

Governance Plan

PCORnet Bariatric Study

**Prepared by: David Arterburn, Kathleen McTigue,
Neely Williams, and Jane Anau
on behalf of the PCORnet Bariatric Study**

Submitted to PCORI	<i>April 29, 2016</i>
Revised	<i>May 27, 2016</i>

PCORnet Bariatric Study Governance Plan

TABLE OF CONTENTS

EXECUTIVE SUMMARY	- 3 -
A. PCORNET OBESITY OBSERVATIONAL RESEARCH INITIATIVE.....	- 4 -
B. CROSS-CUTTING GOVERNANCE GROUPS.....	- 4 -
1. <i>Obesity Demonstration Leadership Council</i>	- 4 -
2. <i>Methods Core</i>	- 5 -
3. <i>Publications Committee</i>	- 5 -
4. <i>Evaluation Team</i>	- 6 -
C. PCORNET BARIATRIC STUDY GOVERNANCE GROUPS.....	- 6 -
1. <i>Scientific Core</i>	- 6 -
2. <i>CDRN Bariatric Lead PIs</i>	- 7 -
3. <i>Executive Bariatric Stakeholder Advisory Group (EBSAG)</i>	- 8 -
4. <i>Secondary Aim/Qualitative Study Workgroup</i>	- 8 -
FIGURES.....	- 10 -
<i>Figure 1. Cross-Cutting Governance Groups</i>	- 10 -
<i>Figure 2. PCORnet Bariatric Study Structure</i>	- 11 -
TABLES.....	- 12 -
<i>Table 1. Core Scientific Team Members and Expertise</i>	- 12 -
<i>Table 2. CDRN Bariatric PIs and Expertise</i>	- 13 -
<i>Table 3. Executive Bariatric Stakeholder Advisory Group Members</i>	- 14 -

EXECUTIVE SUMMARY

The PCORnet Bariatric Study is one of two Obesity Demonstration Projects that were funded by PCORI to: a) address important unanswered questions faced by patients and their clinicians using PCORnet's Distributed Research Network (DRN); and b) formally test and evaluate the capacity of PCORnet's data infrastructure for observational research. An additional goal of these studies is to provide an early opportunity for Clinical Data Research Network (CDRN) and Patient-Powered Research Network (PPRN) investigators, patients, and stakeholders to organize and collaborate in a multisite study and develop an efficient, collaborative process for doing so. This document outlines the governance plan that the PCORnet Bariatric Study has set forth in collaboration with the leaders of the other funded Obesity Demonstration Project, "Short and Long-term Effects of Antibiotics on Childhood Growth".

The two Obesity Demonstration Projects have formed three cross-cutting governance groups to help ensure scientific and operational communication, coordination, and efficiencies across the two studies.

- The Obesity Demonstration Leadership Council (ODLC) is a collaboration between the leaders of the two obesity demonstration projects. Its purpose is to provide a forum for administrative, operational, and scientific coordination across both studies.
- The Methods Core is a cross-functional team that was established by the ODLC to ensure efficiencies across the studies. This "virtual" core serves both obesity studies and is charged with making cross-cutting decisions related to how the studies handle the data flow processes, query development, and progress toward testing and implementation of the queries. This work is done in partnership with the PCORnet Coordinating Center (CC). Both studies fund CC staff to support work on the Obesity Demonstration Projects. Additionally, the Methods Core will assess the appropriateness of study statistical analysis methods and application of privacy preserving methods.
- The Publications Committee will collaborate with the PCORnet Research Committee to develop and then implement an overarching publications policy for our project.

Within the PCORnet Bariatric Study (PBS), we have organized ourselves into four interconnected groups.

- **The Scientific Core** includes the scientists and patient investigators who are ultimately responsible for the success of the entire PBS research process, including developing and implementing the research plan, stakeholder engagement, and all dissemination activities.
- **The CDRN Bariatric PI Group** will provide scientific and operational leadership by assisting and advising the Scientific Core throughout the study on all aspects of the study aims as well as overseeing all the administrative aspects of the work within their respective CDRNs including contracting, IRB approvals, and data sharing agreements.
- **The Executive Bariatric Stakeholder Advisory Group (EBSAG)** will provide broad stakeholder input on all aspects of the study, from the specification of study aims and research design, to implementation of study procedures, and the interpretation and dissemination of findings.
- **The Secondary Aim/Qualitative Study Workgroup** will develop and oversee implementation of the research plan for the secondary aim, focusing on eliciting patient preferences around the risks and benefits associated with three key choices: (a) whether to undergo bariatric surgery; (b) which bariatric procedure to utilize; and (c) optimal follow-up care after bariatric surgery.

A. PCORnet OBESITY OBSERVATIONAL RESEARCH INITIATIVE

As one of two studies in the PCORnet Obesity Observational Research Initiative, PBS is also aligned with the other study, “Long-term Effects of Antibiotics on Childhood Growth” (ABX). Together these two studies have established two cross-cutting governance groups to help ensure efficiencies across the studies. We describe these cross-cutting governance groups below and then describe the governance structure that is specific to the PBS. Figure 1 (below) depicts the relationship between these two studies.

B. CROSS-CUTTING GOVERNANCE GROUPS

1. Obesity Demonstration Leadership Council

a. Purpose

The Obesity Demonstration Leadership Council (ODLC) is a collaboration between the leaders of the two obesity demonstration projects. This team has met regularly since the funding announcements were made in winter of 2015. The main purpose of the ODLC is to provide a forum for administrative, operational, and scientific coordination across both studies. This is a critical function because both studies are using common resources (PCORnet queries and Coordinating Center [CC] functions) and being evaluated with similar metrics over the same 2-year time frame. Also, the ODLC is one of the main decision-making groups for the two projects in that this team is helping to establish the ways in which the obesity studies can most effectively contribute to the PCORnet Commons (repository of processes and procedures for accomplishing observational studies in PCORnet).

b. Membership & Responsibilities

The ODLC is Co-Led by Matt Gillman and David Arterburn, who are Co-PIs and representatives from the Prime sites for the two projects. Along with their project managers, Juliane Reynolds and Jane Anau, Drs. Gillman and Arterburn facilitate each of the ODLC meetings and record minutes, decisions, and action items.

Key members are the other Co-PIs for two projects: Chris Forrest, Doug Lunsford, Kathleen McTigue, and Neely Williams. Their primary roles are to contribute to the shaping of policies and procedures that affect both of the study teams, and they help to strategize solutions to common problems. Since Drs. Forrest and McTigue are both serving as CDRN PIs, they also serve a crucial role in communicating with other CDRN PIs and with PCORnet leadership. Mr. Lunsford and Mrs. Williams play critical roles in connecting the ODLC to the concerns of patients affected by obesity and to each of the two study’s executive stakeholder engagement teams.

Other members of the ODLC are investigators and staff from the PCORnet Coordinating Center (CC), including Dr. Jeff Brown, Dr. Jason Block, Jessica Sturtevant, Mia Gallagher, Nina Lasser, and Beth Syat. Drs. Brown and Block serve critical cross-functional roles by connecting the study teams to the CC query process leadership. Dr. John Holmes and Brie Purcell also participate in the ODLC and are leading the Evaluation Team, which will provide a rigorous assessment of each study and the PCORnet infrastructure.

2. Methods Core

a. Purpose

The Methods Core is a cross-functional team that was established by the ODLC to ensure efficiencies across the studies. This “virtual” core was created to serve both obesity studies and is charged with making cross-cutting decisions related to how the two obesity studies handle the data flow processes, query development, and progress toward testing and implementation of the queries. Additionally, the methods core will assess the appropriateness of study statistical analysis methods and application of privacy preserving methods. Key goals of the Methods Core are to help coordinate communication between the study teams and the CC staff responsible for developing and deploying study queries and to leave behind information for future PCORnet studies in the form of processes and procedures for the PCORnet Commons.

b. Membership & Responsibilities

The Methods Core will be overseen by staff at the CC, chaired by Dr. Jason Block, and will include: experts working on both obesity study teams (Drs. Lingling Li, Darren Toh, and Block); CC personnel (Dr. Brown, Jessica Sturtevant, and Casie Horgan); and study-specific lead investigators (Drs. Arterburn and McTigue for this project; and Drs. Gillman and Forrest for the antibiotics project). Additional study-specific experts will also participate in the Methods Core: Rob Wellman and Tyler Ross (PBS); and Matthew Bryan, Charles Bailey, Sheryl Rifas-Shiman, and Leonardo Trasande (ABX). These core members bring expertise in biostatistics (Li, Wellman, and Bryan), epidemiology (Toh, McTigue, and Trasande), medicine (Arterburn, McTigue, Block, and Bailey), pediatrics (Gillman and Forrest) and distributed research networks (Brown, Li, Toh, and Wellman).

The methods core will meet approximately twice-monthly to ensure consistency across studies and to identify and leverage efficiencies across the projects.

3. Publications Committee

a. Purpose

The Publications Committee will develop/implement an overarching publications policy for the Obesity Studies. A subset of the group will serve on the PCORnet Publications Policy Workgroup, developing a policy for use in diverse PCORnet studies. The full Obesity Demonstration Projects Publications Committee will then implement those policies within the context of the Obesity Demonstration Projects and extend them to address articles intended for a lay audience. Once these overarching policies are in place, each study will create its own Publication Committee to manage study publications.

b. Membership & Responsibilities

The Publications Committee is led by Kathleen McTigue, and includes the bariatric study Project Manager (Jane Anau), as well as two additional representatives from the antibiotics (Jenny Ingber and Leonardo Trasande) and bariatric (Ali Tavakkoli and Elisha Malanga) study teams. The Committee will be responsible for creating a publications policy for the Obesity Demonstration Projects that aligns with recommendations made by the PCORnet Publications Policy Workgroup.

4. Evaluation Team

a. Purpose

A significant aim of the demonstration projects is to test, evaluate, and report on the readiness of PCORnet's data infrastructure and the use of the Distributed Research Network. The projects are also expected to provide the opportunity for Clinical Data Research Networks, Patient-Powered Research Networks, and stakeholders to organize and collaborate in a multisite study and develop efficient, collaborative processes for doing so. The projects will be evaluated on their ability to complete this work. The formal evaluation plan has been submitted to PCORI.

b. Membership & Responsibilities

The evaluation is being led by Dr. John Holmes at University of Pennsylvania. He is supported by Brie Purcell and Beth Syat. For evaluation of PBS, they will utilize input from the Scientific Core, CDRN Bariatric Lead PIs, EBSAG, DRN OC, and CDRN leadership and technical representatives. The evaluation team will report on PCORnet readiness for research and study-specific operational processes; stakeholder engagement; contracting, IRB, and Data Sharing Agreement processes and approvals; data infrastructure readiness and functionality; and overall research readiness every four months, starting in July 2016 and continuing throughout the study period.

C. PCORnet BARIATRIC STUDY GOVERNANCE GROUPS

We have developed a clear organizational structure that engages a core team of multidisciplinary researchers and stakeholders as leaders of the project while also facilitating input broadly from CDRNs, PPRNs, and other key stakeholder partners. Group Health Research Institute (GHRI) will serve as the prime institution for the PBS. Members of the PCORnet CC working on the study are at Harvard Pilgrim Health Care Institute (HPHCI). They will work closely with other members of the PCORnet CC, which is led by the Duke Clinical Research Institute. The PCORnet CC provides maximum flexibility in deployment of resources for rapid project initiation, a high level of responsiveness to complex and diverse requests, and the ability to conduct multiple projects in parallel. As shown in Figure 2 below, the PCORnet CC will provide coordinated infrastructure- and data-related support to the study team in close collaboration with the Methods Core. The Scientific Core, Bariatric Lead PIs, Executive Bariatric Stakeholder Advisory Group, and Secondary Aim/Qualitative Study Workgroup (all described below) are supported by Jane Anau, Project Manager, who manages all aspects of the project and facilitates communications between the different groups.

1. Scientific Core

a. Purpose

This multidisciplinary team has the clinical, operational, and methodological expertise to ensure the successful execution of all aspects of this research study. The Scientific Core includes the scientists and patient investigators who are ultimately responsible for the success of the entire PBS research process, including developing and implementing the research plan, stakeholder engagement, and all dissemination activities.

b. Membership & Responsibilities

The Scientific Core is made up of the three Co-Principal investigators (Arterburn, McTigue and Williams) that were selected by PCORI/PCORnet to lead this project, as well as researchers with expertise in obesity research (Block), bariatric outcomes research (Coleman), bariatric surgery (Courcoulas), PCORnet infrastructure (Janning), and longitudinal and distributed data analyses (Toh and Li). It includes two bariatric patients (Williams and Janning), and incorporates clinician, researcher, surgical, medical, and statistical perspectives. The study biostatistician (Wellman) and lead study programmer (Tyler Ross) are also members of the team. Many members of the study team have established highly productive collaborative relationships over the years through ongoing and completed multi-center projects with numerous prior collaborative publications.

The Scientific Core is responsible for day-to-day operational decision making to accomplish the study aims including the secondary aim and stakeholder engagement process. Table 1 lists members of the Scientific Core and their areas of expertise.

2. CDRN Bariatric Lead PIs

a. Purpose

The purpose of the CDRN bariatric PI group is two-fold: 1) scientific advising and 2) local operational leadership. For scientific advising, the CDRN bariatric PI group will assist and advise the Scientific Core throughout the study on all aspects of the study aims. For local operational leadership, they will oversee all the administrative aspects of the work within their respective CDRNs including contracting, IRB approvals, and data sharing agreements. They will also oversee all queries that are run through their participating sites in their CDRNs. These roles are critical to the successful completion of the project. They also provide a conduit directly to the CDRN participating sites' investigators, to help build collaborative ties to all of the participating sites.

Each CDRN Bariatric Lead PI is supported by a Lead Site Project Manager (CDRN PM). The CDRN PM will work closely with the Lead Site PI to coordinate all operational and administrative tasks within each CDRN. The CDRN PMs will also have monthly calls with the PBS PM, Jane Anau, to ensure all deliverables are on track.

b. Membership & Responsibilities

The CDRN bariatric PIs are scientists with various backgrounds that form a broad, multidisciplinary team made up of 1-2 scientists/clinicians from each participating CDRN (see Table 2 below for full list). Their key roles are as follows:

- Scientific advising:
 - Participate in twice-monthly conference calls over the two years of the project
 - Provide scientific input on all study activities by email and teleconference
 - Opportunity to be a co-author on all manuscripts
- Operational management:
 - Issuing subcontracts or similar agreements with the contributing data marts (node sites) of the CDRN that each Bariatric Lead PI represents
 - Oversight of regulatory (IRB and any necessary data sharing agreements) matters with node sites
- Query management for initial cohort characterization and all scientific aims:

- Running study related queries on Common Data Model (CDM) v3.0
- Trouble-shooting data quality problems specific to node sites,
- Node sites will need to remediate issues with data quality that may be necessary to implement study queries

3. Executive Bariatric Stakeholder Advisory Group (EBSAG)

a. Purpose

This group will function as a core study group similar to the Scientific Core and the CDRN Bariatric PIs for the proposed study. They will have monthly meetings throughout the project which will be led by Dr. Karen Coleman, a scientist with experience in bariatric research and community engagement, and have representation from the Core Scientific Team in Mrs. Neely Williams, Ms. Cheri Janning, and Drs. Arterburn and McTigue. Meetings will be via phone and WebEx. The main purpose of this group is to provide broad stakeholder input on all aspects of the study, from the specification of study aims, to the research design, and to implementation, interpretation, and dissemination.

b. Membership & Responsibilities

This group is made up of stakeholders representing patients, providers, and health system leaders. A full list of EBSAG members is provided in Table 3 below. As specified in greater detail in our stakeholder engagement plan, this group will be responsible for designing and implementing the engagement plans for each of four larger designated stakeholder groups. Each member of the EBSAG will be responsible for assisting Dr. Coleman and the scientific team in engaging a larger group of stakeholder representatives. For example, the bariatric surgeon(s) who are part of the EBSAG will assist in the planning and engagement of the healthcare provider stakeholder group for the proposal. The EBSAG and four stakeholder sub-groups will provide feedback regarding the study design and implementation.

4. Secondary Aim/Qualitative Study Workgroup

a. Purpose

This group will lead the development of the research plan for the secondary aim focusing on eliciting patient preferences around the risks and benefits associated with three key choices: (a) whether to undergo bariatric surgery; (b) which bariatric procedure to utilize; and (c) optimal follow-up care after bariatric surgery. The Workgroup will incorporate input from the EBSAG, CDRN Bariatric PIs, and Scientific Core in this planning process. It will also implement the plan and oversee data collection and analysis.

b. Membership & Responsibilities

The Secondary Aim/Qualitative Study Workgroup is led by Karen Coleman, and includes the study co-PIs (Arterburn, McTigue and Williams), one patient partner with expertise in PCORnet infrastructure (Janning), and one bariatric surgeon (Courcoulas). This Workgroup is responsible for leading and organizing work related to the secondary aim. The Workgroup will develop, in conjunction with the EBSAG and selected scientific study team members, content for patient

focus groups and bariatric surgeon interviews. The Workgroup will conduct analysis of the qualitative data.

FIGURES

Figure 1. Cross-Cutting Governance Groups

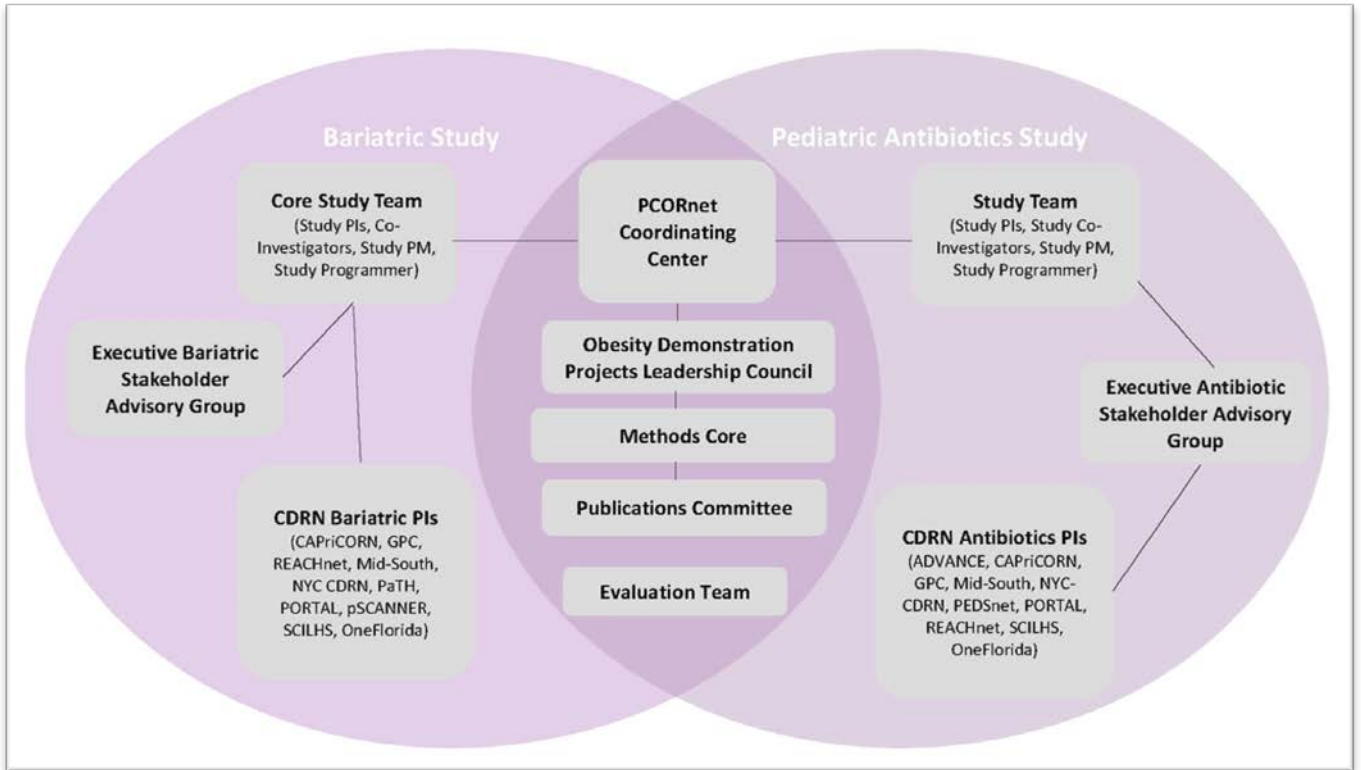
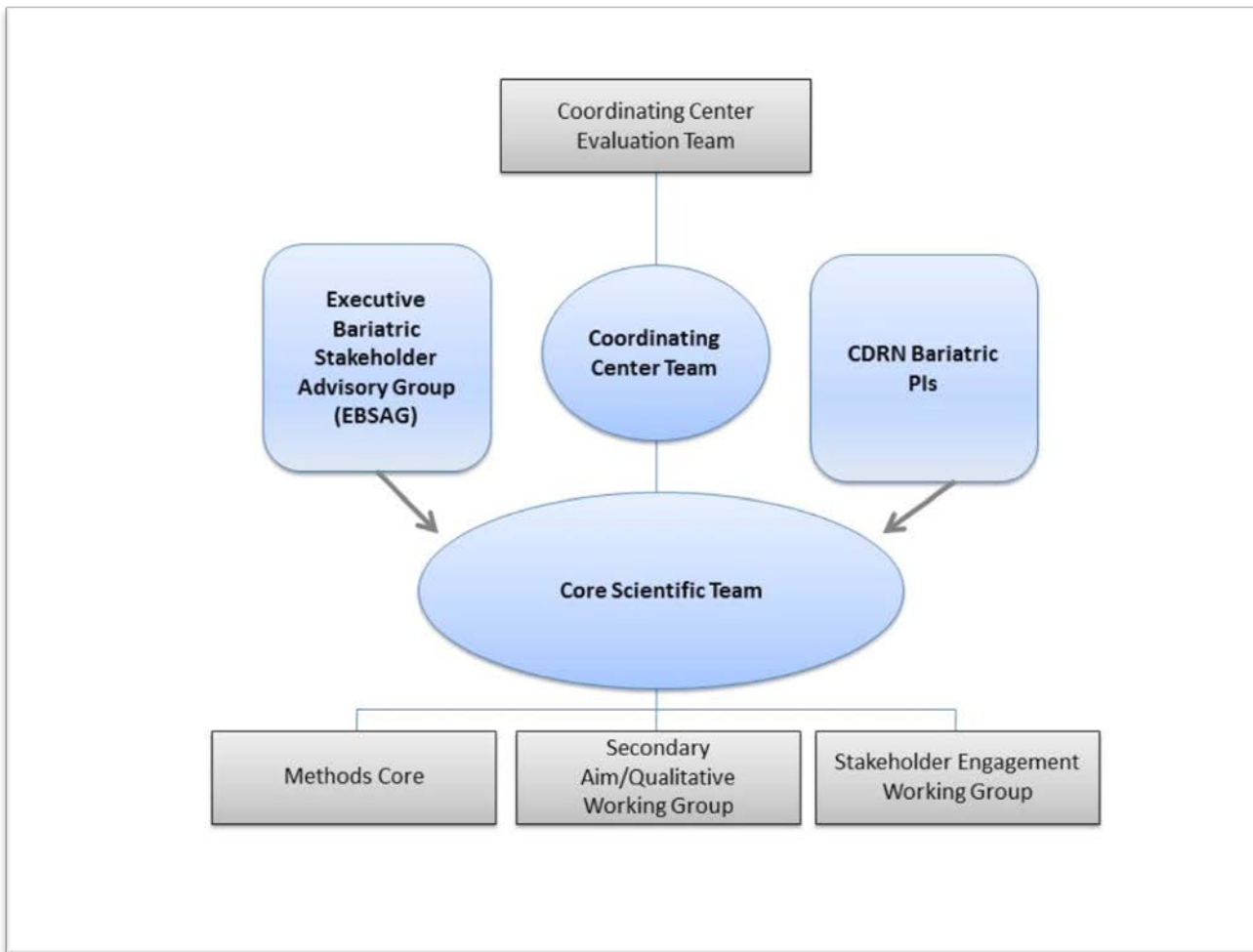


Figure 2. PCORnet Bariatric Study Structure



TABLES

Table 1. Core Scientific Team Members and Expertise

Team members	Areas of expertise
David Arterburn, MD, MPH (Co-PI) Group Health Research Institute, Seattle, WA	<ul style="list-style-type: none"> ● Bariatric surgery outcomes research ● Comparative effectiveness research
Kathleen McTigue, MD, MPH, MS (Co-PI) University of Pittsburgh, Pittsburgh, PA	<ul style="list-style-type: none"> ● Obesity research ● Epidemiology and population health
Neely Williams, M.Div. (Patient Co-PI) Mid-South CDRN, Nashville, TN	<ul style="list-style-type: none"> ● Bariatric patient perspective ● Community advocacy and organization
Jason Block, MD, MPH (Co-I) Harvard Pilgrim, Boston, MA	<ul style="list-style-type: none"> ● Practicing Internal Medicine physician ● Obesity research; epidemiology and population health
Anita Courcoulas, MD, MPH (Co-I) University of Pittsburgh, Pittsburgh, PA	<ul style="list-style-type: none"> ● Practicing bariatric surgeon ● Surgical outcomes research
Karen Coleman, PhD (Co-I) Kaiser Permanente Southern CA, Pasadena, CA	<ul style="list-style-type: none"> ● Bariatric surgery outcomes research ● Behavioral science and community based research
Cheri Janning (Patient Co-I)	<ul style="list-style-type: none"> ● Bariatric patient perspective ● Project manager for PCORnet (former)
Darren Toh, ScD (Co-I) Harvard Pilgrim, Boston, MA	<ul style="list-style-type: none"> ● Privacy-preserving analytic and data-sharing methods ● Comparative effectiveness and safety of therapeutics
Lingling Li, PhD (Co-I) Harvard Pilgrim, Boston, MA	<ul style="list-style-type: none"> ● Simulation studies ● Causal inference
Rob Wellman, MS Group Health Research Institute, Seattle, WA	<ul style="list-style-type: none"> ● Biostatistics ● Distributed research analytics
Tyler R. Ross, MA Group Health Research Institute, Seattle, WA	<ul style="list-style-type: none"> ● Lead study programmer ● Multisite data warehouse studies
Jane Anau Group Health Research Institute, Seattle, WA	<ul style="list-style-type: none"> ● Lead study project manager ● Multisite project coordination and governance issues

Table 2. CDRN Bariatric PIs and Expertise

CDRN	CDRN Bariatric PI	Expertise
Mid-South	David Schlundt, PhD Vanderbilt University	<ul style="list-style-type: none"> Behavioral medicine with specific focuses on nutrition and behavior, and racial and ethnic health disparities.
REACHnet	Lydia Bazzano, MD, PhD Tulane University	<ul style="list-style-type: none"> Nutrition and primary prevention; cardiovascular disease; diabetes mellitus
GPC	James McClay, MD, MS University of Nebraska	<ul style="list-style-type: none"> Biomedical Informatics Emergency Medicine
PEDSnet	Thomas Inge, MD University of Cincinnati	<ul style="list-style-type: none"> General Pediatric Surgeon, Adolescent Bariatric Surgeon, Obesity and surgery research
PaTH	Jeanne Clark, MD Johns Hopkins University	<ul style="list-style-type: none"> Obesity research Efficacy of bariatric and lifestyle treatments for obesity
SCILHS	Ali Tavakkoli, MD Brigham and Women’s Hospital	<ul style="list-style-type: none"> Bariatric Surgeon, Research on surgical outcomes including diabetes resolution after bariatric surgery
NYC-CDRN	Ana Emiliano, MD The Rockefeller University <i>and</i> Rabih Nemr, MD Lutheran Medical Center	<ul style="list-style-type: none"> Endocrinology, metabolism, and obesity Bariatric surgery, obesity
CAPriCORN	Laura Rasmussen-Torvik, PhD, MPH Northwestern University	<ul style="list-style-type: none"> Epidemiology, biogenetics, diabetes
PORTAL	Karen Coleman, PhD , Kaiser Permanente Southern California	<ul style="list-style-type: none"> Bariatric surgery outcomes research Behavioral science and community-based research
pSCANNER	Pietro Galassetti, MD , UC Irvine	<ul style="list-style-type: none"> Obesity, diabetes, and metabolism research
OneFlorida	Steven Smith, MD Florida Hospital	<ul style="list-style-type: none"> Obesity, diabetes, metabolism research, and translational research

Table 3. Executive Bariatric Stakeholder Advisory Group Members

CDRN/PPRN/Organization	Member	Stakeholder Group
COPD PPRN	Elisha Malanga	Community/Advocacy group member
Smart Patients	Roni Zeiger	Community/Advocacy group member
PORTAL CDRN	Sameer Murali	Health System Leader/Bariatric Provider
CAPriCORN CDRN	Joseph Vitello	Bariatric Surgeon
REACHnet	Roz Saizan	Bariatric Patient/Bariatric Provider
Mid-South CDRN	Emily Eckert	Bariatric Provider
NYC CDRN	Tammy St. Clair	Bariatric Patient
PaTH CDRN	Julie Tice	Bariatric Patient
SCIHLS CDRN	Elizabeth Doane	Bariatric Patient/Bariatric Provider
SCILHS CDRN	Caroline Apovian	Healthcare Provider
pSCANNER CDRN	Bryan Sandler	Bariatric Surgeon
PEDSnet CDRN	Nirav Desai	Pediatric Gastroenterologist
PEDSnet CDRN	Marc Michalsky	Pediatric Bariatric Surgeon
OneFlorida CDRN	Joe Nadglowski	Community/advocacy group member
GPC CDRN	Corrigan McBride	Bariatric Surgeon/ Bariatric Patient