Informed Consent

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PILOT STUDY: The metabolic and genetic drivers of body composition changes following weight loss surgery

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The University of Texas Medical Branch at Galveston
More Than Minimal Risk Consent Form

Protocol Title:	The Metabolic & Genetic Drivers of Body Composition Changes Following Weight Loss Surgery
IRB Number:	24-0361
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Please read this consent form carefully, and do not hesitate to contact the principal investigator with any questions or concerns you may have before deciding whether to participate. Taking part in this research study is voluntary. *You do not need to participate, and you may stop at any time.*

The study is unconnected to any medical care you may be receiving from UTMB. You do not have to take part in any research study offered by the investigators. Choosing not to participate in this research study will not affect your medical care.

The overview on the following page only includes some of the information you need before deciding whether to take part. Additional details are given in the full consent document, which can be found on the remaining pages of this document. Be sure to review the rest of this consent form before deciding about participation.

KEY INFORMATION

The key information that follows can help you learn more about this research study. It can also help you decide whether or not to take part in the research. Please read the entire consent form or have someone read it with you. If there is anything that you do not understand, please talk to the study doctor or team to have your questions answered before signing the consent form

Voluntary Participation & Right to Withdraw	Your decision to be in this study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time
Purpose	Weight loss surgery is highly effective at reducing body weight but can also cause the loss of both muscle and strength. There are a small number of people who do not achieve sufficient weight loss following surgery and the loss of muscle and strength can negatively impact their quality of life. The purpose of this study is to understand the behavioral, biological and genetic factors that influence the success of weight loss surgery and its impact on muscle mass. Your involvement would help us understand the metabolic processes that occur in heathy weight individuals.
Key Reasonable Foreseeable Risks and Discomforts	Risks and/or discomforts from participating might include: • The loss of confidentiality of data collected about you. • Brief discomfort during the collection of blood samples. • Short-term exposure to low-dose x-ray radiation.
Reasonable Expected Benefits	There may or may not be direct or indirect benefits to you from participating in this study. You will receive unique insight into your body, such as your body composition
Length of Participation	This study will last up to 2 months. You will be required to attend 2 visits at our Galveston research facilities.
Procedures	If you choose to participate in this study, you will be asked to: 1) Undergo a medical screening to determine your eligibility to participate. 2) Allow investigators to record information about your body size, weight, body composition, lab values from blood draws, and grip strength. 3) Undergo a blood sample collection, full-body low-dose x-ray to assess body composition, have your physical fitness and resting metabolic rate assessed, wear a physical activity monitor for 7 days, keep a food diary for 3 days, and consume a test drink with the collection of the urine you produce for 2 days, enabling your metabolism to be measured. The tests will occur in our Galveston testing facilities and be scheduled depending on your availability.
Alternative to Study Participation	• An alternative treatment is not being offered. • Before joining the trial, you should talk to your doctor about whether this trial is a good choice for you. • Before agreeing to join, you should review the information in the rest of the consent form.
Costs Related to Participation	• You will be reimbursed for your time and effort for participating in this study.
Compensation and Medical Treatment for Research-Related Injuries	• Compensation for an injury resulting from your participation in this research is not available from the University of Texas Medical Branch at Galveston. • In the event of injury, you or your insurance company or health care plan will be billed, and you or your insurance company will be responsible for all expenses.

DETAILED INFORMATION

What is the purpose of this study?
This study aims to understand the biological, behavioral, and genetic events that control the body's response to weight loss surgery, including its ability to maintain muscle mass. Our goals are:

i) to identify targets that can predict the success of weight loss surgery
ii) figure out potential treatment solutions that can help preserve muscle mass after their surgery.

We are seeking healthy weight participants to help us better understand the metabolic differences that occur between healthy weight individuals and those that are overweight and undergoing weight loss surgery.

A full description of this clinical trial will be available on https://www.ClinicalTrials.gov. 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.

Am I required to participate?
Your participation in this study is completely voluntary. You may refuse to participate or withdraw your participation in this research study at any time without penalty or loss of benefits to which you are otherwise entitled. Refusing to participate or withdrawing from this study will not otherwise impact your medical care at UTMB. The tests performed by participating in this research study can be safely stopped at any stage with no adverse effect on your medical care at UTMB.

How long will this study last?
If you agree to take part, your participation will last for up to 2 months and will involve 2 visits to our research facilities at UTMB Galveston.

This study will take place between Spring 2025 and Summer 2027.

How many people will participate in this study?
Approximately 10 healthy weight people will take part in the study. This will be in addition to about 100 patients undergoing bariatric surgery. The research study is only taking place at UTMB.

What tests and procedures are involved in this research study?
Before the start of any study procedures, we will ask for you to sign this document to signify your consent to participate.

Medical Screening:
We will ask you to attend our research facilities located in the School of Health Professionals at UTMB's Galveston Campus to undergo a medical screen. At the visit, which will last approximately 1 hour, we will collect a medical history, measure your height, weight, and blood pressure, and collect a small sample of blood (<10 ml or 2 tsp) for routine blood biochemistry. We will also ask you to complete a short survey asking questions about your general health, how active you are, and your dietary habits.

Following medical clearance to participate, you will attend one further visit at the same research facility as before, and the visit will last approximately 3 hours. We will ask you to attend the visit following an overnight fast (no food or drink except water after 10 pm) and having abstained from alcohol and vigorous exercise for 3 days prior. You will be provided with a small meal at the end of the visit. A description of each test that will be performed at the visit is provided below.

Anthropometry: We will collect data regarding your weight and body size.

Handgrip strength: We will perform a test of your body strength by getting you to maximally squeeze a handheld device that will record the amount of force generated. We will get you to repeat this several times until a reliable reading is recorded.

Blood sample: A small blood sample (10 ml or about 2 tsp) will be collected from a vein in your arm. The blood will be analyzed for markers associated with metabolism and a portion may be stored for future research.

Body Composition Analysis: We will utilize a device called a dual-energy X-ray absorptiometry (DXA) scanner to collect a detailed image of the quantity and location of the fat and lean tissue in your body. The device is used clinically to monitor bone density, often in people at risk of osteoporosis, and it works by administering a low-dose x-ray across your body. The scan, which takes about 10 minutes to complete, requires you to lay motionless on your back throughout. You may be required to temporarily change into clothes provided by the Investigators (e.g. wear scrubs) and remove jewelry if either contain metal. On completion of the visit, you will be provided with a personal copy of the data generated.

Food Diary: We will ask you to keep a food diary for three days (2 weekdays and 1 weekend day). On these days, you will be asked to record the quantity and type of all foods and drinks consumed.

Energy Expenditure: We will measure your resting energy expenditure (the number of calories that you burn at rest), by using a device that samples the gases in your breath when you exhale. To accomplish this, we will ask for you to rest in a chair or on a bed for approximately 30 minutes before having you wear a face mask. The mask will remain in place until a stable reading of your energy expenditure has been obtained (typically 15 to 20 minutes). You will be able to breath normally while wearing the mask and will be free to read or use apps on your cell phone while the measurement is collected. However, you will not be able to talk while data is being collected.

Protein utilization: We will examine the way that your body uses dietary protein by asking you to consume a small test drink (approximately ¼ cup). The drink will contain alanine, an amino acid that your body naturally produces. The version of alanine provided in the drink will be a rare but naturally occurring heavy version of the amino acid. The drink will be flavored with an artificial water enhancer to improve the taste of the drink.

Immediately before consuming the drink, and for two days afterwards, we will ask you to collect all the urine that you produce for analysis. It is crucial that all urine is collected during the period.

At the end of the collection period, we will ask you to transfer several small samples of the urine from these containers into provided tubes, temporarily store the tubes in your refrigerator, and then ship the samples to us in a pre-paid shipping container.

Physical activity: At the visit, we will assess your physical ability to perform common tasks, such as rising out of a chair, being able to stand unaided, and determine your natural walking speed.

At the end of the visit, you will be provided with a wrist-worn physical activity tracker which we will ask you to wear continuously (both day and night) for a seven-day period. You will return the device in the same shipping container provided for the urine samples.

Study Survey: Following your final visit and completion of all study procedures, we will ask you to complete an anonymous survey enquiring about your experience as a participant in the trial.

What are the possible risks for participating in this study?

As a participant in this study, you may be at risk for side effects and complications. Below follows a description of the known potential risks from participating in this study, separated by procedure. You should discuss these risks and complications with the research team, as well as with your primary care provider.

Participants may be at risk for the following:

Anthropometric measures & handgrip strength: There are no risks associated with these procedures.

Regional Body Composition Analysis: This research study involves exposure to radiation from whole body DXA imaging. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you will receive in this study is estimated to be 0.005 mSv or 0.5 mrem, which is approximately equivalent to a uniform whole-body exposure of 14.6 hours of the average annual natural background radiation (300 mrem). This use involves minimal risk and is necessary to obtain the research information desired.

Dietary intake assessment; protein utilization assessment; energy expenditure; physical activity assessment: There are no risks associated with these procedures. There is a small possibility that you may experience skin irritation from wearing the physical activity monitor.

Blood sampling: The blood collection may result in temporary discomfort and/or bruising at the site of collection. No medium or long-term risks are expected.

Loss of confidentiality: Every effort will be made to protect data gathered about you, with access restricted as described elsewhere in this document. Despite this, a risk nevertheless remains that unauthorized individuals could gain access to your data and your involvement in the trial is revealed.

Risk to Sperm, Embryo, Fetus or Breast-fed Infant

Males: Participation in this research is not thought to damage your sperm and no precautions are necessary.

Females: Being pregnant while undergoing a body composition scan (DXA) may expose a fetus to damaging x-rays. For that reason, persons who are pregnant cannot participate in the study. If you can become pregnant, a urine-pregnancy test will be performed at the start of the study and prior to the body composition scan. If you become pregnant during this study, you must inform the research team immediately.

While the study is not thought to pose a risk to breast-feeding infants, given that breast feeding has a profound effect on the metabolism of the mother, the quality of the study data collected would be negatively affected. For this reason, you will not be able to participate if you plan to breast feed during the study.

Risk of Radiation Exposure: Radiation exposure to a woman's reproductive organs may harm an embryo or fetus. Pregnancy tests performed during the early stages of pregnancy do not always reveal pregnancy.

Are there risks related to withdrawing from the study?
If you decide to withdraw from this study early, please discuss your decision with the Principal Investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit will include the return of any study equipment that has been provided to you and, if you're willing, any specimens or data that you have already collected but not provided to researchers (e.g. food diaries and urine samples). There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

If I agree to take part in this research study, will I be informed of any new risks that may be found during the study?
You will be informed of any new information regarding risks that becomes available during the study that is important for your health and safety or that could cause you to change your mind about participating in the study.

What are the potential benefits of participating in this study?
There may or may not be direct or indirect benefits to you from participating in this study. You will be offered a summary of the data collected about you, including details about your resting energy expenditure and body composition. We hope the information learned from this study will benefit other people undergoing weight loss surgery in the future.

Will I be reimbursed for participating in this study?
You will be reimbursed $10 at the end of the medical screening visit to compensate you for your time. You will be reimbursed an additional $100 dollars at the end of the experimental visit after we have safely received the provided activity monitor.

You will be issued a UTMB ClinCard, which is a debit card that your funds are loaded onto following the first visit. At the times indicated above, funds will be approved and loaded onto your card. The funds will be available within 48 hours and can be used at your discretion. You will be issued one card for the duration of your participation. If your card is lost or stolen, you can contact customer service at 1-866-952-3795. In order to issue you a new ClinCard, we will collect some information about you, including name, address, telephone number, date of birth, email address, and your social security number (if you are a U.S. resident). All information is securely stored and will be deleted from the system once the study has been completed and the funds on the card have been used.

Compensation for participation in research may be considered taxable income. The IRS requires that compensation greater than or equal to $600 be reported to the IRS as required by law. Personal information about you, such as your name, address, and Social Security Number (SSN) or Tax Identification Number (TIN), may be provided to the IRS by the participating site for tax purposes. If you receive $600 or more in a calendar year, you may be provided with a 1099 tax form from the sponsor, site, or vendors working on behalf of the sponsor for tax purposes. If you prefer to not receive payment for this study, you may alert the Investigators.

If I agree to participate in this research, can I be removed from the study without my consent?
Researchers in charge of the research can remove you from the research study without your approval. Possible reasons for removal include if you are unable to keep appointments or follow instructions, you no longer meet the inclusion and exclusion criteria, or the researcher believes that further participation in the study is no longer safe for you.

Will my insurance provider or I be charged for the costs of any part of this research study?
Neither you nor your insurance provider will be charged for anything done for this research study (i.e., the screening procedures and experimental procedures).

You will be charged in the standard manner for any procedures performed for your standard medical care outside of the research activities described in this document.

What happens if I am harmed as a result of taking part in this study?
It is important that you report any illness or injury to the research team and principal investigator listed at the top of this form immediately. Compensation for an injury resulting from your participation in this research is not available from the University of Texas Medical Branch at Galveston. In the event of injury, you or your insurance company or health care plan will be billed, and you or your insurance company will be responsible for all expenses.

You will be responsible for paying any costs related to illnesses and medical expenses not associated with the study. There are no plans to provide other forms of compensation.

Reminder: You do not give up any of your legal rights by agreeing to be in this study or by signing this form.

How will my information be protected?
Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed. In an effort to protect your privacy, the study staff will use code numbers or letters to identify your health information instead of your name, whenever possible. If the results of this study are reported in public settings like medical journals or conferences, you will not be identified.

What happens to the data collected in the study?
If you join this study, your data and/or specimens will be used to answer the research questions and publish the findings of this study. You will not own your research data. If researchers use your data or specimens to create a new product or idea, including those that may have commercial value, you will not financially benefit from those efforts.

UTMB researchers and their collaborators may use the data and/or specimens collected in this study for future research purposes and may share some of the data and/or specimens with others. UTMB will do our best to protect and maintain your data and/or specimens in a safe way. One of the ways we protect data and/or specimens is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through de-identifying the data, data sharing agreements and review by oversight groups within UTMB.

In limited circumstances, data and/or specimens may be used or shared with types of information that may be likely to identify you, such as your name, address or medical record number for future research purposes at UTMB, only after the research has been reviewed and approved by the UTMB Institutional Review Board (IRB). The UTMB IRB will review whether additional consent from you is required.

Generally, if your data and/or specimens are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Sharing data is part of research and may increase what we can learn from this study. Often, data 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 may be shared with researchers at UTMB and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data may also be put in government or other databases/repositories.

Because science constantly advances, we do not yet know what future use of research data may include. This future research may be unrelated to the current study and may include outside collaborators. Furthermore, data sharing could change over time and may continue after the study ends.

The use and sharing of your data is required for participation in this research study. If you are not comfortable with the use and sharing of your data in future research without further consent, you should not participate in this study.

If you are required to attend our research facilities at our Galveston Campus and intend to travel by car, we will ask that you provide the make, model and car license plate of the vehicle that you intend to use. This information is required to gain entry to the UTMB Parking Lot adjacent to the research facilities. It will be shared with personnel who manage UTMB's Parking Facilities but will not be used for any other purpose. The Investigators will not retain this information following your completion in the trial.

DNA analysis: Future use of collected specimens may include the analysis of your unique DNA sequence. You may refuse future use of your collected samples for DNA analysis. However, please be aware that at the end of the study, all samples will be permanently deidentified. You must contact the Principal Investigator before the conclusion of the study if you wish to revoke your consent for future DNA analysis. It will not be possible to identify and prevent samples collected from you from being analyzed once they have been permanently deidentified.

The collection of genetic information about an individual present several risks:

i) We may in the future utilize the sample to provide a comprehensive overview of the DNA sequence and modifications contained in your body's cells. As a result of this work, we may capture information that could be used to determine your future risk of developing diseases including some that may have no known cure. While we will not be examining the data with the intention of identifying disease risk, it cannot be ruled out that the study will inadvertently reveal information useful in determining your future risk of contracting certain diseases. As the samples will be deidentified, we will not be able to notify you of what has been discovered.

ii) If collected, the genetic data and key non-identifiable demographic details (e.g. age, sex and body weight status) may be deposited in a public repository for other researchers to access and study. This is common practice in clinical research and a requirement of many journals that publish scientific work. While every step will be taken to protect your anonymity, and any known data that could identify you will not be included in the data uploaded to the database, given the unique and detailed nature of DNA information, it may be possible in the future for a determined individual or entity to establish your identity and provide insight into your future disease risk. This theoretically could have implications for your future life and healthcare insurability.

How will my privacy be protected?
Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

By signing this consent form, you give us permission, called your "authorization" to collect, use, and disclose your personal health information. We have strict regulations, including Federal and State laws, designed to protect information about you. This includes information learned from the procedures described in this consent form. The research team may also collect other information from you, including your name, your address, your date of birth, and information from your medical records. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

Other professionals at UTMB, such as your doctor(s) and the Institutional Review Board, may also see your information. We make this information available to your doctors for your safety. Please inform your doctor If you think this study might affect your clinical care.

People outside of UTMB may also need to see and review your information for this study. UTMB does not allow identifiable information collected during the study to be released to people outside of UTMB except as required by law or otherwise stated in this consent form. Examples include government agencies, such as the Food and Drug Administration (FDA) and individuals who monitor the study for safety purposes.

We cannot do this study and cannot use and distribute your information without your authorization. You do not have to sign this form. However, if you choose not to sign it, you cannot be in the study. Your care or the benefits you receive from UTMB will not be affected if you decide not to be in the study.

You may change your mind and revoke (take back) this authorization at any time. Even if you revoke this authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact the principal investigator in writing.

State law also requires us to report to the Texas Department of State Health cases of certain diseases that a sick person could give to someone else. If we learn you have Hepatitis B, Hepatitis C, or Human Immunodeficiency Virus (HIV) during the study, we will share your name and contact information with the health department.

How long does this authorization to use my information last?
When you sign this form, you agree to let us collect, produce, and share health information about you as we described in this form. Your authorization does not end.

Who can I contact with questions about this research study?
If you have any questions, concerns, or complaints before, during, or after the research study, or if you need to report a research-related injury or bad side effect, you should immediately contact Doaa Abdelrahman (Office: 409-747-2115; Cell: 832-860-7839) or ~~Dr. Andrew Murton at (Office: 409-772-0185; Cell: 409-392-7557)~~ Dr. Emily Lantz at (Office: 409-772-0643; Cell: 563-260-6166).

This study has been approved by the University of Texas Medical Branch Institutional Review Board (IRB). If you have any concerns, complaints, suggestions, or questions regarding your rights as a participant participating in this research study, or if you would like more information about the protection of human subjects in research, you may contact the IRB office at irb@utmb.edu.

Consent to Participate

Sign and initial below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

INITIAL	
	(OPTIONAL) I agree that on completion of the study, the Investigators may retain any biological samples collected during the study for future research purposes. This may include analysis of my genetic information (DNA). The samples will be stored in a manner that will prevent me from being identified as the donor of the sample. I am aware that I can revoke my consent at any stage up to the conclusion of the study, after which it will not be possible for me to revoke my authorization.

Printed Name of Subject	Signature of Subject	Date	Time

With language that is understandable and appropriate, I have discussed this project and the items listed above with the participant.

Printed Name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date	Time