VUMC Institutional Review Board
Informed Consent Document for Research

Study Title: The Gut Microbiota in Metabolic Surgery: A Multi-Ethnic, Multi-Omic, Longitudinal Study
Version Date: 07/17/2023
PI: Danxia Yu, PhD, Associate Professor, Department of Medicine, VUMC

Name of participant:_____Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
This study aims to enroll patients who are scheduled to have a surgical or medical weight loss treatment at the Vanderbilt and identify novel microbial biomarkers related to health improvements after weight loss. You may be eligible to participate, if you are 21 to 65 years old with at least one of the following three conditions, i.e., type 2 diabetes, high blood pressure, and abnormal blood cholesterol levels, but no history of coronary heart disease, stroke, or inflammatory bowel disease.

If you participate, you will be asked to provide a small stool sample and a small fasting blood sample at your visits to the Vanderbilt Weight Loss Center before and 3 months, 1 year, 2 years, and 3 years after surgical or medical weight loss visit. We will also ask you to complete a lifestyle and medical history survey after enrollment and 1 year, 2 years, and 3 years after treatment, which takes ~25 min to complete. If you will undergo bariatric surgery, we will obtain a small piece of liver, small pieces of abdominal fat and muscle (taken at the site of trocar placement), small pieces of your removed stomach and intestines (normally discarded), as well as a blood sample from the intravenous (IV) line placed before surgery, which can be opted out. We will get access to your medical record to obtain information on your clinic appointments, diagnoses, treatments, and/or lab results. Potential risks associated with participation in this study include possible adverse events that occur during blood draw, tissue biopsy, or stool sample collection and an unintended data breach.

Participation in this research study is voluntary. You can withdraw from the study at any time. Your medical care will not be affected by the participation or withdrawal. You will receive $30 after the baseline survey and biospecimen collection, $50 upon completion of 3 months and 1-year post-treatment surveys and biospecimen collections, $30 upon completion of 2-year post-treatment surveys and biospecimen collections, and another $50 upon completion of 3-year post-treatment surveys and biospecimen collections (a total of $160). Your participation will help researchers better understand the role of gut microbiota in weight loss treatment and human health. Thank you!

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

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You are being asked to take part in this research study because you are scheduled to have a surgical or medical weight loss clinic visit at the Vanderbilt Hospital and meet our inclusion criteria for this study.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
Blood draw: Common—risk of pain, redness, soreness, or bruising at the needle stick site; Uncommon—infection at the needle stick site or fainting; Rare—damage to the vein and development of a clot.

Stool collection: Although stool collection is non-invasive, there might be risk of skin irritant or infection by parasites or agents in stool or collection tubes (rare).

Tissue biopsy (only for participants who undergo the weight loss surgery): Common—local discomfort and minor bleeding and increase in the time of surgery and time under anesthesia by a few minutes; Rare—moderate or major bleeding, need for blood transfusion, hospitalization due to bleeding or other complications, infection, damage to bowels, damage to nearby organs, or allergic reaction to the numbing medicine. Rare complications that might occur during anesthesia can be severe and life threatening. If there is any indication of problems developing during surgery, all research activities will immediately stop, and your doctor will decide how the surgery should be completed in your best interest.

Confidentiality: Rare—an unintended breach of confidentiality regarding participants' data collected for this research study, including medical history and lifestyle habits.

Risks that are not known:
There may be unknown or unanticipated adverse effects associated with weight loss/bariatric surgery.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: Increasing evidence suggests that the gut bacteria play a role in human health. Results from this study may advance our knowledge of the role of gut bacteria in surgical and medical weight loss and health improvements, which may translate into novel therapeutics to treat obesity and related diseases.

Procedures to be followed:
After enrollment: We will give you a stool collection kit, including detailed instructions and all collection tools needed. You will self-collect a small stool sample at home and mail the sample and collection form to the Vanderbilt Epidemiology Center using provided shipping label. During your initial surgical or medical weight loss visit, a small blood sample (~4 tablespoons) will be drawn by a VUMC nurse. You will be asked to fast at least 8 hours before blood collection. You will also need to complete a secured online survey about your lifestyle habits and medical history, which takes ~25 minutes to complete.

On the day of surgery (only for participants who undergo the weight loss surgery): We will obtain a blood sample (about 4 tablespoons) from the IV that is placed before surgery. During your operation, your doctor will take a small wedge of liver tissue (about the size of the tip of your pinky finger). Your doctor will also remove a piece of fat (about the size of your thumb) from your omentum, which is located around your stomach and intestines. Also, a slightly larger piece of the fat from your belly area and a small amount of muscle from your abdominal wall (about the size of the tip of your pinky finger) will be taken at the site of trocar placement. We will also obtain portions of your removed stomach and intestine tissues. You will be asked to fast for at least 12 hours and refrain from strenuous exercise for at least 24 hours prior to the surgery.

After treatment: We will give you the 2nd stool collection kit at your scheduled 3-month post-surgical or medical weight loss visit. You will self-collect and mail the stool sample and collection form to the Vanderbilt Epidemiology Center using provided shipping label. During your visit, a small blood sample (about 4 tablespoons) will be collected. You will be asked to fast for at least 8 hours before blood collection.

We will give you the 3rd stool collection kit at your scheduled 1-year visit. You will self-collect and mail the stool sample and collection form to the Vanderbilt Epidemiology Center. During your visit, a small blood sample (about 4 tablespoons) will be collected. You will be asked to fast for at least 8 hours before blood collection. You will complete another online survey about your lifestyle habits and medical history over the past 12 months after surgery or starting medical weight loss treatment.

Similarly, we will give you the 4th stool collection kit at your scheduled 2-year visit and the 5th stool collection kit at 3-year visit. A fasting blood sample (about 4 tablespoons) will also be collected at those visits. And you will complete the same online survey after those visits.

You will receive a text message and/or email reminder about the stool collection and clinic appointment prior to each visit.

Payments for your time spent taking part in this study or expenses:
You will receive $30 after completing the baseline survey and the 1st stool and blood samples collection. You will receive $50 after completing the post-treatment survey and the 2nd and 3rd stool and blood samples collection 1 year after surgery or starting medical weight loss treatment. You will receive another $30 after completing the 4th blood samples collection 2 years after surgery or medical weight loss treatment. You will receive another $50 after completing the 5th blood samples collection 3 years after surgery or medical weight loss treatment. You will receive a total of $160 if you complete the study. We may ask you for your Social Security number and address before you are compensated for taking part in this study.

Costs to you if you take part in this study:
If you agree to take part in this research study, you and/or your insurance **will not** have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance,

financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator with input from the National Institutes of Health (NIH) that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt or the NIH to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or the NIH to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to email bariatric.research@vumc.org or call Dr. Danxia Yu at (615) 936-7389.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
If your doctors decide that staying in the study places you in danger, you will be taken off the study. If you are taken off the study, you will be told why.

What will happen if you decide to stop being in this study?
Participation in this study is voluntary. If you decide to stop being part of the study, you should tell the PI, Dr. Danxia Yu (call 615-936-7389 or email bariatric.research@vumc.org).

Clinical Trials Registry:
A description of this study may be available on 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 Web site at any time.

Confidentiality:
Your consent, survey responses, and information from your medical record will be maintained via a secure Research Electronic Data Capture and management tool (REDCap). Only our clinical research team members and investigators directly involved in this study would have access to the data after PI's approval. Research team members listed as Key Study Personnel with existing electronic health records (EHR) access rights may also be granted use of REDCap Dynamic Data Pull (DDP) and Clinical Data Interoperability Services (CDIS) tools. These tools are designed to enable transfer of relevant

study-related data from the Vanderbilt Research Derivative and/or directly from the EHR into REDCap.

Collected specimens will be labeled with a study ID number. The link between the study ID and personal identifiers will be stored in our locked offices. Specimens will be stored in the freezers of our research laboratories at the VUMC. No name or other personal identifying information defined by HIPAA will be available to laboratory or data analysis personnel.

This study may have some support from the National Institutes of Health (NIH). If yes, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and data collected in this study may be made available to others to use for research. To protect your privacy, we will not release your name or other identifiers. You will not receive any benefit as a result of the tests done on the de-identified samples or the use of de-identified information. These tests may help us or other researchers learn more about the causes, risks, and/or treatments for obesity and related diseases, or how to prevent these health problems. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Study Results:
Results from this study will be published in scientific journals and presented in scientific conferences. Format of any publications, reports, and datasets will ensure that no individuals can be identified. Results will not be shared with participants.

Authorization to Use/Disclose 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 Vanderbilt University Medical Center 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. Additionally, we may share your information with other people at Vanderbilt, for example if

needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. 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.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

Are you willing to have the tissue samples that are described above taken during your operation?

☐ Yes ☐ No

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____

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Date Signature

_____
Printed Name and Title

Time: _____

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Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample will not be put in your health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results.

A single blood sample of 4 tablespoons will be drawn from a vein in your arm using a needle; biopsy tissues will be obtained under anesthesia during surgery. This will take about 5 minutes of your time.

Blood samples – You may feel bothered or pained from the needle stick. You may have a bruise, or the site may get infected. It is rare, but some people faint.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Yu and her research team will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

This genetic research is optional, and you can be in the study even if you do not want your samples stored or used for genetic research.

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At any time, you may ask to have your sample destroyed. You should contact Dr. Yu at (615) 936-7389 to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research in_____.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc).

☐ Yes ☐ No

Signature: _____ Date: _____