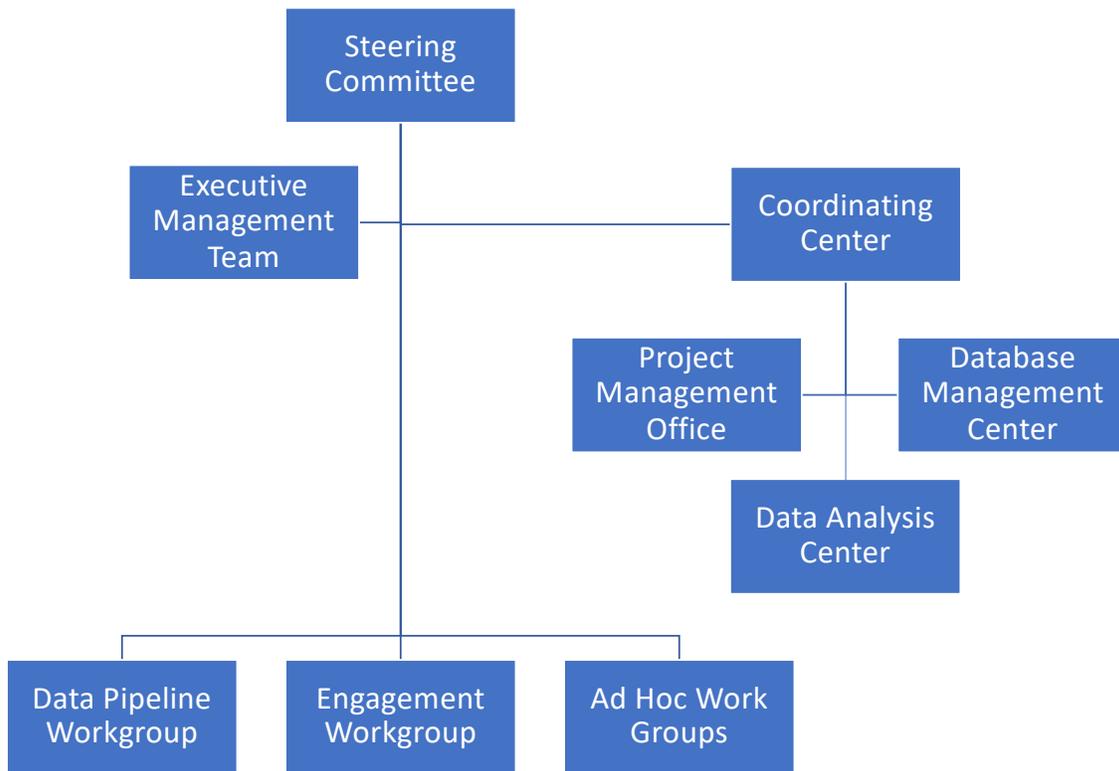
3.4.3 Data Analysis Center

The Coordinating Center will provide data and statistical analysis support for research studies that use the database. Use of the Data Analysis Center is optional for each study.

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;
- Produce reports and manuscripts based on study results; and,
- Archive study data and results.

3.5 ORGANIZATIONAL CHART



3.6 INSTITUTIONAL TEAMS

Each PEDSnet Member Institution will assemble 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.

3.6.1 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.

3.6.2 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 Coordinating Center. The Site Informatics lead is a member of the Data Pipeline Workgroup.

3.6.3 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

3.6.4 Parent Partner

Each member institution will identify a parent to serve on the PEDSnet Engagement Workgroup.

3.6.5 Project Manager

This individual provides administrative and project management support to the Institutional Team, and serves as the institutional representative to Project Management Office.

3.6.6 IRB Specialist

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

3.6.7 Legal Representative

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

3.6.8 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 Steering Committee, Executive Management Team, and Workgroups.

- 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 Committee Vote

The Executive Director will submit to the Steering Committee membership applications for pediatric institutions willing to meet all expectations of membership. 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 sign:

- PEDSnet policies, which can be signed by the Steering Committee member;
- Participation and Data Use Agreement, which an institutional official must sign; and
- SMART Institutional Review Board agreement, which an institutional official must sign.

In addition, each institution must develop and submit a data governance 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 Executive Director.

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. A two-thirds majority vote is required for termination.

6 DATABASE

In order to support a learning health system, PEDSnet fosters the use of data from real clinical settings for research, quality measurement, and improvement of child health. Use of these data makes 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 database employs a number of methods in its data standardization and analyses to reduce privacy risk.

6.1 SUBMISSION OF INSTITUTIONAL DATA

Institutions will submit data to the Coordinating Center for inclusion into the database. The frequency of these submissions will be determined by the Steering Committee, but will be quarterly at a minimum.

In response to findings from data characterization assessments done by the Coordinating Center, institutions will conduct up to one remediation per quarterly data submission cycle.

Study-specific data quality problems will be addressed during the next data remediation cycle.

6.2 LIMITED DATA-SET

The Database 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 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-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 database procedures;

- 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 Director will submit data quality reports on a quarterly basis to the Steering Committee. 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 expansions proposed by the Data Pipeline Workgroup and approved by the Steering Committee.

6.6.2 PCORnet Common Data Model

The PEDSnet Coordinating Center 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 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 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 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 Steering 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 Investigator Directors.

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.

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. The Master Patient Index will not be disclosed to member institutions or to external users. The Coordinating Center will conduct appropriate deduplication when indicated.

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's staff. This approach generally precludes the need for patient-level data to leave 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, the Coordinating Center 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 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 Steering 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 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 data-sets released to investigators. Data provided by PEDSnet can 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 stored in the PEDSnet Database 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

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

The Coordinating Center 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.

All PEDSnet 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. 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 ≤ 10 , (*i.e.* have any records that are identical for 10 or fewer persons), are subject to the following, unless specifically waived during the PEDSnet review process:

6. Replacement of stable identifiers with study-specific identifiers.
7. Shifting of dates within a one-year window centered on the actual date.
8. Replacement of free-text fields with single-use labels.
9. Replacement of geographic information with single-use labels.
10. Removal of data relating to testing or care for HIV, pregnancy, and mental health, excluding educational performance.

Each recipient is responsible for security all copies of the data in their possession, and for requiring anyone to whom they distribute the data assurance of compliance, but neither the PEDSnet DCC nor intermediate recipients can guarantee the 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 meeting the criteria specified in section I.B above 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 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).

6.14 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 must be destroyed following these requirements. These requirements also apply 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 meeting the criteria specified in section I.B above 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 backups, replicates held by other members of the analytic team, and copies committed to version control repositories.
4. The recipient will notify the PEDSnet DCC of compliance with this requirement when destruction has been completed. This must include the data destruction standard used.
5. 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.

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 Steering 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, either the protocol (if a prospective study) or analysis plan (if a retrospective study), must be reviewed and approved by the Steering Committee. Once approved, the study is designated a “*PEDSnet Study*.”

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; and,
- Appropriate engagement of stakeholders in the research.

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);
- Submission of a final report within six months of either completion of data analysis with the Coordinating Center or 12 months of receipt of a data-set;
- 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:
 - 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.

7.3 ELECTIVE PARTICIPATION IN STUDIES

Participation by an Institution in a particular PEDSnet study is voluntary. A written 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 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 Committee will review PEDSnet policies on at least an annual basis. Alterations to PEDSnet policies will require two-thirds of Steering Committee members to ratify the change(s).

10 CONFLICT OF INTEREST

All members of the Steering Committee 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.

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. 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 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 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@email.chop.edu.