**Brief Title: Tailoring a Lifestyle Intervention to Address Obesity Disparities Among Men**

**Identifiers: NCT03037502**

**Unique Protocol ID: 160108**

**Secondary IDs: 1U54MD010722**

**Pg. 1-7: Informed Consent Document for Nashville site; approved by the Vanderbilt Institutional Review Board; Date of approval: 12/16/2019**

**Pg. 8-13: Informed Consent Form for Miami site; approved by the University of Miami Institutional Review Board; Date of approval: 2/26/2020**

**Vanderbilt University Institutional Review Board**
**Informed Consent Document for Research**

**Principal Investigator:** Derek M. Griffith PhD
**Study Title:** TailorMade: Solutions for Your Health
**Institution/Hospital:** Vanderbilt University

**Revision Date: 7/2/2019**

This informed consent document applies to adults.

Name of participant: _____ Age: _____

**The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.**

Your participation in this research study is voluntary. You do not have to answer any questions, share your health screening information, or perform in any activities that you do not want to. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

1. **Purpose of the study:**
The purpose of this study is to conduct a physical activity program to investigate how African- American men in Nashville, TN ages 35-64, respond to a 3-month tailored physical activity intervention and a 3-month follow-up survey. The program aims to increase physical activity and reduce sedentary behavior among this population through behavior goal setting, tailored motivational messages, motivational interviewing and small group sessions. You are being asked to participate because you are an African- American man between 35-64 years of age with a BMI 27 or higher living in Nashville, TN.

2. **Procedures to be followed and approximate duration of the study:**
Being in this study is voluntary. Should you choose to take part, your time in the study will be about 3 months plus a follow-up assessment 3 months after study completion. As a participant, you will be randomly assigned to either the intervention group or the control group. The components of the study include the following:

**<u>During Your Baseline Visit (Assessment #1)</u>**

- You will be asked to complete a survey that asks you to provide information about your health, your current participation in physical activities, and your attitudes about and support for becoming more physically active. The questions should not make you feel uncomfortable. The survey should take approximately 1 hour to complete.
- A physical health screening to assess your biometric measurements will be conducted and includes: height, weight, body fat percentage, neck and waist circumference, blood pressure, and a blood sample. For the blood sample, two separate samples will be taken.
    - The first sample (no more than 5 ml of blood) will be taken by either blood draw or finger stick in one middle or ring finger. This blood sample will be analyzed for total cholesterol, High Density Lipoprotein (HDL),Low Density Lipoprotein (LDL), triglycerides and glucose. The blood collection will take approximately 5 minutes and you will be given a copy of the results.
    - The second sample of blood (no more than 5 ml) will be drawn using a venipuncture from the inside of the elbow (median cubital or cephalic veins). This blood sample will be used for genetic analysis to characterize population-level disease risk in non-European-descent individuals. Your name will not be associated with this blood sample.
- You will be introduced to all study materials and equipment and receive instructions on how to utilize them. You will also select the days and times that you are available to participate in small group sessions.
- If your eligibility requires you to check with your primary care provider before increasing your physical activity level, you acknowledge that you have spoken with a health care provider prior to starting this program and will provide program staff with a signed health care provider form

**Genetic Analysis**

- As part of the study, you are being asked to donate a portion your DNA extracted from blood drawn during the baseline assessment to be used to learn more about genetic information associated with obesity-related disease. Genes carry information that determines your traits, which are features or characteristics that are passed on to you from your parents. We are doing this to learn more about the genes that may carry information related to diseases such as Diabetes and Obesity in African American males.
- The sample of your blood being used for genetic analysis will be stored and shipped to a laboratory for DNA extraction and analysis. The sample will be labeled only with your participant number, and not with your name. Your identity will never be revealed or associated with any information obtained from your sample.
- The research that is done with your blood samples is not designed to specifically help you. It might help people who have obesity-related diseases in the future.

**Fitbit Accelerometer**

- You will be asked to continuously wear a Fitbit accelerometer, a slim device that tracks your daily activity. The collected data will be updated wirelessly on a computer or mobile device providing you the ability to track your progress. By signing this form, you allow for trained study staff to access and monitor your daily activity as it is reported through the Fitbit application and Application Programming Interface (API).

**Weekly Health SMS Text Messaging**

- Participants randomized to the intervention group will be asked to receive text messages containing health messaging. Frequency of these text messages will be approximately 2-3 times per week.

**Weekly Small Group Sessions**

- Participants randomized to the intervention group will meet via conference call with other *Tailor Made* participants and a small group session leader once a week for 3 months.
- With your approval, these calls will be recorded for study evaluation purposes. If any one individual in the small group does not consent to being recorded, the call will not be recorded and notes will be taken instead.
- Each small group session will last approximately 45 minutes and include provision of health education materials and activities that promote positive behavior change for a healthier lifestyle including information about activities that promote physical activity and healthy eating.

**During Your Final Assessment (Assessment #2)**

- You will be asked to complete a final survey that asks you to provide information about your health, your current participation in physical activities, your attitudes about and support for becoming more physically active, your eating habits, and your involvement in the *Tailor Made* program. The questions should not make you feel uncomfortable. The survey should take approximately 30 minutes to complete.
- A physical health screening to assess your biometric measurements will be conducted and includes: height, weight, body fat percentage, neck and waist circumference, blood pressure and a blood sample. A small sample of your blood will be taken by either blood draw or finger stick blood sample using a finger sick in one middle or ring finger (no more than 5ml). Your blood will be analyzed for total cholesterol, High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), triglycerides and glucose. The blood collection will take approximately 5 minutes and you will be given a copy of the results.

**Follow-Up Assessment**

- 3 months following the completion of the program, you will be asked to complete a follow-up assessment

survey. The questions that you will be asked will be about your health, your current participation in physical activities and your eating habits and will take you about 30 minutes to complete.

All data about your biometric measurements, physical activity, health surveys, and lab results will be de-identified and reviewed by the study team.

3. **Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:**
The potential discomforts, inconveniences, and/or risks associated with this study are minimal.
- The risks associated with physical activity appear to be minimal when directed by knowledgeable and experienced professionals, and when progressed in a moderate and appropriate manner. There is minimal risk of potential injury and health problems that may be caused or exacerbated by engaging in or increasing your physical activity level. The possibility of experiencing a serious cardiac event has been estimated to be less than 1 per 20,000 in exercising adults.
- At the baseline and final assessments, blood will be collected by blood draw or blood stick finger sample. A trained phlebotomist using a specific approved protocol will perform the blood collection. Risks that may occur include but are not limited to: lightheadedness, headache, nausea, fainting, and bruising. There is a small possibility of harm (e.g., bruising) from the blood draw via venipuncture. If a finger stick is taken, there may be some discomfort associated with the finger stick. The use of highly trained and experienced phlebotomists makes it less likely that such an event will occur.
    - In response to an elevated or irregularly low blood glucose reading identified via the collected blood sample, which may indicate undiagnosed or uncontrolled diabetes:
        - If participants have insurance, they will be advised to seek care from their primary care physician (PCP).
        - If they do not have insurance, they will be advised to seek care from their primary care provider or from a list of health care providers which provide free/low cost/or services on a sliding scale.
- There is a risk of losing confidentiality during the small group sessions. It is possible some of the participants will know each other. We will try to preserve anonymity, but we cannot promise complete anonymity in small group sessions. We will make clear the importance of maintaining the confidentiality of everything discussed during the small group sessions. Participants will be urged not to repeat information learned during the small group sessions beyond the weekly sessions. We are not discussing highly sensitive information that could pose significant risk to participants if revealed.

The researchers have taken steps to minimize these risks by ensuring that participants receive updated and accurate health resource and information from reputable sources. Please tell the researchers or your primary care provider about any injuries or other problems you have during the study. If you develop serious health issue during the intervention, your primary healthcare provider will have to verify that it is safe for you to continue.

By agreeing to be in this study, you do not give up your right to seek compensation if you are harmed as a result of participation.

4. **Good effects that might result from this study:**
- **The benefits to science and humankind that <u>might</u> result from this study.** By taking part in this study, you will lend knowledge to the research and medical community about the effects of tailoring behavioral motivational messaging to improve the physical activity and health of men within the study population. The possible benefits of research from your blood sample includes learning more about what causes obesity-related diseases, how to prevent them, and how to treat them. This knowledge may help develop personalized health promotion materials and efforts aimed to reach African American men.

- **The benefits you might get from being in this study.** You may lose weight, learn about new physical activity exercises and healthy eating habits, and improve your overall health.

5. **Alternative treatments available:**
   There are no alternative treatments. You may choose not to participate.

6. **Compensation for participation:**
   Participants can receive up to $70 in incentives: baseline assessment ($30) and final assessment ($40). Participants will also receive a Fitbit device and weight scale together worth approximately $150. Participants will also receive a study tshirt. If a participant does not show up to an assessment, he will not be eligible to receive that assessment's corresponding incentive.

7. **What happens if I am injured because I took part in this study?**
   If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, they you and/or your insurance will not have to pay for the cost of immediate and necessary care provided at Vanderbilt to treat your injury. There are no plans for Vanderbilt or the Sponsor 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 Sponsor to give you money for the injury.

   You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

8. **Circumstances under which the Principal Investigator may withdraw you from study participation:**
   Early termination of your participation will be due to:
   - Any reaction or undesirable event that occurs while you are in the research protocol whether or not it is considered related to a part of the study. Such events include illness, signs, symptoms, or clinically significant laboratory test abnormality that has appeared worsened during the course of the research study regardless of casual relationship to the study.
   - You may be withdrawn from this study if you receive bariatric surgery after eligibility screening but prior to or after the start of the intervention.
   - You may be withdrawn from this study if it is indicated through the eligibility screening process that it is recommended for you to seek physician approval to participate and you are do not provide the necessary physical activity clearance documentation.

9. **What happens if you choose to withdraw from study participation:**
   You have the right to refuse to be in this study. If you decide to be in the study and change your mind, you have the right drop out at any time. There is no penalty to you if you withdraw from the study.

10. **Contact Information.** If you should have any questions about this research study or possible injury, please feel free to contact Derek Griffith at (615) 322-0648 or the *Tailor Made* Project Director at 615-936-3610. For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

11. **Confidentiality:**
    All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. The researchers have taken steps to minimize breeches of

confidentiality. Reports and publications from this study will not include any information that would identify participants. Your email address and other facts that might point to you will not appear when this study is presented or its results published. We will collect phone numbers, email address, and mailing address for scheduling purposes and to send out study materials. Names and contact information will not be linked in any way to other data collected. We will not contact you again unless you indicated that you would like to be contacted to participate in future studies. If you do not indicate that you would like to be contacted again, we will delete all contact information, including your name, email address, mailing address, and phone number upon completion of the study.

The researchers will carefully store and protect participants' data. Digitally recorded information will be stored on a password protected computer. The surveys will be stored on a secured server, and any hard copies will be kept in a locked file cabinet of which only key personnel will have a key. After imputing data into a file, all surveys will be destroyed. Please note that this study does not use, access or update any information in your medical record.

**Certificate of Confidentiality:**

This study may have some support from the National Institutes of Health (NIH). If so, 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.

**12. Privacy:**

Your information may be shared with Vanderbilt or the government, such as the Vanderbilt University Institutional Review Board or the Federal Government Office for Human Research Protections or representatives of the American Cancer Society, if you or someone else is in danger or if we are required to do so by law.

**13. Authorization to Use/Disclose Protected Health Information**

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University may share the results of your study and/or non-study linked [genetic analysis results], as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University, and National Institutes of Health. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Griffith in writing and let him know that you withdraw your consent. His mailing address is 2301 Vanderbilt Place, PMB 401814, Nashville, TN, 37240. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

## Consent for Genetic Research

A main outcome 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 draw 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 draw of no more than 5 ml (about 1 teaspoon) will be drawn from a vein in your arm using a needle. 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.

To maintain confidentiality, 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 Derek M. Griffith and the project staff 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 making a decision 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 up to 5 years for future research. The sample will be destroyed when it is no longer needed.

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At any time, you may ask to have your sample destroyed. You should contact Derek M. Griffith or Emily Jaeger at 615-936-3610 or crmh@vanderbilt.edu 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 may not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples.

Please check Yes or No to the questions below:

**Principal Investigator:** Derek M. Griffith PhD
**Study Title:** TailorMade: Solutions for Your Health
**Institution/Hospital:** Vanderbilt University

**Revision Date: 7/2/2019**

- 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 obesity. ☐ 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

**STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY**

**I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.**

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____

# Permission to Take Part in a Human Research Study-- SBS



**Title of Study:** Tailor Made: Solutions for Your Health
**Principal Investigator:** Natasha S. Solle, PhD, RN
**Department:** Department of Medicine
**Phone Number:** 305-243-7191 and 24-hour contact number, 954-609-1187
**Email Address:** n.schaefer@umiami.edu
**Study Contact Name, if other than PI:** Neysarí Arana
**Study Contact Telephone Number:** 305-243-1327
**Study Contact Email:** narana@miami.edu
**Sponsor:** National Institutes of Health (NIH)

The purpose of this study is to examine the effect of a weight loss program tailored for Hispanic/Latino men ages 35-64 living in Miami or surrounding areas. The program intends to increase physical activity and reduce sedentary behavior among Hispanic/Latino men.

***How many people will take part in the study?***

We expect about 40 men will be in this research study in Miami and its surrounding areas and another 80 nationally.

***What happens if I say yes, I want to be in this research?***

- You will assigned by chance, like flipping a coin, to a study group. One of the groups will take part of an online-based physical activity program. The other group receive educational materials on health promotion.
- Both groups will receive a Fitbit and a scale. You will be asked to wear and use the Fitbit device to track your daily activity. The collected data will be updated on a computer or mobile device providing you the ability to track your progress. By signing this form, you allow the research team to access and monitor your daily activity as it is reported through the Fitbit application. The scale will be linked to your Fitbit and will also track your weight. We ask that you use these devices for a period of 3 months.
- You will be asked to complete a baseline assessment including surveys, a blood draw, and collection of your health vitals. The entire assessment will take approximately 1 hour to complete. You will be asked to complete a similar assessment after completing the program which will take approximately 45 minutes.
- The surveys that you will be completing will ask questions about you, your health, eating habits, current participation in physical activities, and your attitudes about becoming more physically active.
- The health vitals collected during the first and second assessments will include your height, weight, body fat percentage, waist size, neck size, and blood pressure.

- For the blood samples collected during your baseline assessment, two separate samples will be collected. One will be drawn using a finger stick in one middle or ring finger (approximately 1/10$^{th}$ of a teaspoon of blood). This blood sample will be used to measure cholesterol and glucose levels. You will be given a copy of the results. The other sample of blood (no more than 5 ml) will be drawn from a vein on the inside of your elbow. This blood sample will be used to for genetic testing to characterize the risk of disease in Hispanic/Latino men. Your name will not be associated with this blood sample.
- During the post-program assessment, you will be asked to provide one blood sample using a finger stick once again to measure cholesterol and glucose levels.
- We will follow-up with you 3 months after your completion of the program (approximately 6 months after your baseline assessment) and will ask you to answer a survey. The questions will be about your health, your current participation in physical activities and your healthy habits. The survey will take approximately 30 minutes to complete.
- Participants assigned to the online-based physical activity program will meet through a conference call with other participants and a group facilitator once a week for 3 months, 12 sessions in total. Each session will last approximately 45 minutes.
- We ask for your permission to audio record the group sessions. If a member of the group does not consent to be recorded, the call will not be recorded. We ask to record the sessions for the purpose of evaluating how the program is carried out.

***What should I think about before I enroll in this research?***

You should ask any questions you may have and obtain answers before you decide.

***Do I have to be in this research?***

No. Your participation in this study is voluntary. You do not have to be in this study if you do not want to, and you can leave the study at any time. You will not lose any services, benefits, or rights you would normally have if you choose not to be in the study or if you leave the study early.

***Is there any way being in this study could be bad for me? (Detailed Risks)***

The potential discomforts or risks associated with this study are minimal.

1. The risks associated with data collection (surveys, interviews) for this study are minimal, since the topics are not highly sensitive. There is a risk of losing confidentiality during the virtual small group sessions. It is possible some of the small group members will know each other. Participants will be urged to not repeat information learned during the small group sessions beyond the weekly sessions. We are not discussing highly sensitive information that could pose significant risk to participants if revealed.

2. There are minimal risks associated with blood draws. Risks that may occur include but are not limited to discomfort, lightheadedness, headache, nausea, fainting, infection, and bruising. There is a small possibility of harm (e.g., bruising) from the blood draw when using a needle. To reduce these risks, blood will be drawn by a trained phlebotomist using a specific approved protocol
3. There is a risk of injury from increased levels of physical activity. Participants will be given resources and tools and informed of types of physical activity that would reduce risk of potential injury for individuals who are not currently regularly physically active. However, the benefit of increased physical activity greatly outweighs the potential risks involved with increased physical activity level and decreased sedentary behavior.

***What if I get hurt because of my participation in this study?***

Although risks are unlikely, if injury should occur, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not available.

***What are the benefits to being in this study?***

By taking part in this study, you will help the researchers and the medical community learn the effects of tailoring a behavioral motivational program to improve the physical activity and health of Hispanic/Latino men. The possible benefits of research from your blood sample includes learning more about what causes obesity-related diseases, how to prevent them, and how to treat them. This knowledge may help develop personalized health promotion materials and efforts to reach the needs of Hispanic/Latino men.

A direct benefit from your participation is not guaranteed, however you may lose weight, learn about new physical activity exercises and healthy eating habits, and improve your overall health.

***What happens to the information collected for the research?***

The researchers will keep all study records, including any codes to your data, in a secure location. All data will be stored at the office of the investigator under locked file cabinets. Research records will be labeled with a code. A master file that links names and codes will be kept in a separate and secure location. All electronic files containing identifiable information will be password-protected. Only the members of the research staff will have access to the passwords. At the end of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

Your information may be looked at and/or copied for research or regulatory purposes by:

- The sponsor;
- Department of Health and Human Services (DHHS);
- other government agencies;
- other University of Miami employees for audit and/or monitoring purposes; and
- other organizations collaborating in the research

If information is revealed that you are at risk to harm yourself or others, to abuse or neglect a child or elderly person, or other forms of abuse, we are required by law to report this immediately to the proper authorities.

Please remember that while we (the researchers) will keep your information confidential and will remind all participants that what is said in the group should not be repeated outside of the group, we have no control over what happens outside of the group. You are reminded to not share anything you would not want repeated outside of this group.

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

***Will the information collected be used in future research?***

Your blood sample will be used to make DNA that will be kept for up to 5 years for future research. Your sample will be identified by a code and not your personal information. The sample will be destroyed when it is no longer needed.

***Payment***

If you agree to be in this research study, we will pay you up to $70 for your time and effort: $30 after completing the baseline assessment and $40 after completing the post-program assessment. You will also receive a Fitbit device and weight scale worth approximately $150. You will also receive a study t-shirt.

You must complete a W-9 form to receive payment for participation. If payment exceeds $600 per calendar year, the University of Miami will report the amount to the Internal Revenue Service. This information will not be linked to any of the study data and will only be used for payment purposes.

**Consent for Genetic Research and other Optional Elements:**

We are interested in looking at genes (DNA) and how they affect health and disease. 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 draw 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. It will be used for the purpose of research only.

A single blood draw of no more than 5 ml (about 1 teaspoon) will be drawn from a vein in your arm using a needle. This will take about 5 minutes of your time. To keep your sample confidential, it 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. Natasha S. Solle and the project manager will have access to your name.

Your sample will be used to make DNA that will be kept for up to 5 years for future research. The sample will be destroyed when it is no longer needed.

You may ask to have your sample destroyed at any time. You should contact Dr. Natasha S. Solle at 305-243-7191 or n.schaefer@umiami.edu, or Neysarí Arana at 305-243-1327 or narana@miami.edu, to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been collected using your sample. Also, if your identity was removed from the samples, we may not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples.

Please check Yes or No to the questions below:

- My blood sample may be used for gene research in this study.
  ☐ Yes ☐ No

- My blood sample may be stored/shared for future gene research in obesity.
  ☐ Yes ☐ No

- My blood sample may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc.)
  ☐ Yes ☐ No

- The study team can audio record the group sessions. These recordings will not be shared, only the investigator and study team will have access to them.
  ☐ Yes ☐ No

- I would like to be contacted for future studies.
  ☐ Yes ☐ No

***Who can I talk to?***

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at *305-243-1327.*

This research has been reviewed and approved by an Institutional Review Board ("IRB"). The Human Subject Research Office (HSRO) provides administrative support to the University of Miami's IRBs. Please call the HSRO at 305-243-3195 if you are a participant in any research being conducted by UM, and:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

**PARTICIPANT'S STATEMENT/SIGNATURE**

- *I have read this form and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I will receive a copy of this consent form after I sign it.*

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date