

## **BIB Implant Device and Schedule of Appointments**



BIB implant device for patient who are selected. The balloon is implanted in an outpatient setting and left in the stomach for six months. The procedure takes approximately an hour and is done endoscopically. The balloon is inflated with saline solution.

### **Schedule of appointments:**

#### **Participants randomized into the balloon part of the study appointments;**

Day 1, weeks 1, 2, 4, 8, 12, 16, 20, 26 (BIB® removal), 28, 30, 32, 34, 36, 39, 42, 44, 46, 48, 50, and 52. During these visits, your study doctor will ask you a number of questions, assess your vital signs, have your height and weight measured to calculate your BMI. Your blood (about 4 teaspoons) will be taken from a vein in your arm for regular laboratory tests. Your medications, adverse events, and nutritional and exercise plans will be reviewed.

#### **Participants randomized into the wellness program part of the study appointments;**

If you are randomized to the Control group, the balloon will **not** be placed in your stomach. You will complete the behavioral modification program and be on a long-term low calorie (1000-1500 calories/day) supervised diet and on an exercise plan for 52 weeks. At each scheduled study visit your study doctor will measure your height and weight to calculate your BMI. You will have a physical exam and your waist and hip circumference will be measured. Your blood (about 4 teaspoons) will be taken from a vein in your arm for regular laboratory tests. You will also have any necessary tests that need to be repeated if the tests were abnormal or if your study doctor would like to repeat any tests. You will also be asked to complete some questionnaires that ask about quality of life, physical function, eating habits and your feelings.