

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.