

## 5 ACCESSING PEDSNET RESOURCES

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

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

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

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

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

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

### 5.2 FRONT DOOR UNIT

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

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

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

### 5.3 TYPES OF INQUIRIES

#### 5.3.1 FEASIBILITY OR DESCRIPTIVE ANALYSES

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

#### 5.3.2 REQUEST FOR PEDSNET COLLABORATORS

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

#### 5.3.2 PEDSNET STUDY APPROVAL

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

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

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

*The expectations of PEDSnet Studies include:*

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

### 5.4 ELECTIVE PARTICIPATION IN STUDIES

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