Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Derek M. Griffith PhD **Revision Date: 12/13/2017**
Study Title: Mighty Men: A Faith-Based Weight Loss Program to Reduce Cancer Disparities
Institution/Hospital: Vanderbilt University

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 faith-based physical activity program to investigate how African-American men in metro Atlanta, GA ages 35-74, respond to a 6-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, and small group sessions with a personal trainer. You are being asked to participate because you are an African-American man between 35-74 years of age with a BMI 29 or higher living in metro Atlanta, GA.

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 6 months plus a follow-up assessment 12 weeks after study completion that lasts about 2 hours. 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, waist size, blood pressure, and a blood sample. A small sample of your blood (approximately 1/10th of a teaspoon) will be drawn using a finger sick in one middle or ring finger. Your blood will be analyzed for total cholesterol, High Density Lipoprotein (HDL) and glucose. The blood collection will take approximately 2 minutes and you will be given a copy of the results.
- You will be introduced to all study materials and receive instructions on how to utilize them. You will also select the days and times that you are available to participate in the small group sessions.
- If your eligibility requires you to check with your primary care provider before engaging in physical activity, you must produce a letter from this provider prior to starting this intervention.

<u>FitBit Accelerometer</u>
- You will be asked to continuously wear a FitBit wristband accelerometer, a slim device that tracks your daily activity. You will also be asked to download the Fitbit app on your mobile phone and log-in to the app once installed, to allow for the CRMH to collect your Fitbit data via the registered Tailor Made

research platform, for the time that you are actively a participant in the study. The collected data will be updated wirelessly on a computer or mobile device providing you the ability to track your progress. Trained Center for Research on Men's Health (CRMH) staff will also be able to access and monitor your daily activity via the Fitbit API and Tailor Made research platform. The collected data will be de-identified and stored within the HIPPA compliant and secure Tailor Made research platform.

During Your Weekly Small Group Sessions

- You will meet with other Mighty Men participants and a small group session leader once a week for a total of 24 weeks (6 months).
- Each session will last approximately 45 minutes and include activities that promote flexibility, strength, balance and conditioning. The personal trainers leading the sessions are experienced with assisting people who have varied physical limitations, health issues, and fitness levels to become more active in a safe manner.

Mid-Study Assessment Visits (Assessment #2)

- A physical health screening to assess your biometric measurements will be conducted at the beginning of your small group and includes: height, weight, body fat percentage, waist size, blood pressure, and a blood sample. A small sample of your blood (approximately 1/10th of a teaspoon) will be drawn using a finger sick in one middle or ring finger. Your blood will be analyzed for total cholesterol, High Density Lipoprotein (HDL) and glucose. The blood collection will take approximately 2 minutes and you will be given a copy of the results.
- You will also be asked to complete a mid-point 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, and your eating habits.

During Your Final Assessment (Assessment #3)

- 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 Mighty Men 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, waist size, blood pressure and a blood sample. A small sample of your blood will be drawn using a finger sick in one middle or ring finger. Your blood will be analyzed for total cholesterol, High Density Lipoprotein (HDL) and glucose. The blood collection will take approximately 2 minutes.

Follow-Up Assessment Visit

- Twelve weeks following the completion of the program, you will be asked to attend a follow-up assessment where you will be asked to complete a follow-up 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.
- A physical health screening to assess your biometric measurements will be conducted and includes: height, weight, body fat percentage, waist size, blood pressure and a blood sample. A small sample of your blood will be drawn using a finger sick in one middle or ring finger. Your blood will be analyzed for total cholesterol, High Density Lipoprotein (HDL) and glucose. The blood collection will take approximately 2 minutes.

All data about your biometric measurements, physical activity, health surveys, and lab results that you have will be 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 of this study include the minimal risks and discomfort associated with finger stick as well as risk of potential injury and health problems that may be caused or exacerbated by participation in physical activity. However, the researchers have teken steps to minimize these risks by ensuring that participants will only exercise with skilled, certified personal trainers. Please tell your trainer, 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. 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.

4. Good effects that might result from this study:

a) 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. This knowledge may help develop personalized health promotion materials and efforts aimed to reach African American men.

b) 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 $135 in incentives: baseline visit ($25), assessment visit 2 ($30), final assessment visit ($40) and follow-up assessment visit ($40). If a participant does not show up to an assessment, he will not be eligible to receive that assessment's corresponding incentive.

7. Compensation for Research Related Injury:

If you get injured as a direct result of being in the study, depending on what insurance you may have, Vanderbilt University may pay for some or all of the costs for your medical treatment of the injury if it:

a) Is not a medical condition that you had before you started the study;
b) Is not the result of the natural progress of your disease or condition
c) Is not caused by your failure to follow the study plan or procedure
d) Is not proved to be directly caused by the negligence of a Vanderbilt employee. "Negligence" is the failure to follow a standard duty of care.

If your case meets all four of these requirements and you are uninsured or have Medicare or Medicaid, then Vanderbilt will pay all of the costs of your medical treatment for the injury.

If your case meets all four of these requirements and you have private insurance, Vanderbilt will look at the claims for these costs to see if they can be sent to your insurer for payment. Your insurer may be told that you are in a research study and given information about your treatment.

You will have to pay for any costs that the sponsor or your insurer does not pay. Vanderbilt University will pay for any of the costs that are not paid by your insurance provider. Vanderbilt University will not pay for costs like co-payments that your insurer says you have to pay.

8. Circumstances under which the Principal Investigator may withdraw you from study participation:
You may be withdrawn from this study if it is indicated through the eligibility screening process that you need physician approval to participate and you are unable to 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 Mighty Men Project Manager 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.

13. 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 and/or email addresses for scheduling purposes. Names and contact information will not be linked in any way to other data collected. We will not contact you again. We will delete all contact information, including your name, email 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.

14. 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.

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 _____