Title of Study: Socioecological Factors Associated with Ethnic Disparities in Bariatric Surgery Utilization and Post-Operative Weight Loss (Substudy)

Consent to be part of a Research Study
To be conducted at
The University of Texas Southwestern Medical Center

Key Information about this Study

The purpose of this study is to learn more about the relationship between the blood and gut microbial composition and how it is affected by weight loss surgery and ethnicity.

Participants in this study will have blood and stool samples collected. Your samples will have genetic analysis completed. The results will not be given to you, the study doctor, or your personal doctor. In addition, you will be asked to complete a 24-hour food log for three days prior to the blood and stool sample collections.

Your participation will last from seven to ten days and will involve one visit to UT Southwestern for a fasting blood sample collection.

Risks of taking the blood sample are discomfort and/or bruising; infection, excess bleeding, clotting, or fainting are also possible.

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Your doctor is a research investigator in this study. S/he is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator

The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Benjamin Schneider, M.D., Department of Surgery at The University of Texas Southwestern Medical Center

Funding

National Institute of Minority Health and Health Disparities, a federal agency that promotes scientific research, is funding this study. This organization is providing money to the University of Texas Southwestern Medical Center so that the researchers can conduct the study.

Purpose – "Why is this study being done?"

We are conducting this sub-study to learn more about the relationship between the blood and gut microbial composition and how it is affected by weight loss surgery and ethnicity. Understanding this relationship could potentially help us to create better obesity treatments to improve cardiometabolic outcomes.

Information about Study Participants – "Who is participating in this research?"

We are asking you to take part in this sub-study. You are being asked to be a participant in this study because you have a BMI >35 kg/m2 or you had a bariatric surgery within the previous six-eight months, are between 18 and 60 years old, and belong to one of our interest ethnic groups (non-Hispanic White [NHW] or non-Hispanic Black [NHB]), and do not have any electronic implants (e.g., pacemaker) or active prostheses.

How many people are expected to take part in this study?
This study will enroll approximately 100 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

If you agree to participate in the study, we will ask you to write down everything you eat and drink for a period of three days (including amounts in grams or household measures, brands, and times at which you eat). At the end of the three days, you will be asked to collect a stool sample by using collection material previously provided by our staff. Once your sample has been collected, you will schedule your fasting blood work preferentially within 48 hours of stool sample collection. A period of 8-12 hours of fasting will be requested prior to the blood draw. We will take about 20 mL or two tablespoons of blood from your arm. It will take about 8-10 days to complete the study. You will donate a total of one blood sample (two tubes at the same time point) and one stool sample. When you come for your bloodwork, you will also be seen in clinic by the study team to obtain your body measurements. The study team will use a body composition scale and measure your body weight, height, and waist circumference.

Could your participation end early?
There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

Your tissue contains DNA. DNA makes up the genes that serve as the "instruction book" for the cells in our bodies. By studying genes, researchers can learn more about diseases such as cancer. There are many different types of genetic tests. As part of this study, you are being asked to participate in a gut microbial genetic study by providing stool samples. Genetic research involves the analysis of your gut microbial genes, or DNA (deoxyribonucleic acid). Microbial genes can influence susceptibility to certain diseases. The results of genetic research using your biological samples will not be used in your medical care. The results will not be given to you, the study doctor, or your personal doctor. The goals of gut microbial genetic testing include learning how microbial genes work and advancing our understanding of how they can influence human health.

The testing on your tissue samples might include genetic testing called whole genome sequencing. Whole genome sequencing looks at all the known genes in your cells. This type of testing can provide useful information to researchers. It can also present risks if the test results became known to others, for example you could have problems with family members or insurance companies. There is also a risk that these test results could be combined with other genetic information to identify you.

How long will you be in the study?
If you agree to take part, your participation will last from seven to ten days and will involve one visit to UT Southwestern. You will first receive a call from one of our research coordinators who will explain you the protocol in detail. If you agree to participate, we will send you an email containing a QR code that will lead you to our digital informed consent which will ask for your digital signature. After you have electronically signed the informed consent, we will call you back to request your address which we will use to ship the materials needed for stool sample collection. In addition to the kit, we will also send you a copy of the informed consent for your records. After receiving the kit, you can start writing down everything you eat and drink for a period of seven days. Time after which you will collect your stool sample using the provided materials. Once the stool sample has been taken you will schedule an appointment to the lab (within 48 hours of stool sample collection) and come after a fasting period of 8-12 hours. Once you are at the lab, we will proceed with obtention of your stool sample (previously collected at your home) and the blood sample collection.

Risks – "What are the risks of participation in the research?"
It is possible that blood draws could lead to pain and bruises however, proper pressure will be applied upon removal to reduce bruising. Less likely, but also possible, in response to the blood draw are dizziness and fainting if you are unaccustomed to having blood drawn. To minimize any potential complications only trained phlebotomists wearing personal protective clothing (gloves, lab coats, etc.) will collect your blood sample. You will be seated in a phlebotomy chair, a tourniquet will be applied high on the brachium, tight enough without causing discomfort. The site will be cleaned with an alcohol pad. Once the sample (two tubes) has been taken the needle will be disposed in an appropriately, labeled sharps container. The site of the blood draw will then be cleaned with a sterile alcohol pad and a sterile band-aid will be placed on the site.

There is also a risk that information about you may become known to people outside this study, however, all information will remain confidential to the extent permitted by law. Re-identification is possible, however, the probabilities of re-identification are low as only microbial but not human deidentified genomic data will be analyzed and shared. Lastly, it is possible that there may be some risks that the study doctors do not yet know about.

For more information about risks and side effects, ask one of the researchers or study staff.

Genetic Informational risks
As part of this study, you are being asked to participate in a gut microbial genetic study by providing stool samples. Genetic research involves the analysis of your gut microbial genes, or DNA (deoxyribonucleic acid). Microbial genes can influence susceptibility to certain diseases. Genes are made up of DNA. The results of genetic research using your biological samples will not be used in your medical care. The results will not be given to you, the study doctor, or your personal doctor. The goals of gut microbial genetic testing include learning how microbial genes work and advancing our understanding of how they can influence human health.

This research study includes genetic testing. Human tissue contains genes that determine many of a person's physical characteristics, such as the color of eyes and hair. In some cases, genetic testing of tissues can be used to indicate a risk for the development of certain diseases. Genetic information is unique to each individual and could potentially be used to discover possible changes in a person's future health status or life expectancy, or that of his/her children and family members.

Releasing this information to you could cause psychological distress, anxiety or family problems. Releasing this information to others, such as including it in your medical record, may pose a possible risk of discrimination, or increase difficulty in obtaining or maintaining disability, long-term care, or life insurance.

These risks would occur if your information is released by mistake. The measures being taken to protect your privacy are discussed below and make this possibility unlikely.

Even though the results of genetic testing may not be linked to you, it is possible that people of your ethnic background may be found to be at more risk for certain diseases based on future genetic research and this information might harm you in the future as a member of the group. Also, there may be unknown risks of genetic testing in the future.

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. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time, or even at different times, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you have an injury or illness from the study device, taking the study drug, or the procedures required for this study, medical care will be provided. Depending on the circumstances, the reasonable medical expenses required to treat such injury or illness may be paid for by the study sponsor.

The coverage for such injury or illness is only available if the principal investigator and study sponsor, if applicable, have decided that the injury/illness is directly related to the study drug, device, or procedures and is not the result of a pre-existing condition or the normal progression of your disease, or because you have not followed the directions of the study doctor. If your insurance is billed, you may be required to pay deductibles and co-payments that apply. You should check with your insurance company about any such payments.

We have no plans to give you money if you are injured. If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"
You will not benefit from participation in this study, however, results from this research may help us to understand potential differences in the gut and blood microbial composition of patients who have undergone bariatric surgery versus those who qualify but have not yet undergone bariatric surgery. Understanding the effect of bariatric surgery on the gut and blood microbiotas can potentially help us to create future gut- and/or blood-targeted obesity and metabolic treatments. Furthermore, this study will also help us to evaluate if there are differences in the gut and blood microbial composition at baseline and in response to bariatric surgery between NHW and NHB participants. No direct benefits to participants are expected from any secondary research on de-identified individual-level data or genomic summary results that may be conducted.

Payments – Will there be any payments for participation?
You will be compensated $100 USD as an Amazon gift card for your participation in this sub-study. This card will be e-mailed to you at the provided email address within a week of the completion of your participation.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Certificate of Confidentiality:
To help us further protect your information, the investigators will obtain a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and will help researchers protect your privacy.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, where we will voluntarily disclose information consistent with state or other laws, such as:

- to DHHS for audit or program evaluation purposes;
- information regarding test results for certain communicable diseases to the Texas Department of State Health Services, including, but not limited to HIV, Hepatitis, Anthrax, and Smallpox;
- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

How will my information and/or tissue samples be used?
Your information and/or biospecimens may be used for a variety of research purposes. The specific testing that will be part of this study includes: in blood, fasting blood glucose, fasting insulin, HOMA index, HbA1C, lipopolysaccharides, lipopolysaccharide binding protein, ghrelin, and LEAP2, and 16Sr RNA; in fecal samples, 16S rRNA and whole genome sequencing (this second one only in half of the samples).

With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

By agreeing to participate in this study, your information or tissue samples could be used for future research studies or sent to other investigators for future research studies without additional consent from you. The information that identifies you will first be removed from your information or tissue samples. If you do not want your information or tissue samples to be used for future research studies without your consent, you should not participate in this study.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical

care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

Milestones and de-identified data will be shared monthly with NIH during the data collection months and during annual reports. The final dataset and all relevant documentation (data dictionary, collection forms, lab results, microbial genomic data, etc.) will be transferred as an AES-256 encrypted data archive. The encrypted file can be transferred through Secure File Transfer Protocol (sFTP) or a secure upload website. 16SrRNA will be performed on all blood and stool samples.

Genomic Data Sharing (GDS): The dataset will be prepared in accordance with requirements for NIH data repository datasets and associated documentation for submission to the Specimen and Data Repository Information Coordinating Center. We will follow the NIH Policy for Genomic Data Sharing. Microbial genomic and laboratory data, and any other data relevant to the study will be generated and may be shared broadly and used for future research in a manner consistent with the participant's informed consent and all applicable federal and state laws and regulations. Prior to submitting the data to an NIH-designated data repository, data will be stripped of identifiers such as name, address, account and other identification numbers and will be de-identified by standards consistent with the Common Rule and HIPAA. Safeguards to protect the data according to Federal standards for information protection will be implemented. Access to de-identified, individual-level participant data will be controlled. Raw FASTQ files from this study will be submitted to the NIH Sequence Read Archive, which is the primary NIH archive of high-throughput sequencing data and is part of the International Nucleotide Sequence Database Collaboration.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

- medical history,
- lab tests,
- questionnaires, and microbial genetic information (no human genetic information will be performed on your samples)

We will get this information by asking you.

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- the Sponsor, NIH, funding the study. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- the committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason.
- the members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center

- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group 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 when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the University of Texas Southwestern Medical Center for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time . However, you need to say this in writing and send your letter to

Dr. Benjamin Schneider, M.D.
UT Southwestern Medical Center
5323 Harry Hines Boulevard, Dallas, TX 7530

If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.
Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Benjamin Schneider can be reached at 214-648-0267.

If primary is not available, contact:
The UTSW Department of Surgery Research Office can be reached at 214-648-7200

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

Title of Study: Socioecological Factors Associated with Ethnic Disparities in Bariatric Surgery Utilization and Post-Operative Weight Loss (Substudy)

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM

Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:

By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM