CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research:	Modifying Diet and the Gut Microbiota to Reduce Obesity and Health Disparities
UAB IRB Protocol #:	IRB-300003207
Principal Investigator:	Tiffany L. Carson, Ph.D
Sponsor:	National Institutes of Health/National Institute for Minority Health and Health Disparities (NIMHD)

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to determine whether gut microbiota can improve the relationship between a calorie-restricted diet and weight change among a diverse sample of women.
Duration & Visits	You will visit UAB five days a week for four weeks and 3 times over a 2 week period, for a total of 23 visits over 6 weeks (42 days).
Overview of Procedures	You will only eat study-provided food for 28 days. You will consume one meal at the Clinical Research Unit (CRU) every weekday and will carry out food for the remaining two meals of the day and snacks. Weekend meals will be packaged for consumption at home. After the 28-day period, you will return to the CRU on day 35 and day 42 for follow-up. You will wear an accelerometer to monitor your physical activity levels for 42 days. You will collect a stool sample at home on a weekly basis. You will provide a blood sample on Days 1, 28 and 42. You will provide demographics and complete surveys about stress, physical activity, your usual diet and dietary patterns, and your current health.
Risks	The most likely risks include the possibility of slight distress with providing information about stress levels, adverse reactions to food consumed, pain or bruising from the blood draw, and loss of confidentiality.
Benefits	You may not benefit directly from taking part in this study. However, this study may help us better understand the link between microbiota and diet in black and white women. You will be assigned to a group by chance, which may prove to have more or less benefits than the other group.
Alternatives	The alternative is to not participate in this study.

Purpose of the Research Study

We are asking you to take part in a research study. The purpose of this research study is to examine the gut microbiota (groups of bacteria that live in the human body) of black and white women on a calorie-restricted diet. We will also examine the effects of the DASH (Dietary Approaches to Stop Hypertension) diet on the gut microbiota and explore how behaviors may affect the types and amounts of bacteria in the gut. This study will enroll 28 participants in the Birmingham metropolitan area.

Study Participation & Procedures

If you agree to join the study, you will be asked to complete 23 visits to the Clinical Research Unit (CRU) at UAB over a 6 week (42 day) period. There will be a four-week intervention period followed by a two-week follow-up period. We will provide you with breakfast, lunch, dinner, and snacks for the 28 days of the intervention period. You will provide a total of 7 stool samples and 3 blood samples. You will be weighed at each visit to the CRU and your height will be measured at the initial visit to calculate body mass index (BMI). At the initial visit you will provide demographic information (e.g., age, income, education) and complete 5 surveys about your usual diet and dietary patterns, your general health, your physical activity, and major and minor stress in your life. You will be randomly picked (like the flip of a coin) by a computer to receive either a calorie-restricted DASH diet or a calorie-restricted standard American diet during the 28-day intervention period.

- During the 4 week intervention period (Days 1-28):
    - You will only consume food provided by the study
    - You will consume one meal every weekday at the CRU and carry out food for the remaining 2 meals a day and snacks. Weekend meals will be packaged for consumption at home.
    - You will be given a kit to take home to collect a stool sample at the initial visit and on Days 7, 14, 21, and 28. You will collect the stool sample in a specimen pan provided by the study. From that collection, you will scoop a small spoonful of the stool sample into a small cup that you will return at your next visit. All collection and storage materials will be provided by the study.
    - A trained clinical staff person will collect a 10 mL blood sample (approximately 2 teaspoons) that will be used to measure inflammation at the initial visit..
- During the 2 week follow up period (Days 29-42) you will make 3 visits to the CRU, immediately following the intervention period (Day 29) and on Day 35 and Day 42. At the Day 29 and 42 meetings you will complete 2 surveys on major and minor stress in your life and a trained clinical staff person will collect a 10 mL blood sample. At both the Day 35 and Day 42 visits you will complete a 24-hour diet recall. You will also collect one stool sample each week. .

You will wear an accelerometer for the duration of the study (42 days). This is a small plastic physical activity monitor that is worn on the hip using a belt strap. The monitor needs to be worn for the entire 24 hours during the 42-day period and should only be removed for bathing/swimming purposes to avoid getting it wet.

If you have used any antibiotics or probiotics within the previous 90 days, we ask that you not participate in this study.

We are performing analysis of bacteria in your body and completing surveys solely for the research purposes described above. The analysis of bacteria and the surveys are not clinical tests and are not intended for diagnostic purposes. Individual survey and accelerometer data will be reported in aggregate. Analysis results (including individual research results) will not be returned to you.

Your de-identified private information and de-identified biospecimens (private information and biospecimens with all identifiers removed) may be used for future research studies or distributed to another researcher for future research studies without additional informed consent. This is only when there are no identifiers associated with the data or biospecimens.

Risks and Discomforts

You will be assigned to a group by chance, which may prove to be less effective than the other study group or alternatives.

There is a potential risk associated with the collection of blood samples. Some participants experience discomfort and/or bruising at the collection site. There is also a slight risk of infection. To minimize these risks, blood samples will be collected by clinical staff trained in the collection of blood samples.

You may feel physical discomfort from providing stool samples.
You may also experience slight distress about providing personal information, particularly about stress levels.

A risk is associated with potential loss of confidentiality. To minimize this we will take standard precautions to minimize risk and assure confidentiality of data. Individual responses to survey questions will only be identifiable by ID number and kept in locked storage cabinets with limited access. Stool and blood samples will be kept in locked freezers in secure labs on the UAB campus.

Benefits

You may not benefit directly from taking part in this study. However, this study may help us better understand the link between microbiota and diet in black and white women. You will be assigned to a group by chance, which may prove to have more or less benefits than the other study group.

Alternatives

An alternative would be for you not to participate in the study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?

All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who may use and give out information about you?

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?

All Individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your

information may also be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the National Institute for Minority Health and Health Disparities (NIMHD)
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, Children’s of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the UAB IRB and its staff

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants may visit the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute for Minority Health and Health Disparities which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self of others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal
Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation
There will be no cost to you for taking part in this study.

Payment for Participation
The total payment you may receive is $100. You will be paid $60 for completion of the 28-day intervention period and $40 for completing the Day 35 and Day 42 follow-up visits. Payments will be made at 4 weeks and 6 weeks if you complete the entire study. If you do not finish the entire study, you will be paid at the time you decide to stop taking part in the study. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

Payment for Research-Related Injuries
UAB and the National Institutes of Health have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

New Findings
You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Optional Research

Future Research Use of Private Information and/or Biospecimens
We would like your permission to keep your private information (data containing personal information) and biospecimens (blood and stool) collected in this study for future research. The future research may be similar to this study or may be completely different. Your private information and biospecimens will be stored indefinitely or until used.

Your private information and biospecimens will be labeled with a code that only the study doctor can link back to you. Results of any future research will not be given to you or your doctor.

You can take part in this study even if you decide not to let us keep your private information and biospecimens for future research.

If you give us permission now to keep your private information and biospecimens, you can change your mind later and ask us to destroy it. However, once we have analyzed your private information and biospecimens, we may not be able to take it out of our future research.

We may share your private information and biospecimens, so that others can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your private information and biospecimens with other researchers, we will not be able to get it back.

Minimal risk to you is anticipated with the use of your information for future research. Future research use of your private information and biospecimens will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your private information and biospecimens. Allowing us to do future research on your private information and biospecimens will not benefit you directly.

Initial your choice below:

___ I agree to allow my private information and biospecimens to be kept and used for future research on chronic diseases.

___ I do not agree to allow my private information and biospecimens to be kept and used for future research.

Questions
If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact Dr. Tiffany Carson. She will be glad to answer any of your questions. You may contact Dr. Carson at 205-934-1443.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

_____

Signature of Person Obtaining Consent Date

Reviewed by:

_____

Signature of Principal Investigator Reviewing Consent Document Date