



Department of Veterans Affairs

## VA RESEARCH CONSENT FORM

Version Date: 6/13/2022

<b>Title of Study:</b>	Beige Fat, Energy, and the Natriuretic Peptide System		
<b>ID#: 1551444</b>			
<b>Principal Investigator:</b>	Katherine N. Bachmann, MD, MSCI	<b>VAMC: (626)</b>	Tennessee Valley Healthcare System (VA TVHS)
<b>Participant Name:</b>		<b>Date:</b>	

### PURPOSE OF THE STUDY

You are being asked to take part in a research study at the VA Tennessee Valley Healthcare System Medical Center because you are a healthy volunteer without significant medical problems, and you have a body mass index (BMI) either in the normal range ( $18.5 \leq \text{BMI} < 25 \text{ kg/m}^2$ ) or in the obese range (greater than or equal to  $30 \text{ kg/m}^2$ ). We intend to enroll approximately 155 subjects for this study (50 lean and 105 obese) who are 18-55 years old. This study is sponsored by the VA.

In recent years, we have learned that there are different types of fat in the body—white fat and brown fat (or “beige” fat). White fat is the most common kind of fat in our body and is thought to be “unhealthy” when there is too much of it. In contrast, brown and beige fat may actually be a “healthier” type of fat that helps burn off calories and may be associated with better health outcomes, including better glucose tolerance. The purpose of this study is to learn how types of fat profiles differ between lean and obese individuals, and how they differ between racial groups. We are also interested in learning about the relationship of fat profiles with natriuretic peptide hormones, which are hormones produced by the heart.

The study will consist of 2 visits: Screening Visit and Study Visit.

- Screening Visit: Approximately 60 minutes duration
- Study Visit: (Within Approximately 4 weeks after Screening Visit):  
Approximately 3-hour duration

### DESCRIPTION OF THE PROCEDURES

If you agree to participate in this research study, it should take you less than 1 month to complete the study. During this time, we will ask you to come in for a screening visit to determine eligibility. If eligible, you will complete an additional study visit.

Before each visit, you will be asked COVID-19 screening questions before entering the VA medical center. Based upon your answers, the study team will either schedule or postpone your visit. For your health and safety, we strongly encourage you to wear a face mask. If you do not have a face mask, one will be provided to you.

**Research investigational procedures being performed at Vanderbilt University Medical Center (VUMC):**

Some or all aspects of the screening visit (as detailed below) may occur at Vanderbilt University Medical Center (VUMC). If you are deemed eligible for the study, the subsequent main study visit will occur at the VUMC Clinical Research Center (CRC), located at the Vanderbilt University Medical Center main campus. Details for the study visit are outlined below. Also, VUMC is permitting access to your medical records to the research study team. This will allow the study team to have access to information that may be relevant to your study participation.

**Screening Visit**

This visit will be approximately 60 minutes in length. During this visit, we will tell you about the study and review the consent form in detail, have you sign the consent form, and perform tests and procedures to see if you qualify to take part in this research study. The study doctor will review the results of these tests. If you do not qualify, the study staff will tell you why.

At this visit, we will:

- Ask about your medical history.
- Give you a physical exam, including measurement of height, weight and vital signs (e.g. blood pressure and heart rate).
- Test your blood or urine for pregnancy if you are a woman able to become pregnant. (Women who are pregnant or breastfeeding cannot take part in this research study).
- Collect a blood draw of about 18 ml (approximately 1 tbsp) to check your thyroid function, blood counts, electrolyte and fluid balance, kidney function, liver function, and glucose levels.

We may ask you to stop taking certain medications or diuretics (water pills) about 4-6 weeks prior to the 'study visit' at Vanderbilt's CRC. This will be discussed with you at the screening visit. We may ask to collect an additional blood draw to confirm your eligibility for the study. This will be determined by the study doctor.

Whenever possible, we will combine the research screening tasks and procedures with standard-of-care tasks and procedures that you receive from your usual clinical providers. If the study team can determine your eligibility based on your information gathered from your standard-of-care tasks and procedures, you may not need to come in for a specific screening visit. This will be at the discretion of the study team.

**Study Visit**

During the study visit, you will arrive fasting. This means that you cannot eat or drink anything (other than water) for at least 8 hours before your visit. This visit will take approximately 3 hours to complete. Upon your arrival to the research facility, we will place a blood pressure cuff and chest leads to monitor your heart. You will then be asked to lay supine (flat on your back) for 30 minutes. Because body positioning is crucial for stable and reliable evaluation of our hormone measurements, you will need to remain supine (flat on your back) for



approximately 2 hours during the visit. While you are laying flat on your back, a non-restrictive clear hood will be placed over your head that has a tube which allows air (oxygen) in and air (carbon dioxide) out. The use of this machine (called a metabolic cart) will allow us to measure your resting energy expenditure. You will wear this hood for 30 minutes. While still laying flat on your back, we will collect a blood sample of approximately 75 ml (or approximately 5 tablespoons). You will also provide a urine sample.

You will undergo a biopsy of your subcutaneous fat tissue (under-the-skin fat tissue) on your abdomen, a few centimeters away from your belly button. This procedure will be performed by a trained medical provider using sterile technique. A local anesthetic (lidocaine) will be used to numb the site of biopsy. A small incision (approximately 0.5 cm (1/5 inch)) will be made. The trained medical provider may decide to first inject some sterile fluid into the fat tissue under the skin if they feel this may help with obtaining enough fat tissue during the biopsy. Then a small liposuction cannula, with a syringe attached, is inserted and moved parallel to the skin until a small sample of tissue (less than the weight of a dime) is collected. After the biopsy is complete, antibiotic ointment will be applied followed by a steri-strip and adhesive bandage.

You will receive a Dual Energy X-Ray Absorptiometry (DXA) scan during the study. A DXA scan uses x-ray technology to measure bone thickness. During this test, X-ray pictures of your body will assess the amount of bone, fat, and muscle in your body. You will lie flat on a table and a machine will take pictures of different areas of your body. This test will last about 15 minutes. In the event of scheduling issues, the DXA may be performed within about 2 weeks before or after the main study visit.

### **Research procedures being performed at VA TVHS:**

VA TVHS's role in this study is to screen your medical records and to obtain your informed consent regarding accessing to your records and performing study procedures as detailed above. The VA is permitting access to your medical records to the research study team, so that the study team to have access to information that may be relevant to your study participation. Also, some or all aspects of the screening visit (as detailed above) may occur at the VA depending on scheduling and availability.

Procedure	Screening Visit	Main Study Visit
Informed Consent	X	
Medical History & Physical exam	X	
Vital Signs, height, weight	X	X
Pregnancy test	X	X
Clinical Laboratory sample collection	X	X
Fat Biopsy		X
Metabolic Cart		X
DXA scan		X



The table above and the description of study procedures above reflect the intended schedule of events. However, due to scheduling and logistical issues, there may be minor differences in the occurrence/sequence of events.

### **DESCRIPTION OF STUDY RELATED COSTS**

Costs solely related to the purpose of this research study will be paid by the VA, as this study is funded by the VA. You will not be required to pay for any treatment received or blood test done solely for the purpose of this research study. Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study. You will be charged co-payments for any routine treatment of your usual medical conditions not related to this study.

### **PAYMENT FOR PARTICIPATION**

You will receive compensation to help cover the cost of time and inconvenience. You will receive \$250 for completing the entire study. You will not receive compensation if you only complete the screening visit and do not complete the entire study. The amount that you are reimbursed is commensurate with the time and inconvenience incurred that you otherwise would not have incurred. You will receive the payment in the mail after you have completed your participation in the study. You must agree to the release of personally identifying information such as your name, address and social security number to the VA Tennessee Valley Healthcare System so that you may receive your money. Your payment will be issued from the Austin Financial Service Center which will generate the IRS Form 1099 regardless of the amount of your participation compensation.

### **MEDICAL TREATMENT FOR RESEARCH-RELATED INJURY**

Every reasonable safety measure will be used to protect your well-being. The VA has the authority to provide medical treatment to participants injured by participation in a VA project. VA medical facilities will provide necessary medical treatment to you as a research participant if you are injured as a result of your participation in this study.

Compensation may or may not be available to you under applicable state and federal law in the event that you suffer physical injury or illness arising from this study. By agreeing to participate in this study you are not waiving or giving up your legal rights to seek compensation. If you have questions you may contact the VA TVHS Institutional Review Board office at 615-873-6076 or the Research and Development Service office at 615-873-8694.

**COMPENSATION FOR RESEARCH-RELATED INJURY**

If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S. Government. If you sign this document, you are not giving up your right to make a legal claim against the United States.

If it is determined by the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at the Nashville VA to treat the injury, if you have VA benefits.

**DESCRIPTION OF THE DISCOMFORTS, INCONVENIENCES, AND/OR RISKS**

Fasting: Inconvenience and low fluid status in the body. To minimize this risk, please drink plenty of fluids the day before the visits. Also, there is a potential risk of hypoglycemia (low blood sugar) while fasting. However, the risk of hypoglycemia in healthy individuals while fasting for this amount of time is low. Signs of hypoglycemia include dizziness, lightheadedness, extreme sweating, and extreme hunger; please let us know if you experience any of these symptoms.

Phlebotomy: The risks associated with phlebotomy in healthy individuals are minimal. Risks include pain, bruising, inflammation, and rarely fainting and infection. Other possible risks include low fluid status in the body and anemia (low blood counts).

Hemodynamic monitoring (blood pressure monitoring and heart rate monitoring by cardiac telemetry): A non-invasive technique with no symptoms aside from minimal discomfort.

Subcutaneous adipose tissue biopsy: Possible risks of the biopsy procedure include pain, local skin irritation, bleeding, bruising, and hematoma at the site. There is potential risk for local or systemic infection, more severe bleeding, or a small scar; however, the risk of these events is extremely low.

Lidocaine: May cause local discomfort during injection, or a rash, redness or soreness at the injection site. In rare cases, lidocaine could potentially cause hypersensitivity reactions, confusion, or induce a temporary alteration in heart rhythm.

Metabolic cart: This is a non-invasive technique which involves placing a ventilated hood over the subject's head for approximately 30 minutes. Subjects with history of claustrophobia will be excluded from the study.



Dual Energy X-ray Absorptiometry (DXA): You will be exposed to some radiation because DXA is an x-ray. The amount of radiation from the one DXA scan is equal to the amount of radiation in the natural environment if you were to walk around outside for 9 days.

### **ANTICIPATED BENEFITS RESULTING FROM STUDY PARTICIPATION**

Taking part in this study may not personally help you, but your participation may lead to knowledge that will help others. Your participation may benefit science and humankind through the results of this study. It is possible that we may learn information that will help to improve prevention and/or therapy for diseases like obesity and obesity-associated complications, like insulin resistance and cardiovascular disease. The results may help patients in the future.

### **ALTERNATIVE PROCEDURES/OTHER TREATMENT AVAILABLE**

You are not required to take part in this research study. This is not a treatment study. Your participation is entirely voluntary. You can refuse to participate now, or you can withdraw from this study at any time after giving your consent without affecting your healthcare/services or other rights. This will not interfere with your regular medical treatment if you are a patient.

The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related illness or injury. You may be withdrawn from the study if laboratory tests suggest that it is not safe for you to continue.

### **GENETIC RESEARCH**

Samples and information about you may be shared with others to use for research; however, we will not release your name. Because certain genetic information may be unique to an individual, it is possible that your genetic information could link research information to you.

It is possible that a commercial product, test or findings will be developed as part of this research. These may have value and may be developed and owned by the study staff, and/or others. If this happens, there are no plans to provide money to you.

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. Health insurance companies and group health plans may not request your genetic information that comes from this research.



A new federal law, the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

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

All health insurance companies, and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

## **RESEARCH RESULTS**

In the event new information becomes available that may affect the risks and/or benefits associated with this study or your willingness to participate in it, you and your physician will be notified so you can make a decision whether or not to continue your participation in this study.

Your study records and data will be stored in a secure database. The database will reside in a password protected secure website supported by the TVHS VA. Information in the database will only be available to study personnel. Your biological samples will be stored with a study ID label in a locked freezer. This label will not include any identifying information. Only key study staff will have access to your identifying information. All key study personnel involved in the design or conduct of this study will receive the required education on the protection of human participants.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

A description of this clinical trial will be available on <http://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.

You have the option to receive a copy of the summary of study results once the study manuscript is published.

## **DISPOSITION OF RESEARCH DATA AND/OR SPECIMENS**

This research study is anticipated to last 3.5 years. This study involves access of PHI data/limited data set for research as listed: Name, SSN for screening candidates (necessary for reimbursement), date(s) of lab tests, radiology scans, and other test results, and phone number for follow-up phone calls.



The research data will be stored in a RedCap database which is a password protected, secure web-based application maintained by the TVHS VA and retained in your research record in accordance with Veterans Health Administration (VHA) and Federal Records Control Schedule policies after the study is completed. Research data will be used/shared outside TVHS at the PI's and study staff's offices at Vanderbilt University Medical Center.

Sensitive Research data (hard-copy data such as signed consent form, case reports forms):

- PI's workspace in VA TVHS
- PI's office at VUMC
- Study staff's office at VUMC
- Electronic sensitive research data
  - PI's folder on VA TVHS Server
  - PI's folder on VUMC Server

The code linking your name with your ID number will be stored electronically on the VA's secure computer network.

- Data collected (per the HIPAA Authorization page 1) will be stored in the VA REDCap database on the TVHS computer server. A copy of this data collected will also be stored on the PI's TVHS Research Folder.

The coded research specimens will be stored at Dr. Bachmann's freezer in TVHS in Nashville. Specimens may also be stored at Vanderbilt University Medical Center before they are processed. Research samples will be retained indefinitely for future use, as applicable to this protocol, and may also be used in future research.

We may look at information collected in your medical record prior to the study and continue to view information in your records collected after the completion of the study. This is so we may view your medical chart before and after you complete the study.

Your samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

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

Should you qualify for future studies, we ask that you give us permission to contact you to discuss your interest and eligibility.



☐

Yes, I give my permission to be contacted in the future regarding other research projects I may qualify for.

☐

No, I do not give my permission to be contacted in the future regarding other research projects I may qualify for.

### **CONTACT INFORMATION**

If you have questions about this study, wish to express concerns or complaints about the research, or to report a research-related injury, you can contact:

- Clinical Trials Manager: Cassandra Reynolds (615) 875-9854
- Principal Investigator: Dr. Katherine Bachmann (615) 875-9520

For 24-hour availability: (615)-835-8267, the automated voice will prompt you to enter your phone number in order for Dr. Bachmann to return your call. Once you have entered your phone number, please hang up.

If you have general questions about giving consent or your rights as a participant in this study or wish to discuss problems or concerns, offer input, or you want to make sure this is a valid VA study, or request information you can call the VA Tennessee Valley Healthcare System (VATVHS) Institutional Review Board Office at (615) 873-6076 or the Research and Development Service Office at (615) 873-6940. You may also contact the VATVHS Patient Advocate at 1-800-228-4973, extension 67225 or 1-800-876-7093 extension 22560, or (615) 873-7225 to discuss problems or concerns and ask questions not related to the consent process, offer input, or request information.

### **CONFIDENTIALITY AND PRIVACY**

Your rights of privacy will be maintained in the following manner. Your medical records will be maintained according to this medical center's requirements and the Privacy Act of 1974. All information obtained about you during the research study will be kept as confidential as legally possible and will be accessible only to the investigators and members of the research team, the sponsor (when applicable), and any appropriate government agency. Research records, like any other hospital records, may be inspected by federal regulatory authorities, including the VA Office of Research Oversight, the VA TVHS Research Compliance Officer, the Food and Drug Administration (FDA), state regulatory authorities, and legally authorized parties.

Your permission to allow access to your medical information and a description of your rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) is addressed in a separate HIPAA Authorization document. By signing the separate HIPAA Authorization form you agree to allow access, use and disclosure of your personal health information as described in the HIPAA Authorization form. By signing the consent form, you are voluntarily choosing to participate in the study as described below in this consent form.

**STATEMENT & SIGNATURE OF PERSON AGREEING TO PARTICIPATE IN THIS RESEARCH STUDY:**

**Signatures.** I agree to participate in this research project as described in this consent form. I will be given a signed copy of this consent form for my records. I have read or have had this consent form read to me.

- This study has been explained to me and all of my questions have been answered by the person obtaining consent. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. If I have questions later, I understand I can contact the researcher or a member of the research team.
- If I do not take part in this study, my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.
- I have been told my rights as a research subject, and I voluntarily consent to participate in this study. I have been told what the study is about and how and why it is being done. All my questions have been answered.
- I will receive a copy of this consent form and a copy will be forwarded to the VA Tennessee Valley Healthcare System Research Compliance Office.

**SIGNATURES:** (Note: **ALL** signatures and dates of signature below **are required** for legally effective research consent and HIPAA authorization.)

\_\_\_\_\_  
Study Participant's SSN – ***full SSN required***

\_\_\_\_\_  
Study Participant Name (Print)

\_\_\_\_\_  
Study Participant Signature

\_\_\_\_\_  
Date