Protocol Title: Outcome of body composition assessment in patients with severe obesity undergoing metabolic surgery

Short Title: Body Composition Outcomes in MS patients (BCOMS)

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Objectives

The objective of this project is to generate pilot data substantiating our hypothesis that advanced body composition measurement tools will provide more accurate and clinically relevant data on the outcomes of metabolic surgery (MS) in patients with severe obesity compared to traditional methods.
To achieve this objective, we propose the following aims:

Aim 1: Evaluate the effectiveness of different body composition measurement tools in assessing outcomes in patients with severe obesity undergoing MS. We hypothesize that advanced body composition measurement tools will provide more accurate and clinically relevant data on the outcomes of MS in patients with severe obesity compared to traditional methods.

Aim 2: Assess the changes in body composition and muscle strength following MS. We hypothesize that 6 months post MS, patients will experience a reduction in muscle strength, along with a more significant decrease in fat mass compared to muscle mass.

Aim 3: Compare body compositions changes between SG and RYGB patients. We hypothesize that RYGB patients will experience greater reductions in subcutaneous, visceral, and total fat compared to SG patients after 6 months.

Background

Metabolic surgery (MS) is the most effective long term obesity treatment in patients with severe obesity[1-4]. The prevalence of obesity among US adults is 40.3% and the prevalence of severe obesity is 9.4% (2021-2023)[5-6]. Despite the prevalence and severity of obesity, there is a significant knowledge gap regarding the most effective tools for assessing body composition in this population[4]. Traditional methods such as BMI and waist circumference may not accurately reflect changes in body composition, particularly

in patients with higher BMI. Current literature on body composition measurements in patients with severe obesity undergoing bariatric surgery is limited.

Our study design and rationale are inspired by a 2003 study by Das et al.[7], which assessed body composition using four measurement tools: the 3-compartment (3C) model, isotope dilution, densitometry, and BIA. This study involved 20 women with BMIs ranging from 37 to 76 who underwent RYGB. The findings indicated that a simple 3-compartment model using air displacement plethysmography and BIA is effective for clinical evaluation in this population. To date, this remains the only study focusing on higher BMI patients undergoing MS. However, its limitations include being conducted solely on a female population and using these four measurement tools exclusively in RYGB patients with severe obesity.

As mentioned earlier, the goal of this project is to generate pilot data substantiating our hypothesis that advanced body composition measurement tools will provide more accurate and clinically relevant data on the outcomes of MS in patients with severe obesity compared to traditional methods.

Inclusion and Exclusion Criteria

We will recruit 20 participants with severe obesity (BMI ≥ 40) who are scheduled to undergo MS. Overall, participants must be ambulatory, able to withstand lying flat (for MRI and DXA), stand without aid for 2 minutes, weighing less than 440 pounds.
Inclusion and exclusion criteria are as follows:

Inclusion criteria:

- Being either male or female
- Being an adult greater or equal to 18 years of age
- BMI ≥40 kg/m^2
- Weigh less than 440 pounds
- Being willing to comply with the study procedures
- Being scheduled for primary metabolic surgery (either Sleeve Gastrectomy or Roux-en-Y Gastric bypass)

Exclusion criteria:

- Previous bariatric surgery or other complex abdominal surgery
- Poorly controlled medical or psychiatric disorders
- For women in child-bearing ages, being pregnant or attempting to become pregnant or currently breastfeeding
- Having metal-containing objects in their body that may cause artifact on MRI
- Having medical implants such as a pacemaker or metal joint replacements
- Having a body weight greater than 440 pounds
- Comorbid conditions that may affect body composition measurements, such as advanced liver disease or severe cardiovascular disease.
- Cannot understand risks, benefits, and compliance required to participate.

Number of Subjects

This is a single-center, non-randomized clinical trial to evaluate body composition outcomes in participants undergoing MS. The pilot study will recruit 20 participants with severe obesity undergoing MS.

We will attempt to recruit participants of all racial and ethnic backgrounds. The majority of our participants live in the area surrounding Baton Rouge.

Equitable Selection of Participants: Individuals of either sex or individuals from any social class, are eligible to participate in the study if they are deemed acceptable candidates based on inclusion/exclusion criteria.

Recruitment Methods

The eligible and interested participants in the current study will be recruited at the Metamor Institute, PBRC. Participants should be scheduled for metabolic surgery prior to enrollment.

Once prospective participants are identified, the clinical research coordinator and/or study investigator will contact the potential participant and determine if the participant has any questions regarding the study and/or consent form. The participant's medical history will be reviewed as well as determination of the subject meeting inclusion and exclusion criteria.

After determination of eligibility by the study staff, the participant will be scheduled for a study visit. An email copy or paper copy of the consent form will be provided to the subject that will subsequently be signed upon arrival on the first study day.

Upon arrival on the study day, the informed consent document will be signed, vital signs and body weight/body mass index confirmed. Pregnancy testing will be performed on women of childbearing potential per current PBRC policy.

Duration of Study Participation
Each participant will complete a single study visit that will take approximately 5 hours.

There will be a total of 2 study visits. The first visit will be before MS and the second visit will be 6 months after surgery.

Procedures	**Visit #1 (before surgery)**	**Visit #2 (6 months after surgery)**
Informed Consent	X	
Blood taking and urine testing (pregnancy test in women of childbearing age)	X	X
Vital sign	X	X
Drink Deuterium then Bromide dilutions	X	X
Dual-Energy X-ray Absorptiometry (DXA)	X	X
BodPod (Densitometry/ Air Displacement Plethysmography)	X	X
Complete diet, eating habit and physical activity questionnaires	X	X
3D Optical imaging	X	X
Waist Circumferences measurement	X	X
Six-minute Walk	X	X
Leg strength and endurance	X	X
Collect blood samples at 4 hours post (Deuterium then Bromide dilutions)	X	X
Bioimpedance Analysis (BIA)	X	X
Abdomen, Pelvis and Thigh MRI	X	X

Pre-visit requirements:
Participants will fast at least 8 hours prior to their study. Participants will not exercise, shower, or use steam rooms or saunas at least two hours before evaluation.
Participants will bring their own form-fitting clothing attire that does not have metal- containing objects, like zippers, buttons, etc. We can provide clean linen for those that do not have form-fitting clothing attire. Patients will be asked to refrain from ingesting any dyes, calcium or barium supplements as this may affect DXA results.

In-person Measurements:
Each procedure and the measurement tool are listed down in sequence. A summary of the in-person measurements is described in table 1. The following body composition procedures will take place at the outpatient clinic (Clinical Trials Unit Core) at PBRC.

Table 1: In-person study measurements breakdown

Sequence	Procedure	Time	Total time
Arrive at PBRC	Consenting Process	20m	20m
Outpatient Clinic	Vital signs; Fasting blood work, Urine testing (pregnancy test in women of childbearing age)	30m	50m
Baseline Measurements	Body Weight/Height	10m	1h
Isotopes	Drink Deuterium then Bromide dilutions.	10m	1h10m
Questionnaires	Complete diet and physical activity questionnaires	20m	1h30m
Dual-Energy X-ray Absorptiometry (DXA)	Measure body composition	20m	1h50m
BodPod	Measure body volume	20m	2h10m
3D Optical imaging	Automatically measure body dimensions with several devices	30m	2h40m
Anthropometrics	Waist Circumferences with tape measure	20m	3h
Six-minute Walk	Measure distance to complete 6 minutes of walking	20m	3h 20m
Muscle Strength & Endurance measure	Measure leg strength and endurance	30m	3h 50m
Outpatient Clinic	Blood samples follow up (collected at 4h post- dose)	20m	4h10m
Bioimpedance Analysis (BIA)	Measure body composition with several devices	20m	4h30m
Abdomen, Pelvis and Thigh MRI	Measure skeletal muscle, visceral and subcutaneous fats	40m	5h10m
Complete Study Measurement			

Study Timelines

The duration anticipated to enroll and complete data collection is 8 months after the IRB has been approved. These milestones will help ensure that this pilot study stays on track and achieves its objectives within the 1-year grant period.

Study Timeline (1-year)

Study Quarterly	Milestones
Q1 July-September 2025	a. Complete the final study protocol b. Submit the protocol & any other related documents for review to the Ethics Board/IRB. c. Receive Ethics Board/IRB protocol approval d. Participant recruitment
Q2 October-December 2025	a. Training and calibration of assessment tools b. Participant recruitment b. Baseline data collection c. Clean data d. Preliminary data analysis
Q3 January-March 2026	a. Continued data collection b. Follow up assessment c. Enter and clean data d. Data analysis e. Prepare manuscripts
Q4 April-June 2026	a. Data analysis b. Prepare manuscripts and the final report c. Present findings

	Year 1											
Activity	**Q1**			**Q2**			**Q3**			**Q4**		
Recruitment Screening and recruitment	■	■	■	■	■	■						
Data Collection Baseline and follow up data collection		■	■	■	■	■	■	■	■			
Data Analysis						■	■	■	■	■		
Draft and submit manuscripts											■	■

Study Endpoints

The primary endpoint of this pilot study is to evaluate the effectiveness of different body composition measurement tools (aim 1) before and 6 months after metabolic surgery (MS), and the secondary endpoints are to study the aim 2 and 3.

Aim 1: Evaluate the Effectiveness of Different Body Composition Measurement Tools

Rationale: Traditional methods like BMI and waist circumference may not accurately reflect changes in body composition, especially in patients with severe obesity. Advanced tools can provide more precise data.

Approach:

Participants: Recruit patients with severe obesity (BMI ≥ 40) scheduled for MS.

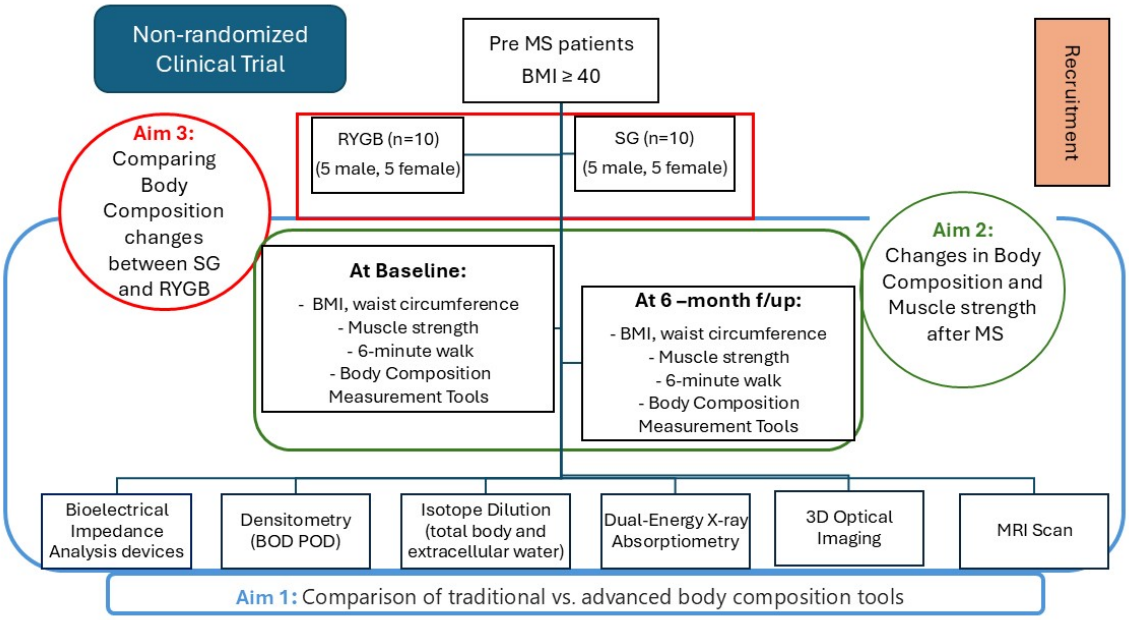
Body Composition Measurements**:** BMI, waist circumference, leg strength, skeletal muscle mass, fat mass, free fat mass, extracellular water (ECW) and total body water (TBW)
Measurement Tools: Use the Bioelectrical Impedance Analysis (BIA), 3-compartment (3C) model optical imaging, isotope dilution, densitometry (BOD POD), Dual energy X-ray Absorptiometry (DXA), and MRI scan
Data Collection: Measure body composition using traditional and advanced measurement tools at baseline (pre-surgery) and 6 months post-surgery.
Analysis: Compare the effectiveness of each tool in assessing body composition changes.
Expected Outcome: Advanced tools will provide more accurate and clinically relevant data compared to traditional methods. We will use DXA as the reference standard and compare other methods against it.

Aim 2: Assess Changes in Body Composition and Muscle Strength Following MS

Rationale: Understanding changes in body composition and muscle strength post-surgery can help improve patient outcomes and tailor post-operative care.
Approach:
Participants: Same cohort as Aim 1.
Measurements: Same cohort as Aim 1
Data Collection: Measure at baseline and 6 months post-surgery.
Analysis: Compare pre- and post-surgery data to evaluate changes in muscle strength and body composition.
Expected Outcome: Patients will experience a reduction in muscle strength, along with a more significant decrease in fat mass compared to muscle mass.

Aim 3: Compare Body Composition Changes Between SG and RYGB Patients

Rationale: Each metabolic surgery procedure may result in varying body composition outcomes. Comparing these can inform surgical decisions and patient counseling.
Approach:
Participants: Divide the cohort into two groups based on the type of surgery (SG or RYGB). Each group has 10 participants (5 male and 5 female)
Measurements: Use the same body composition tools as in Aim 1.
Data Collection: Measure at baseline and 6 months post-surgery.
Analysis: Compare body composition changes between the two groups.
Expected Outcome: RYGB patients will experience a greater reduction in subcutaneous, visceral, and total fat compared to SG patients after 6 months



Schematic of Non-Randomized Clinical Trial and Project Aims for BCOMS

Procedures Involved

Details of the procedures for this pilot study are:

Urine Collection (5 minutes): All participants will provide a urine sample to test for urine specific gravity. In addition, a urine pregnancy test will be administered for female participants that are pre and perimenopausal. A negative pregnancy result is required prior to proceeding with the following measurements.

Manual Anthropometry (20 minutes): Weight and height will be measured twice. Circumferences of waist, hip, midarm and midthigh (left and right) will be measured three times and recorded.

Blood draws (15 minutes): Phlebotomist collect blood samples at baseline and again at 4 hours. During the visit, a phlebotomist will complete two blood draws. The blood samples will be completed at the beginning of the visit. Blood samples (3ml) used for the sodium bromide and deuterium at baseline and 4hrs post-dose.

Deuterium Dilution (4 hours): Deuterium is a stable, non-radioactive isotope of Hydrogen. It is given orally as deuterium oxide and after mixing with body water, it is eliminated from the body in urine, saliva, sweat, etc. Deuterium oxide is handled in the body the same way as water, and it is dispersed through the body within a matter of hours. First, a baseline sample of blood (3 ml) will be collected. Participants will then be given water that's mixed with the weight-appropriate deuterium dose. A blood sample will be collected at 4 hours. A maximum of 2 samples will be collected. If the participant is thirsty during the protocol, study staff will weigh the drink before the participant consumes it. If the participant needs to use the bathroom during the protocol, study staff will record the weight of the

participant prior to and following a void. The samples collected will have the participant ID number, date, and time of collection. All samples will be sent to PBRC for processing.

Sodium Bromide Dilution (4 hours): Extracellular water provides information on nutritional status in health and disease. The dilution of non-radioactive sodium bromide is widely used in clinical research to measure ECW (1-3). A blood sample of 3ml will be collected before ingesting an appropriate amount of sodium bromide based on body weight diluted in deionized water. A blood sample of 3ml will be collected 4 hours after ingestion. During the 4-hour period participants must refrain from eating anything, but they can drink water if needed. Study staff will weigh the drink before the participant consumes it. If the participant needs to use the bathroom during the protocol, study staff will record the weight of the participant prior to and following a void. The samples collected will have the participant ID number, date, and time of collection. All samples will be processed at PBRC.

Vital Signs (5 minutes): Blood pressure and pulse rate will be measured twice and recorded.

6-minute walk (20 minutes): Study Co-Ordinator will time the 6-minute walk of the participant.

Bioimpedance Analysis (BIA) (20 minutes): This is a measurement of conductance of extremely low frequency through water, fat, and muscle. This measurement allows us to measure the amount of water inside and outside of cells, as well as the muscle and fat in the body. BIA devices involve placement of electrode patches or metal touch-type electrodes on the skin, either on each hand and ankle or bottoms of the feet. One test takes about a few minutes to complete. Each participant will complete duplicate tests using several different BIA devices.

Dual Energy X-Ray Absorptiometry (DXA) (10 minutes): This scan measures the amount of bone, muscle, and fat, along with the mass of the head, arms, trunk, and legs. The scan will be performed using a Hologic DXA scanner. The participant will be required to remove all metal-containing objects from the body and to lie down on the table. The participant will be carefully positioned on the table. A scanner emitting low energy X-rays and a detector will pass along the body. One scan takes approximately 3 minutes. Each participant will complete one scan.

Densitometry/ Air Displacement Plethysmography (15 minutes): The BOD POD estimates the amount of fat mass and fat-free mass. Participants will be required to remove all metal-containing objects from the body. Participants will be required to wear form-fitting clothes and a swim cap during the procedure. We will provide a clean swim cap. Participants will sit inside the system like they are sitting on a chair. The door of the system will be closed, but there is a window so they can see outside while the measurements are completed. Each participant will complete one scan.

3D Optical Scanning (10 minutes): Body shape will be imaged and measured (circumferences and body volumes) using 3D optical scanners. Each participant will be scanned twice. Participants will be positioned standing on a flat surface while the cameras capture their body shape. The participants will need to stay as still as possible. The scan time takes about 1 minute to complete.

Muscle Strength & Endurance (30 minutes): Biodex Isokinetic Machine: Strength testing in the upper leg muscle will be completed. Participants will be seated in a chair attached to a computer. To isolate the tested muscles, feet, and hips will be secured with a strap like a seatbelt. The leg tested will be extended (straightened at the knee) against the machine.

Questionnaires (20 minutes): Participants will complete a questionnaire about their physical activity (attached) and diet (https://asa24.nih.gov/).
Participants will also complete 3 brief questionnaires that assess eating behaviors[8-11] (attached).

Abdomen, Pelvis and Thigh MRI scan (40 minutes): This scan will estimate the amount of skeletal muscle and regional (visceral) fat in the body. Participants will be required to remove all metal-containing objects from the body. Participants will be provided with earplugs and/or a headset to put over their ears for the duration of the scan. Participants will be given a call button if they need to notify the MRI tech during the scan. Participants will lie on their backs on the scanner table. The scan will start at the abdomen and proceed down to the thigh. The body will be scanned in sections. For the abdominal sections, participants will be asked to try their best to hold their breath a few times for approximately 15 seconds each time. Each participant will complete one scan.

Statistical Methods

Many of the comparisons will be exploratory and will need to be confirmed by follow-up studies. Continuous variables will be descriptively summarized by sample size, mean, standard deviation (SD), and standard error of the mean (SE). Type-II errors, i.e., failing to detect a significant effect when they exist, is important to this study. All tests of significance for comparisons will be performed at an alpha of 0.05. To address the goals outlined in the Aim, parametric statistical modeling, including analysis of covariance, multiple regression method and correlation analysis, will be employed where feasible. Paired testing will be used as well given the repeated measures design.

Data and Specimen Management

Each participant will have a hard-copy study file kept in a locked cabinet under control of the study coordinator in the participant's chart located in the Medical Records Department (PBRC). Digital data will include the electronic data exported from each system. All results will be kept in locked cabinet files and/or restricted-access computers. All of those will be kept separate from records with names and other personal information. No information about them, or provided by them during the research, will be disclosed to others without their written permission, except if it is necessary to protect their rights or welfare (for example, in case of injury or emergency care), or if it is required by law. When the results of the research are published or discussed at conferences, no information will be included that would reveal the identity of these subjects. All data will be kept in locked files, and subjects will be identified by codes when the data gathered in this procedure is presented or published.

Provisions to Protect the Privacy Interests of Participants

Screening, data collection, and other interactions including physical locations, telephone contact, mail or email solicitations will be performed to afford protection against interactions with participants being witnessed, overheard or inadvertently intercepted or viewed. A private setting with door closed will be used to conduct physical measurements, record and discuss private medical information. We will ask beforehand if it would be convenient to answer sensitive questions by telephone while at home or work.

The information being collected will only be the minimum amount of data necessary to accomplish the research purposes. Upon enrollment participants will be given a study ID. Data collected will be identified by the given study ID. The code linking the study ID to the participants' name will remain on encrypted, password protected document. That document will be accessed by limited study personnel (PI, Program Manager, Study MD, and Study Coordinator).

If information from this study is published or presented at scientific meetings, all names and other personal identifying information will not be used. PBRC may look at and/or copy the coded data for research, quality assurance, and data analysis for 5 years (2026-2030).

Data Security

Data will be protected so that it is HIPAA compliant as follows:

- The de-identified data will only be on a network-shared drive or password protected computers stationed within a locked room.
- All staff members at PBRC with access to the data will have up-to-date HIPAA training.
- Any users connecting to the data will use a secure Pennington Center network share.

Provisions to Monitor the Data to Ensure the Safety of Subjects

While SAEs are not expected, any adverse events experienced by participants while participating in the protocol will be reported to the medical investigator and appropriate actions will be taken. A log of adverse events will be kept by the study coordinator and reviewed periodically with the study investigators. The investigators will determine safety triggers for bone density and body composition measures that may warrant further review by the MD on the study. Any outliers will be included in a quarterly quality control report that will be reviewed by study investigators. Any measures that fall below the safety thresholds will be reported to the participants and they will be given counseling by the investigators on what if any action should be taken.

Personnel Responsible for the Safety Review and Frequency

The Safety Officer will be responsible for monitoring the data, assuring protocol compliance and conducting the safety reviews at the specified frequency, at a minimum of every 6 months (including at the time of continuing review). During the review process, the Safety Officer will evaluate whether the study should continue unchanged, require modification/amendment or should close to enrollment. Findings must be reported at the time of continuing review. The IRB, PI or regulatory body has the authority to stop or suspend the study or require modifications.

Although the proposed study is more than minimal risk, the potential exists for anticipated and/or unanticipated adverse events, serious or otherwise, to occur since it is not possible to predict with certainty the absolute risk in any given individual or in advance of firsthand experience with the proposed study methods. Therefore, we provide a plan for monitoring the data and safety of the proposed study as follows:

Adverse Event Grading

Adverse events for each subject participating in the study will be monitored and attributed to the study procedures/design by the Safety Officer according to the following categories:

- Definite: Adverse event is clearly related to investigational procedure(s)/agent(s).
- Probable: Adverse event is likely related to investigational procedure(s)/agent(s).
- Possible: Adverse event may be related to investigational procedure(s)/agent(s).
- Unlikely: Adverse event is likely not related to the investigational procedure(s)/agent(s).
- Unrelated: Adverse event is clearly not related to investigational procedure(s)/agent(s).

Plan for Grading Adverse Events
The following scale will be used in grading the severity of adverse events noted during the study:

- Mild adverse event
- Moderate adverse event
- Severe or medically significant

Plan for Determining Seriousness of Adverse Events
In addition to grading the adverse event, the Medical Investigator will determine whether the adverse event meets the criteria for a Serious Adverse Event (SAE). An adverse event is considered serious if ANY of the following apply:

- It is life-threatening.
- It results in inpatient hospitalization or prolongation of existing hospitalization.
- It results in persistent or significant disability or incapacity.
- It results in a congenital anomaly or birth defect.
- It results in death.
- Based upon appropriate medical judgment, it may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.
- It adversely affects the risk/benefit ratio of the study.

An adverse event may be graded as severe but still does not meet the criteria for a SAE. Similarly, an adverse event may be graded as moderate but still meets the criteria for an SAE. It is important for the PI to consider the grade of the event as well as its seriousness when determining whether reporting to the IRB is necessary.

Plan for Reporting Adverse Events
The investigator will report the following types of adverse events to the IRB:

- Serious AND unanticipated AND possibly, probably or definitely related events.
- Anticipated adverse events occurring with a greater frequency than expected.
- Other unanticipated problems involving risks to subjects or others.

These adverse events or unanticipated problems involving risks to subjects or others will be reported to the IRB within 10 working days of becoming known to the investigator, using the appropriate forms found in IRB Manager.

Withdrawal of Subjects
Participation in this study is voluntary. Participants can withdraw at any time, including during the two study visits, without any penalty or loss of entitled benefits. Data already collected, along with information from medical records, may still be used, but no new data will be collected.

Although participants are not obliged to give their reason(s) for withdrawing from a trial, a reasonable effort will be made to ascertain the reason(s) while fully respecting the participants' rights.

Sharing Results with Subjects

Participants will receive body composition reports which will include their bone density, fat mass, and lean mass estimates, leaving them informed of new and useful health information.

Risks to Subjects

The BCOMS study risk cannot be classified as minimal. Continuous monitoring by the PI will minimize all potential risks and discomforts. Research participants will be immediately withdrawn from the study upon evidence of any significant adverse event.

Potential risks with the study procedures involved are listed in the table below

Procedure:	Potential Risk(s):
Blood collection/IV placement	Bruising, bleeding, pain, Infection. These will be minimized by our trained phlebotomists using aseptic technique.
Manual Anthropometry	There is no known risk associated with manual anthropometry measurements.
Deuterium Dilution	There is no known risk associated with this measurement when digesting in small doses. Deuterium is a stable non- radioactive isotope that has been previously administered to humans in numerous clinical research studies.
Physical activity and diet Questionnaires	No risks for questionnaires. If participant is uncomfortable answering or does not want to answer a question, it can be skipped.
Six-minute Walk test	This test is performed by having the participant walk along a straight hallway for six minutes and measuring the distance walked and the sensations of leg fatigue and dyspnea. The test is largely self-directed and self-limited. Participants are closely monitored by study staff throughout the test duration. As with any exercise test, there is a theoretical risk that a participant could suffer cardiac risk from arrhythmia or sudden arrest. However, we have performed thousands of tests without adverse events.
Bromide Dilution	There is no known risk associated with this measurement when digesting in small doses. Sodium Bromide Dilution has been previously administered to humans in numerous clinical research studies.
Bioimpedance Analysis (BIA)	There is no known risk associated with the BIA measurement. The BIA uses a very small electric current, which passes between electrodes placed on the hand and foot. This amount of current is slight enough that it cannot be felt and poses no risks to humans. However, there is a slight risk that this low current could disrupt an artificial pacemaker or defibrillator. Participants will be screened at the time of enrollment and will be excluded if such a device is present.
Dual Energy X-Ray Absorptiometry (DXA)	We will perform Whole body scan. This scan measures the amount of bone, muscle, and fat in the body. The scan will be performed using a whole-body scanner. Participant will be required to wear a hospital gown, to remove all metal-containing objects from the body, and to lie down on the table. A scanner emitting low energy X-rays and a detector will pass along the body. Participant is asked to remain completely still while the scan is in progress. This scan is for research purposes only and not for diagnostic treatment. **Risks:** The amount of radiation used for this procedure is very small. The radiation dose for a DXA scan is equivalent to the radiation you are naturally exposed to in the environment in less than one day. Scans will not be performed on any subject who is pregnant. Urine pregnancy testing will confirm pre/perimenopausal women are not pregnant prior to DXA evaluation.

	Lifetime radiation exposure: We are exposed to radiation in the environment on a daily basis; however, some scientists have suggested that humans have a lifetime maximum exposure limit. Exposure to radiation is not without risk, but it is difficult to quantify the exact amount someone is exposed to. By participating in this study, participants will be exposed to radiation that will add to this lifetime maximum exposure limit. If participants is exposed to a significant amount of radiation as part of occupation or due to treatment for a specific medical condition, participants should notify the study team to discuss whether or not this study would be appropriate for them.
Air Displacement Plethysmography (BodPod)	There is no known risk associated with the BodPod measurement. There is a large window so participants can easily view outside of the BodPod during the measurement; however, this measurement may be uncomfortable if you are claustrophobic.
3D Optical Imaging (3DO)	There is no known risk associated with the 3DO measurement. The 3DO scans are not a standard procedure for patients; however, the scanning process does not involve using the imaging cameras in any unusual way.
Abdomen, Pelvis and Thigh MRI	We will perform abdominal MRI together with a single-slice thigh acquisition for the study participant. There are no known biological risks associated with magnetic resonance scanning. It has been used routinely for over 20 years. It produces side effects in very few situations. Those situations include: **Metal**: Because the magnetic resonance machine uses a magnetic field, it can move any metallic objects that are inside the body. This disruption of metal inside the body is extremely dangerous and may even be life threatening. If you think you may have a cardiac stent, metallic implant, metallic piercings, shrapnel, or any other metallic material in your body, it is of utmost importance that you alert the study coordinator or MR technician. If you have metallic materials in the body that cannot be removed, the MR Technician, in consultation with the Medical Investigator of the study, will evaluate the safety of MRI scanning in the presence of those metallic materials and may exclude you from MRI for that reason. **Electronics**: Magnetic resonance imaging involves the use of radio frequency energy that can disrupt the functioning of electronic devices. If you think you might possess a pacemaker or any other electronic medical device inside your body, it is of utmost importance that you inform the study coordinator or MR technician. If you have any such electronic devices we will exclude you from this study for your safety. **Tattoos and cosmetics**: Some tattoos and cosmetics contain metallic materials that can heat up during scanning, especially if they are located on the part of the body being scanned. If the metallic material heats up enough, you may feel an uncomfortable burning sensation, and a skin burn may develop. If you have any tattoos or cosmetics that might contain metallic materials, please alert the study coordinator or MR technician. If you feel a burning sensation on your skin, alert the study coordinator or MR technician. In some cases, the amount of metallic material in the area being scanned is so excessive that the scan must be stopped. In other

	cases, a cold compress placed over the metallic material will be used to prevent the burning sensation. **Confinement**: During the MR scan, you will be lying down on a table inside of a metal tube. The metal tube is a confined place. This might produce a feeling of claustrophobia, which can be distressing. If you have experienced claustrophobia in the past, you might become too distressed to complete the scan. If you become distressed during the scan due to confinement in the scanner tube, please alert the MR technician and the scan will be halted. **Noise:** The MRI machine creates a loud, rhythmic noise that sounds like grinding or churning. This can be distressing to those who are sensitive to loud noises. You will be provided with earplugs to reduce the noise. But if you find the machine noises distressing, alert the MR technician and the scan can be halted. **Peripheral nerve stimulation**: During the MRI scan, the magnetic field around the body goes through rapid changes. These changes are all within safety limits set by the Food and Drug Administration. But some people experience twitching in the nerves of their arms or legs as a result of these magnetic field changes. This twitching is generally not painful, and it stops at the end of the MRI scan. But the feeling of inadvertent muscle twitching may make individuals feel disoriented or uncomfortable. Any participant who experiences this and wishes to stop the scan as a result will be allowed to do so. **Venous thromboembolism**: In some elderly or obese individuals, prolonged immobilization may be associated with an increased risk of venous thromboembolism. The MRI technologist reduces this risk in two ways. First, every effort is made to keep scan times for elderly and obese individuals as short as possible, usually 1 hour or less. Second, during breaks in the MRI acquisition, the MRI technologist encourages the participant to move all extremities and reposition the body. Such breaks occur in between acquired MRI sequences—roughly every 10 to 20 minutes. **Physical frailty**: The MRI technologist performing the scan has received extensive training in how to position all participants, including elderly ones, in the MRI machine safely and comfortably. However, some older people have a more difficult time walking or moving their bodies due to arthritis and other conditions. There is a slight chance that these individuals could feel discomfort or fall during transitions into or out of the MRI scanner. The technologist will insure that the walkway to the scanner is safe for participant to walk on, will place cushioning on the scanner table for participant comfort, and will carefully guide movements around the scanner to minimize this risk.

Other Related Risks:

Metabolic Surgery: MS carries a risk for complications and nutritional deficiencies. Both Roux-en-Y gastric bypass and sleeve gastrectomy surgeries have similar risks. Abdominal hernias are the most common complications requiring follow-up surgery. Rare complications include leakage through staples or sutures, ulcers in the stomach or small intestine, blood clots in the lungs or legs, stretching of the pouch or esophagus, persistent vomiting and abdominal pain, inflammation of the gallbladder, and failure to lose weight (very rare).

Psychological: The patients may have anxiety related to the course of their disease and/or the requirement for invasive surgery and medication side effects.

Risk Classification: The study risk cannot be classified as minimal.

Minimizing Risks:

Continuous monitoring by the PIs will minimize all potential risks and discomforts. Research participants will be immediately withdrawn from the study upon evidence of any significant adverse event.

Potential Benefits:

There is no direct benefit to the participants, but knowledge may be gained that will benefit others. Participants will receive body composition reports which will include their bone density, fat mass, and lean mass estimates, leaving them informed of new and useful health information.

Payment for Participation:

Participants will receive $100 for each complete study visit, totaling $200 for both visits. If a participant does not complete both visits, they will only be compensated for the visits they have completed. There is no compensation for the time spent on screening.

Financial Obligations of the Subjects:

Pennington Biomedical Research Center and the study Sponsor are not responsible for these costs.

Emergency Care and Compensation for Research-Related Injury:

No form of compensation for medical treatment is available from the Pennington Biomedical Research Center. In the event of injury or medical illness resulting from the research procedures participants will be referred to a treatment facility. Medical treatment may be provided at their expense or at the expense of their health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage.

Vulnerable Populations

This research does not involve individuals who are vulnerable to coercion or undue influence. We will seek consent only under circumstances that provide the prospective participant with an adequate opportunity to consider whether or not to participate. Once enrolled, a participant can voluntarily withdraw at any time point during the study.

Setting and Resource Available

Metamor Clinic (Jan-Dec 2023)	
Total Number of Outpatient visits	
Obesity Medicine	5000
Bariatric Surgery	1215
Dietitian	2520
Clinical Psychologist	1680
ANNUAL TOTAL	**10 415 patients**

Selection of study site: The study will be conducted at the Metamor Institute and PBRC which has a proven record of recruiting and treating patients with severe obesity. In 2023, the Metamor Institute had 1215 bariatric surgery outpatient clinic visits and performed 420 surgeries.

Experience in metabolic surgery in patients with severe obesity.
Dr. Schauer is a pioneer of metabolic surgery (MS), has. refined the techniques and approaches for patients with severe obesity.
In 2023, the total number of sleeve gastrectomy and gastric bypass procedures performed at Metamor were 201 and 117 cases, respectively. Majority (70%) of these patients have severe obesity (BMI ≥ 40) and more than 70% were female.

2023 Metabolic Surgery Volumes

OLOL RMC	Total Volume	Sleeve Gastrectomy	Gastric Bypass	Duodenal switch/ SADI	Revisions/ Conversions
Total Cases	420	201	117	5	72

Metamor census: Metabolic Surgery (Jan-September 2023)							
Total Patients	BMI ≥ 40	Female	Male	African American	White	Asian	Others
306	216	192	24	125	89	1	1

This pilot study leverages the expertise at the Metamor Institute, the Metabolism and Body Composition Laboratory and the Biomedical Imaging Center, at PBRC. By integrating knowledge from metabolic surgery, metabolism, advanced imaging, we aim to develop an innovative approach to assessing body composition outcomes in metabolic surgery patients. This collaboration will enhance the robustness and applicability of our findings.
With state-of-the-art facilities and robust institutional support, PBRC provides the ideal environment to achieve our research goals. Our well-structured and highly skilled team collaboration is uniquely equipped to conduct this pilot research and deliver meaningful outcomes.

Prior Approvals
There is no prior approval.

Data Collection, Storage and Confidentiality

All results will be kept in locked cabinet files and/or restricted-access computers. All of those will be kept separate from records with names and other personal information. No information about them, or provided by them during the research, will be disclosed to others without their written permission, except if it is necessary to protect their rights or welfare (for example, in case of injury or emergency care), or if it is required by law. When the results of the research are published or discussed in conferences, no information will be included that would reveal the identity of these subjects. All data will be kept in locked files, and subjects will be identified by codes when the data gathered in this procedure is presented or published.

PRIVACY & CONFIDENTIALITY

Where and how data or specimens will be stored locally? Data will be stored on Pennington servers as part of the computer cloud computing system.

How long will the data or specimens be stored locally? Identifiable data will be stored for 5-years following the completion of the study. Deidentified versions of the data will be stored indefinitely.

Who will have access to the data or specimens locally? Only the research personnel and PI will have access to study data. Password protected imaging and laboratory data will be kept locally at Pennington.

Who is responsible for receipt or transmission of the data or specimens locally? All data specimens will be kept locally at Pennington Biomedical.

What information will be included in that data or associated with the specimens? All specimens will be assigned a de-identified study number and stored with that number for location purposes.

Where and how data or specimens will be stored? De-identified data will be stored indefinitely on password-protected computers. Only the PI and co-investigators will have access to the full data during the study.

How long will the data or specimens be stored? Electronic, de-identified data will be stored indefinitely on password protected computers. De-identified biological samples will be stored indefinitely.

Provisions to Protect the Privacy Interests of Subjects

Describe the steps that will be taken to protect subjects' privacy interests. Usual care and conduct of research studies at Pennington Biomedical involves a large team of many different individuals and providers. However, participants choosing to participate in this study will have contact with the research staff as necessary to participate in the study. Most of the staff will not have access to their full PHI but will only have the relevant information on their testing or necessary information for safety purposes. Only the PI will have access to all protected health information as well as data gathered for research purposes. Other provisions to protect privacy will include health history or exam result discussions in a private area and asking any accompanying family members/acquaintances to temporarily leave the room.

Economic Burden to Subjects

There are no costs that participant may be responsible for because of participation in the research.

Consent Process

Prior to undergoing any study procedures, participants will be consented in a private room. These interactions will be kept confidential, and records maintained in a secure, designated location at each facility. A trained member of the study team (investigators, study research coordinator) will review the protocol. Interested participants will be given time to ask any questions about the study procedures. Informed written consent will be obtained from the participant. They will be informed that there will be no consequences if they decide not to enroll in the study and, if they enroll, they may withdraw from the study at any point with penalty.

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