EXECUTIVE SUMMARY

The PCORnet Bariatric Study ("the study") team has prepared a detailed analysis plan for accomplishing the main study aims. This plan was developed by the Methods Core with feedback from the Scientific Core, Executive Bariatric Stakeholder Advisory Group, and the Clinical Data Research Network (CDRN) Bariatric Principal Investigators.

The study seeks to answer three main scientific questions:

Aim 1: To what extent does weight loss and weight regain differ across the three most common bariatric surgical procedures in the United States – Roux-en-Y Gastric Bypass (RYGB), Adjustable Gastric Banding (AGB), and Sleeve Gastrectomy (SG) – at 1, 3, and 5 years after surgery?

Aim 2: To what extent do the three most common bariatric procedures in the United States differ with respect to diabetes status at 1, 3, and 5 years after surgery?

Aim 3: What is the frequency of major adverse events for the three most common bariatric procedures in the United States at 1, 3, and 5 years?

Population: The study will include adults, children, and adolescents less than 80 years old at time of surgery who had one of the three most common procedures in the United States (RYGB, AGB, or SG) during the years 2005 to 2015. To be eligible for the study all patients will also need to have a Body Mass Index (BMI) measurement in the year prior to surgery that is at least 35 kg/m^2.

Data: All data necessary for accomplishing the main scientific aims of this study will be derived from the PCORnet Common Data Model (CDM). In the plan below we have specified each CDM table that will be accessed as well as the key variables that will be examined. Although all of the tables described are necessary to complete the study, of greatest interest are the procedures, diagnosis, vitals, prescribing, dispensing, and death tables. All data for this study will be abstracted from the CDM tables at each participating health care site and then sent using secured file transfer methods to the data coordinating center at Harvard Pilgrim and to Group Health Research Institute for analysis.

Analyses: The "primary analyses" will address the main study questions outlined above using individual-level patient data. There is also a set of "secondary analyses" for each of the main study questions, which will only use aggregate or summary-level data from each participating site. We will conduct three pair-wise comparisons for each study aim – comparing AGB versus RYGB, SG versus RYGB, and AGB vs. SG. To address potential confounding bias in each comparison, we will first use a logistic regression model to estimate the propensity score (PS), which is defined as the probability of receiving a treatment of interest (e.g., RYGB) in each pairwise comparison given the potential confounders variables plus calendar year. We will conduct sensitivity analyses to assess for changes in outcomes by calendar year, and we will use a multiple imputation approach to address missing outcome information. Finally, for each aim, we will seek to identify heterogeneity of treatment effects, with are any differences in the effects of the bariatric procedures across key subgroups (e.g., race/ethnicity).

Methodology Standards: Throughout the document, references are made to PCORI's Methodology Standards (e.g., [RQ-1]). A description of these standards can be found here on the PCORI website