If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **B**ariatric **E**mbolization of **A**r**T**eries with imaging visib**L**e **E**mbolic**S** (**BEATLES**) Study: Protocol Version 4

Application No.: **IRB00143169**

Sponsor/Supporter/Funded By: **BTG**

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You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

There are over 40 hormones produced in the body that limit food intake, but only one hormone (called ghrelin) has been shown to stimulate immediate eating. In obese people, eating does not limit ghrelin levels in the body, which is believed to prevent people from feeling full after a meal and leads to overeating. Recent data has shown that blocking blood vessels to a particular portion of the stomach – a procedure known as bariatric embolization – can temporarily lower levels of ghrelin and decrease short-term weight gain.

In this study we will use very small beads (smaller than a period at the end of a sentence) to slow down (but not stop) blood flow to a specific area of the stomach. The use of these beads has not been approved by the Food and Drug Administration (FDA); however, these beads are a modified version of an FDA-approved product commonly used in patients. About half of participants in the study will have the beads infused during a minimally-invasive, non-surgical procedure called angiography (an imaging technique used to see blood vessels in the body) and embolization. The second half of participants in the study will not receive the beads but undergo "sham" angiography, in which we will mimic but not actually perform the bariatric embolization procedure. Neither you nor the study team will know whether you received the investigational beads or not. Only the operating physician, room staff, and research nurse will know who received the beads. This is the first study to use "sham" angiography in bariatric embolization.

Once you have undergone an 8-week screening period and been found to be eligible to take part in the study, you will have the bariatric embolization procedure done. We will then follow-up with you at weeks 1 and 2, and months 1, 3, 6, and 12 post-procedure. Procedures done during the study will include blood draws, magnetic resonance imaging (MRI), computed tomography (CT) angiography, upper gastrointestinal (GI) endoscopy, and nuclear medicine gastric motility/emptying examination (if applicable). There are risks to participating in this study, which are described later in this document. Some risks could be serious and not all side effects/risks associated with the study device and procedure are known.

2. Why is this research being done?

The purpose of this study is to evaluate the safety and effectiveness of bariatric embolization to treat obesity.

Although there are over 40 hormones produced in the body that limit food intake, only ghrelin has been shown to stimulate immediate eating. Due to the strong hunger-inducing effects of ghrelin, this hormone has been a target for the treatment of obesity and weight loss. More recently, ghrelin has been shown to have a significant role in the long-term weight loss outcomes in bariatric (obesity) surgery where ghrelin levels have been shown to be much lower when compared to untreated patients.

The current treatment for obesity consists of diet, exercise, medications, and sometimes surgery. Recent animal data has shown that blocking the blood vessels that supply a particular portion of the stomach (bariatric embolization) can temporarily decrease levels of the appetite-inducing hormone ghrelin, and thus decrease short-term weight gain. This procedure is nearly identical to endovascular angiography and embolization, which has been used for over 30 years to treat bleeding in the stomach. Bariatric embolization uses minimally-invasive, non-surgical angiography and embolization not to treat bleeding, but to lead to weight loss or alterations in hunger.

In this study, bariatric embolization will be performed using tiny (100-200 μm), radiopaque (visible on X-ray) beads (referred to as BTG-001933) in order to suppress the body's signals for feeling hungry, which we predict will lead to weight loss. The device is a bead product which is very similar to a market product that has been cleared by the Food and Drug Administration (FDA) for embolization of hypervascular tumors or arteriovenous malformations, but not for use in weight loss. BTG-001933 is slightly different from this FDA-approved device in that the beads are smaller in size and have lower iodine content. Specifically, the FDA-approved device used in the previous study was slightly larger, at 300-500μm, while our current study device is smaller, at 100-200μm. As our study device is smaller than the FDA-approved product, we expect the beads to go further down the artery and be more

effective at stopping blood flow. For the same reason, however, it is also possible that the smaller bead size may lead to more ulceration than in the previous study.

Are there any investigational drugs/devices/procedures?
The use of BTG-001933 in this research study is investigational. The word "investigational" means that BTG-001933 is not approved for marketing by the Food and Drug Administration (FDA). However, the FDA is allowing the use of BTG-001933 in this study.

How many people will be in this study?
This study is being done at Johns Hopkins Hospital and 59 people are expected to be enrolled.

Who can join this study?
You may qualify to join this research study if you are between the ages of 21-70, have failed prior conservative weight loss therapies, and are obese with a BMI greater than or equal to 35.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Study Summary
This is a double-blind study with 2 arms for enrollment: 27 participants will be enrolled in the interventional arm and 27 participants will be enrolled in the control arm. In other words, this means that about half the participants in the study (the control group) will not receive the study beads.

You will be randomly assigned (by chance, as with the flip of a coin) to either the intervention or control arm of the study. Neither you nor the study team will know if you received the study beads. Only the operating physician, room staff, and research nurse will know who received the study beads.

Screening and Pre-procedure Assessment
Prior to the bariatric embolization procedure, you will have a screening evaluation, which will include evaluation by two physicians, an interventional radiologist and an internist who specializes in obesity, as well as the following exams, tests, and procedures:

- Detailed medical history
- Initial psychological evaluation
- Physical exam

If you are a woman who is able to become pregnant, you will have a urine pregnancy test on the day of initial evaluation. The result of this test must be negative for you to continue in the study. We encourage that participants not become pregnant because that could result in weight gain. It is also possible that the procedure may involve unforeseeable risks to subject, or to the embryo or fetus should the subject become pregnant. As such, if you agree to participate in the study, you will be asked to use birth control (oral contraceptive pills) for the duration of the study unless you are post-menopausal, have an intrauterine device (IUD) or other implanted birth control device, have undergone tubal ligation or hysterectomy, or are otherwise unable to get pregnant.

Blood tests include complete blood count, tests of liver and kidney function, and H. pylori blood antibody test to see if the patient has been exposed to a specific type of bacteria that can cause stomach ulcers. A few tablespoons of blood will be needed for this initial blood testing. A stool occult blood study will also be performed to identify any gastrointestinal bleeding as a part of the screening process.

Weight Management Schedule Before and After Embolization:

- Before Embolization - You will have a total of eight visits at the Johns Hopkins Greenspring Campus Healthful Eating, Activity & Weight Program. This will include an initial 1-hour intake with a physician followed by weekly 15-minute meetings with either a physician for follow-up or other medical staff for weight checks. After you complete your intake visit, you will be placed on a reasonable, controlled diet—a diet plan will be outlined for you. After the first visit, you will return weekly for seven more visits over eight weeks. Some visits may occur using a secured telemedicine link (see supplemental form).
- After Embolization - The first two months after the procedure, you will have weekly visits with the Johns Hopkins Healthful Eating, Activity & Weight Program (HEAWP), alternating between having a visit with a HEAWP physician and a weight check each week. In months 3 to 5, you will have a visit with a HEAWP physician every other week (i.e. two visits a month). In month 6, you will have one visit with a HEAWP physician and one visit with other medical staff at the clinic for a weight check. Lastly, from month 7 to 12, you will have monthly visits with a HEAWP physician. Each follow-up visit should take around 15 minutes.

Psychological Evaluation:

- The initial evaluation will be, on average, 1.5 hours. Follow-up visits are usually 1 hour long, and will largely depend on the established plan with the Johns Hopkins Healthful Eating, Activity & Weight Program and the degree to which you require follow-up, determined after your initial evaluation by the psychiatrist. You will have to meet with the specialist 2-4 weeks after the procedure and develop a follow-up plan which will be adjusted to suit each individual participant's needs. At a minimum, this will include scheduled visits at 1, 3, 6, and 12 months; follow-up visits may be conducted more frequently than specified (i.e. optional 9-month visit). Psychology visits may be completed remotely (i.e. telehealth) if clinically indicated—this will be at the discretion of the study psychologists.
- You will follow up with the same psychologist who conducts the initial evaluation, except in urgent or emergency situations in which the particular psychologist is not available. This means your psychology visits will either all take place in a clinic on the Bayview Campus or on the East Baltimore Campus.

If you are still eligible for the study, the following procedures will be performed:

- CT angiography, if not performed within the last 5 years: This is a non-invasive procedure in which an x-ray contrast (dye) is injected into a vein at the time of a CT scan, so that the blood vessels to the stomach can be examined.
- Upper GI endoscopy, also known as esophagogastroduodenoscopy (EGD): A long, flexible, lighted tube, called an endoscope, is guided through the patient's mouth and throat, then through the esophagus, stomach, and duodenum (first part of the small intestine). A video camera in the endoscope projects images onto a monitor so that the doctor can then examine inside these organs and detect abnormalities. In addition to performing a visual examination of the upper GI tract with the endoscope, the doctor can insert instruments through the endoscope to obtain tissue samples for a biopsy. Pre-procedure and post-procedure biopsies will be obtained to look at the hunger-related hormone (ghrelin) levels in your stomach, and the health of your stomach's lining. Specifically, the biopsy will be accomplished using a device that looks like a small alligator clip at the end of the endoscope which will close over a very small sample of stomach tissue and allow for its extraction. In the case that an ulcer, inflammation, or mass is noted on endoscopy, additional biopsies may also be taken for further analysis of those regions. A video camera in the endoscope projects images onto a monitor.

- Nuclear medicine gastric motility/emptying examination (for diabetics ONLY): This procedure is performed by nuclear medicine physicians and measures the speed with which food empties from the stomach and enters the small intestine. For a gastric emptying study, the patient will eat a meal in which the solid, liquid, or both components of the meal are mixed with radioactive material. A scanner is placed over the patient's stomach to monitor the amount of radioactivity in the stomach for several hours after the test meal is eaten. The rate at which the radioactivity decreases in the stomach reflects the rate at which food is emptying from the stomach.
- MRI with AMRA Profiler: A 30- to 38-minute MRI scan with special software that provides precise body fat composition measurements. The scan includes non-standard clinical sequences that will help us get a better look at the relationship between fat, muscle, and development of disease to allow us to predict health events in future patients. Magnetic resonance imaging (MRI) scans create images of the body using a strong magnet and radio waves. There is no radiation involved in an MRI exam.
  During your MRI visit you will also record a baseline body composition and metabolic assessment using the HealthReel application and a waist measurement will be collected
  You may not take part in this study if you have any metal or device in your body which is not compatible with MRI. Examples include certain pacemakers, defibrillators, aneurysm clips, or other implanted electronic or metallic devices, shrapnel, or other metal. If you have a history of metal in your head or eyes, you cannot take part in this study.
  The MRI machine periodically makes loud banging noises. We will provide earplugs or headphones for you to wear during the MRI exam.
- Various questionnaires and surveys assessing eating behaviors, food intake, hunger and satiety, and quality of life will be performed as a part of your baseline assessment.
- If you are a woman who is able to become pregnant, a urine pregnancy test will be performed within a week of your CT angiography, endoscopy, and nuclear medicine gastric emptying study. The result of this test must be negative for you to receive the abovementioned tests and continue in this study.

If you qualify for this study, and the following exams were done more than 30 days before the day of the procedure during screening, then you will repeat the following tests as a baseline assessment within 30 days of the bariatric embolization procedure:

- Medical history and physical examination, including height and weight
- Blood tests including:
  - Complete blood count (CBC)
  - Liver functions tests (LFTs)
  - Serum albumin measurement
  - Electrolytes, urea, creatinine measurements (EUC)
  - Serum or urine pregnancy tests
  - Fasting chemistries, including glucose and insulin
  - If you are a woman who is able to become pregnant, you will have a repeat pregnancy test on the day of or the day before the embolization procedure. The result of this test must be negative for you to continue in the study.

Pre- and Post-Procedure Medications

You will be asked to take a daily oral proton pump inhibitor (Omeprazole 40 mg) and an oral cytoprotective agent (Sucralfate 1 g, taken two times a day), which coats and protects the stomach lining for 2 weeks before and 6 weeks after the procedure to prevent stomach irritation. We will provide the Omeprazole and will give you a prescription for the Sucralfate. After the procedure, you may be given Ofirmev (IV acetaminophen also commonly known as Tylenol) for pain as needed.

Bariatric Embolization Procedure

- The bariatric embolization procedure will be performed under moderate sedation. You will feel sleepy and may fall asleep during this procedure. You may also be asked to do small tasks such as hold your breath. This procedure will take about 1 ½ to 3 hours.
    - You will be placed on the X-ray fluoroscopy table, and the doctor will access an artery in your wrist or groin.
    - You will receive local anesthesia in the skin of your leg or wrist, and then a small catheter (plastic tube) will be placed through your skin into an artery that leads to your abdomen.
    - 2-dimensional and 3-dimensional angiography will be performed throughout the procedure to identify and track the embolic.
    - The study device, which looks like small plastic spheres, is delivered through the small catheter until the doctor sees that the blood flow has slowed down to a specific rate.
    - Upon completion, the catheter will be removed, and the physician will hold pressure on the area or use a closing device to prevent bleeding from the access site.
    - There is a specific amount of radiation you are allowed to receive in this procedure. There are many procedures in place to make sure the physician does not go over the limit. Any participant receiving a greater radiation dose will be evaluated for dermal (skin) injuries during follow-up, and if necessary, will undergo additional evaluation and treatment by a dermatologist.
    - All patient vital signs will be monitored during the procedure, per standard protocol for interventional radiology procedures.

Post-Procedure

- You will be monitored in the post-sedation recovery room for 4 hours until you are deemed medically ready to be transferred to a regular hospital bed for observation overnight. You will be admitted to the hospital for observation for at least 23 hours and up to 48 hours post-procedure.
- You will need to have someone available to drive you home after the procedure.
- You will be asked to avoid exertion for 48 hours following the procedure.

Follow-Up Visits

You will be in the study for up to 2 years. For the 12 months of follow-up post-procedure, you will be asked to continue recording your diet, hunger levels, weight, and symptoms (abdominal pain, nausea, cramping, etc.), and come for follow-up visits for physical exams, blood tests, endoscopy, and imaging at selected time points after the procedure. Clinic visits will be at weeks 1 and 2, and months 1, 3, 6, and 12. Blood tests will be performed at weeks 1 and 2, and months 1, 3, 6, and 12. Follow-up MRI imaging will be performed at months 3, 6, and 12. Please see the Study Calendar below for details.

- During each clinic visit, you will be evaluated by the interventional radiologist, asked to fill out questionnaires, and your food log (tracked using the Lose It! application) will be recorded. You will undergo physical examinations at 1-week, 2-weeks, and 1-month post-procedure.
- You will also be evaluated by an internist who specializes in weight management.
- Medication changes will be documented.
    - Participants and their primary physicians will be asked not to change dosing for oral hypoglycemic medications for the duration of the protocol, unless deemed absolutely necessary.
- You will be asked to eat nothing after midnight prior to their clinic visits.
- You will undergo a 30-38 minute whole-body MRI to assess multi-compartment fat distribution (AMRA Profiler assessment).

- You will complete the ASA24 questionnaire (24-hour food recall), which will be conducted over the phone by a member of the study team, at the specified time points on the study calendar
- A small plastic catheter (an IV) will be inserted into a vein to collect blood samples for all the blood tests at these visits.
- You will have an upper gastrointestinal endoscopy with biopsy at 12 weeks (range: 10-14 weeks) post-embolization or earlier if you are symptomatic. If you have an abnormal result at the 12-week evaluation, another test will be performed at your 6-month visit to confirm recovery. Any treatment deemed necessary will be administered by the gastroenterologist and study team.

Procedure	Pre-Procedure[§]	Procedure Day	Follow-Up					
			1 week (±1 day)	2 weeks (±3 days)	4 weeks (±3 days)	3 months (±14 days)	6 months (±14 days)	12 months (±14 days)
Informed Consent	X							
Demographics	X							
History & Physical	X	X	X	X	X			
Study Team Visit[β]	X		X	X	X	X	X	X
Psychological Evaluation[Δ]	X				X	X	X	X
Blood & Urine Tests	X	X***	X	X	X	X	X	X
Pregnancy Test*	X	X***				X	X*	X*
Stool Occult Blood Study	X							
3D CTA	X							
Gastric Emptying*	X					X	X	
Endoscopy	X					X[◊]	X*	X*
Quality of Life Questionnaires	X		X	X	X	X	X	X
Hormone Tests	X		X	X	X	X	X	X
MRI	X					X	X	X
Weight Management Counseling (Johns Hopkins Healthful Eating, Activity & Weight Program) †	8[α] visits over 2 months		Months 1-2: MD/WC alternating weekly, starting w/ WC Months 3-5: MD 2x/mo Month 6: MD 1x/mo, WC 1x/mo Month 7-12: MD 1x/mo					
Randomization		X						
Bariatric Embolization**/ Sham Procedure		X						
CBCT		X						
Assessment of AEs		X	X	X	X	X	X	X
Lose It! Food Log	Start 7 days prior to first WM visit		Subject completes food log on Lose It! application daily, reviewed at each WM provider visit					
ASA 24	X			X	X	X	X	X
Hunger Satiety Scale	X				X	X	X	X
HealthReel	X					X	X	X
Unblinding Survey					X			X

*If applicable, e.g. in diabetic patients only (gastric emptying), female of child-bearing ability (pregnancy tests at baseline and 3 months), in case of symptoms (endoscopy in months 6 and 12), in case of endoscopy (pregnancy tests in months 6 and 12)
**Participants may will be admitted to the hospital after the embolization or sham procedure.
***These labs will be performed if previous test results are >30 days old.

†Weight management schedule: weekly visits with the Johns Hopkins Healthful Eating, Activity & Weight Program in 8-week run-in and first 8 weeks post-procedure, consisting of either a visit with a physician or a weight check with a nurse. (MD: physician visit, WC: weight check)
αWeekly visits with the Johns Hopkins Healthful Eating, Activity & Weight Program, with the following schedule: week 1: intake with provider (1 hour); weeks 2-3: weight check (15 minutes); week 4: provider follow-up visit (15 minutes); weeks 5-6: weight check (15 minutes); weeks 7-8: provider follow-up visit (15 minutes)
βStudy team visits will consist of a meeting with one of the interventional radiology fellows or study physicians as well as the study coordinators in order to check in with the patient regarding how they are doing. The post-procedural study team visits at 2- and 4-weeks post-procedure will include a physical exam.
ΔPsychology visits may be completed remotely (i.e. telehealth) if clinically indicated—this will be at the discretion of the study psychologists..Follow-up visits may be conducted more frequently than specified (i.e. optional 9-month visit).

Incidental Findings

As part of this research study, you will undergo an imaging procedure. Where applicable, a qualified professional will review your imaging. This research imaging will not include the full diagnostic information that you would get if your primary doctor referred you for diagnostic imaging. The CT, endoscopy, nuclear medicine gastric motility/emptying studies (if applicable), and angiography will all be overread by a diagnostic radiologist. The MRI will not produce diagnostic-quality data and therefore will not be read by a diagnostic radiologist.

There is a possibility that while reviewing your imaging we may see an unexpected abnormality. This is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail, email, or phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have the option to decline information about an incidental finding from an imaging procedure.

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

What could happen if there is an incidental finding?

- An incidental finding may cause you to feel anxious.
- Since a report of the incidental finding will be part of your medical record, it will be available to those accessing your medical record for your clinical care and may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that may come from the incidental finding, such as the need to see a doctor to diagnose or treat an incidental finding, will not be paid for by this research study. These costs would be your or your insurance company's responsibility.

4. What happens to data and biospecimens that are collected in the study?

Johns Hopkins and our research partners work to advance science and public health. The data and biospecimens we collect from you are important to this effort.

Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

If you join this study, you will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from these efforts.

What testing or procedures may be done with your biospecimens?

Your biospecimens may be used for a variety of research purposes. The specific testing that will be part of this study includes complete blood count, liver functions tests, albumin measurement, electrolytes, urea, creatinine measurements, fasting chemistries, including glucose and insulin, and pregnancy testing.

How will your data and/or biospecimens be shared now and in the future?

Sharing data and/or biospecimens is part of research and may increase what we can learn from this study.

Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas.

Your data and/or biospecimens may be shared:

- directly with research collaborators, other researchers, sponsors, government agencies, publishers of papers and other research partners
- through government or other databases/repositories

Data/biospecimen sharing could change over time and may continue after the study ends.

We will do our best to protect and maintain your data/biospecimens in a safe way. Generally, if we share your data/biospecimens without identifiers (such as your name, address, date of birth) further review and approval by an IRB is not needed. However, when we share data/biospecimens, we limit the uses of the information and whether these data/biospecimens can be shared with another research team. If data/biospecimens are shared with identifiers, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

Johns Hopkins researchers may also use the biospecimens collected in this study for future research purposes, which may include gene sequencing and genetic testing. Each cell contains your complete DNA. Gene sequencing of your DNA provides researchers with the code to your genetic material. This future research may be unrelated to the current study and may include outside collaborators. Because science constantly advances, we do not yet know what future testing may include. If biospecimens are tested/used in ways not described above, further IRB review and approval may be needed and the IRB will determine whether additional consent is required.

If you are not comfortable with the use of your data/biospecimens in future research, you may not want to participate in this study.

5. What are the risks or discomforts of the study?

There are certain risks and discomforts that may be associated with this research study. Previous studies have shown the side effects to be:

Bariatric embolization procedure:

Of the 47 patients who received bariatric embolization in published literature about 40% of patients had nausea, vomiting, or abdominal pain lasting up to 48 hours. One of these patients had mild abdominal discomfort after the procedure lasting less than 2 weeks.

In our prior study, one patient was found to have transient pancreatitis, with evidence of mild abdominal pain, nausea, and elevation of lipase levels, during the scheduled post-procedure hospital stay. The patient improved with supportive care (anti-emetics and intravenous pain medication) and was discharged at 48 hours in good condition. The patient was asymptomatic at the one-week follow-up and remained so subsequently. A second patient had mild gastritis at the three-month follow-up endoscopy. One patient had delayed gastric emptying at one month. However, the patient's repeat gastric motility test at the six-month follow-up appointment was normal.

In 13 of the 47 published patients, there were superficial, asymptomatic ulcers found at the two-week endoscopy. These events were minor, and some ulceration was expected based on previous data.

One study from Europe reported major adverse events in one patient, including severe pancreatitis, splenic infarction, and late gastric perforation. The patient had a total one-month of hospital and intensive care unit stay.

Possible side effects may result from particles lodging into areas outside the targeted stomach area (called non-targeted embolization), resulting in blockage of the blood vessels to the bowel, liver, gallbladder, pancreas, spleen, or other vascular territories. If severe, this might require surgery to correct.

Other possible events include nausea, vomiting, inflammation of the stomach, ulceration, or bleeding from the stomach. Stomach rupture or death from this procedure is also possible, although this has never been described or published.

Bleeding from the area in your thigh or wrist where the catheter goes in, allergic reaction to contrast agent, an effect on fertility, damage (perforation) to a blood vessel which could lead to hemorrhage, a temporary contraction in a blood vessel (vasospasm), or bruising in the groin or wrist area (hematoma) are also possible.

Blood clots in your veins (deep vein thrombosis) or lungs (pulmonary embolism) or death are unlikely. As this procedure has been performed in only a small number of people for the purpose of blocking ghrelin production, it is possible that there will be other short- or long-term complications. For example, having this procedure may preclude patients from having future gastric surgical procedures (i.e. Roux-En-Y, gastric sleeve). If gastric surgery may be required in the future, pre-procedure angiography to determine gastric vascularity would be recommended.

Risks of Sedation:
The risks of moderate sedation include low oxygen level; breathing difficulty or failure to breath; inhalation of stomach contents; pneumonia; seizure; adverse or allergic drug reaction; nausea or vomiting; changes in blood pressure; heart failure; heart attack; brain injury; death. Treatment of some of these may include insertion of a breathing tube.

Risks from gastro-protective medications:
Omeprazole is a proton pump inhibitor (PPI). It works by decreasing the amount of acid produced by the stomach. Omeprazole is typically used to treat certain conditions where there is too much acid in the stomach. It is used to treat gastric and duodenal ulcers, erosive esophagitis, and gastroesophageal reflux disease (GERD). Sometimes omeprazole is used in combination with antibiotics (e.g., amoxicillin, clarithromycin) to treat ulcers associated with infection caused by the H. pylori bacteria (a germ).

Omeprazole is also used to treat dyspepsia, a condition that causes sour stomach, belching, heart burn, or indigestion.

The most frequent significant adverse effects occurring in at least 1% of patients include:

- Central nervous system: Headache (7%), dizziness (2%)
- Respiratory: Upper respiratory infection (2%), cough (1%)
- Gastrointestinal: Abdominal pain (5%), diarrhea (4%), nausea (4%), vomiting (3%), flatulence (3%), acid regurgitation (2%), constipation (2%)
- Neuromuscular & skeletal: Back pain (1%), weakness (1%)
- Dermatologic: Rash (2%)

There are other very rare, potential concerns related to adverse effects:

- Bacteria-associated diarrhea
- Increased risk of pneumonia
- Osteoporosis-related fractures
- Hypomagnesemia
- Concern has been expressed regarding vitamin B12 and iron malabsorption, but effects seem to be clinically insignificant, especially when supplement therapy is provided.

Sucralfate is used to treat and prevent duodenal ulcers. This medicine may also be used for other conditions as determined by your doctor. Sucralfate works by forming a "barrier" or "coating" over the ulcer. This protects the ulcer from the acid of the stomach, allowing it to heal. Sucralfate contains an aluminum salt. The most common side effects of the medication are constipation (2-3%) and bezoar formation. Less commonly reported side effects include flatulence, headache, hypophosphatemia, and dry mouth.

Risks of IV Acetaminophen

IV Acetaminophen is an FDA approved medication that is used for pain and to reduce fever. The most common adverse event associated with IV acetaminophen are nausea, vomiting, headache, and insomnia.

MRI:
While no significant risks have been found from the use of MRI scans, you may be bothered by the noise made by the MRI scanner and by feelings of being closed in (claustrophobia). Some patients may also feel warm during the MRI.

CT Angiography:
Allergy to the contrast agent or injury from radiation exposure during imaging are possible risks. If you have an allergic reaction to contrast you will not be allowed to have the embolization procedure.

Radiation Exposure:
This research study includes exposure to radiation from x-rays or gamma rays (CT scan, gastric-emptying study, bariatric embolization). This radiation exposure is for research purposes only and is not part of your medical care. X-rays and gamma rays can damage the genetic material (DNA) in cells. At low doses, cells usually can repair this damage.

The radiation exposure that you will get in this research study is within acceptable clinical limits at approximately 4.2 rem (a rem is a unit of absorbed radiation). This is more than the 0.3 rem that the average person in the United States gets each year from natural sources like the sun, outer space, air, food, and soil. It is less than the 5 rems of radiation that is allowed each year for people who are exposed to radiation in their jobs.

The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other tests outside of this study that are a part of your medical care. Radiation risk builds up with each exposure. You should think about your own history of radiation exposure from tests (like x-rays or CT scans) in deciding whether to undergo the radiation in this study. If you have questions about the total amount of radiation you will be receiving, you should ask your doctor.

Endoscopy:
Upper endoscopy with clamshell biopsy is a very safe procedure. However, it carries a very small risk of complications. Rare complications include:

Bleeding: Your risk of bleeding complications after endoscopy is increased if the procedure involves removing a piece of tissue for testing (biopsy) or treating a digestive system problem. In rare cases, such bleeding may require a blood transfusion.

Infection: Most endoscopies consist of an examination and biopsy, and risk of infection is low. The risk of infection increases when additional procedures are performed as part of the endoscopy. Most infections are minor and can be treated with antibiotics. Your doctor may give you preventive antibiotics before your procedure if you are at higher risk of an infection.

Tearing of the gastrointestinal tract: A tear in your esophagus or another part of your upper digestive tract may require hospitalization, and sometimes surgery to repair it. The risk of this complication is very low — it occurs in an estimated 3 to 5 of every 10,000 diagnostic upper endoscopies.

Other risks:
You may also experience some brief and/or minor discomfort associated with the tests required.

Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

While every reasonable effort will be made to ensure confidentiality of your protected and sensitive personal medical information, there is a risk this confidentiality could be compromised, although the study doctors to not expect this to occur.

Future possibility of weight loss surgery will be limited after participating in this research study as the degree of risk of complications are not known and will need to be discussed with the surgeon.

There is the risk that information about you may become known to people outside this study.

There may be side effects and discomforts that are not yet known.

6. Are there risks related to pregnancy?

Because the effects of BTG-001933 on an embryo or fetus are not known, care must be taken to avoid pregnancy in female subjects or in female partners of male subjects during this study.

If you are a woman who is pregnant or plan to become pregnant, you cannot be in this study. Women must have a negative pregnancy test at the screening visit, on the procedure day, and at the 3-month follow-up appointment during the study. Pregnancy tests will also be performed a week before any additional endoscopies or nuclear medicine gastric emptying scans, and, likewise, must be negative for the participant to remain a part of the study.

You must protect yourself or your partner from becoming pregnant before, during, and after the study. Women, and men with female partners capable of becoming pregnant, must use effective methods of birth control. Your study doctor will discuss the accepted methods of birth control and will need to document what type(s) of birth control you are using.

It is unknown whether this research may hurt an embryo or fetus.

7. Are there benefits to being in the study?

You may or may not benefit from being in this study. If you take part in this study, you may help others in the future.

8. What are your options if you do not want to be in the study?

If you decide not to join this study, other options are available. You do not have to join this study to get treatment. Other treatments include medications, surgery, and routine clinic visits. If you do not join the study, your care at Johns Hopkins will not be affected.

9. Will it cost you anything to be in this study?

No. You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet. This sheet will give you the following information:

- The procedures, tests, drugs, or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

10. Will you be paid if you join this study?

You can receive up to $945 after your bariatric embolization. The chart below describes the payment schedule.

Weeks 1-3	Weeks 4-8	Months 3-5	Months 6-11	Month 12
Food Log $30	Food Log $20	Food Log $20	Food Log $30	Food Log $40
Hunger Satiety $30	Hunger Satiety $20	Hunger Satiety $20	Hunger Satiety $30	Hunger Satiety $50
Hormone Test $20	Hormone Test $30	Hormone Test $35	Hormone Test $40	Hormone Test $50
		MRI $45	MRI $50	MRI $50
		Endoscopy $70		
Weight Mgmt. (3 visits) $40	Weight Mgmt. (5 visits) $50	Weight Mgmt. (6visits) $55	Weight Mgmt. (7 visits) $60	Weight Mgmt. (1 visit) $5
Blood Tests $10	Blood Tests $10	Blood Tests $10	Blood Tests $10	Blood Tests $15
Total $130	**Total $130**	**Total $255**	**Total $220**	**Total $210**

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

11. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you choose to withdraw from the study, you must notify your study doctor immediately. Your study doctor will ask you to have a final evaluation. This evaluation could include any of the assessments/tests previously mentioned in this document and any other procedures that the study doctor feels are medically necessary. You may be asked questions about your experience with the study procedure. You may also receive telephone calls to ask about the status of your disease.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful to you.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- It is decided that another therapeutic approach can improve your medical care.
- You not complying with study visits.
- The study is cancelled.

- You develop any of the following conditions during the 6 month period following the procedure:
  - Stomach ulcers have been observed at the follow-up endoscopy that requires surgical therapy. If the stomach ulcer can be managed medically, it will be treated by a medical provider in the Johns Hopkins Healthful Eating, Activity & Weight Program and you will remain in the study
  - A blockage in your small intestine (Small bowel obstruction) , hernia, small bowel hernia, fluid collection in the abdomen (abdominal abscess), gastrointestinal bleed, low blood pressure, new onset cardiac ectopy (heart skips a beat or adds extra beats, slow heart rate, faster heart beat, a hole in your bowel, collapsed lung, pneumonia, low level of oxygen in your blood, azotemia, heart failure, carbon dioxide, abnormal heart rhythm,, fluid in lungs, septicemia, shock, ulcer (anastomotic, peptic), blood clots that drain blood from your intestines, deep vein thrombosis, blood clot in lungs or death.
- There may be other reasons to take you out of the study that we do not know at this time.

All decisions to take you out of the study, or stop the study as a whole, will be made by a multidisciplinary team.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

13. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol, or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example, if needed for your clinical care or study oversight. To improve the coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers, and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
Your confidentiality and privacy is strictly held in trust by the study doctor, his staff, and the sponsor(s) and their interventions.

Your research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the Johns Hopkins University, Division of Brain Injury Outcomes (an academic research organization). This will not include your contact or identifying information. Rather, all research data will be identified by a unique study identification number. The study data entry and study management systems used by clinical sites and by Johns Hopkins University research staff will be secured and password protected. At the end of the study, all study databases will be de-identified and archived at the Johns Hopkins University

This confidentiality is extended to cover testing of biological samples in addition to the clinical information collected from you. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

All research activities will be conducted in as private a setting as possible.

14. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers. You will be asked to give us a list of other health care providers that you use.

15. What does a conflict of interest mean to you as a participant in this study?

A researcher has a financial or other interest in this study.

In some situations, the results of this study may lead to a financial gain for the researcher and/or Johns Hopkins. This financial interest has been reviewed in keeping with Johns Hopkins' policies. It has been approved with certain conditions, which are intended to guard against bias and to protect participants.

If you have any questions about this financial interest, please talk to Brian Holly at 410-614-1622. This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Office of Policy Coordination (410-361-8667) for more information. The Office of Policy Coordination reviews financial interests of investigators and/or Johns Hopkins.

16. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

17. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether or not you wish to continue to participate.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study doctor and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?

Call the principal investigator, Dr. Weiss at 410-614-1046. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call Dr. Weiss at 410-614-1046 during regular office hours and at 410-283-2835 after hours and on weekends. If this doctor is not available, the operator will page the "on-call physician."

18. Optional Study Components:

This part of the consent form is about optional component(s) of the study that you can choose to take part in or not. You can still take part in the main study even if you say "no" to this/these optional component(s).

Future Contact

We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Johns Hopkins from contacting you about other research.

Please sign and date your choice below:

YES ☐ _____ _____
Signature of Participant Date

NO ☐ _____ _____
Signature of Participant Date

19. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, had a chance to ask questions, and agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT PROCESS

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).