

**UNIVERSITY OF MISSOURI**  
**CONSENT FORM AND HIPAA AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY**

**PROJECT TITLE:** The interplay between androgens, insulin, and adipose tissue metabolism

**INVESTIGATOR'S NAME:** Talyia Fordham, BS, Jill Kanaley, PhD, Albert Hsu, MS, MD, Elizabeth Parks, PhD

**PROJECT IRB #:** 2095704

**KEY INFORMATION ABOUT THE STUDY**

You are being asked to participate in a research study. The purpose of the study is to understand how weight loss improves the health of body fat by studying two hormones insulin and testosterone. Testosterone is naturally produced in small quantities in a woman's body. In high concentrations, both testosterone and insulin can have negative health effects such as prediabetes. If you participate in the study, you will enter an eight-week weight loss program in which blood and fat samples will be taken. You will be given food to eat during part of the study to help promote weight loss. You will meet with a registered dietitian who will provide individualized nutrition counseling to help you change your diet. One possible risk of being in this study would be that you may experience discomfort at the site where the fat sample is taken.

Please read this form carefully and take your time. You can discuss this study with your family, friends, or a doctor if you want. Let us know if you have any questions before participating. The research team can explain words or information you do not understand. Research is voluntary and you can choose not to participate. If you do not want to participate or choose to start the study and then stop later, there will be no penalty or loss of benefits to which you are otherwise entitled.

**PURPOSE OF THE RESEARCH**

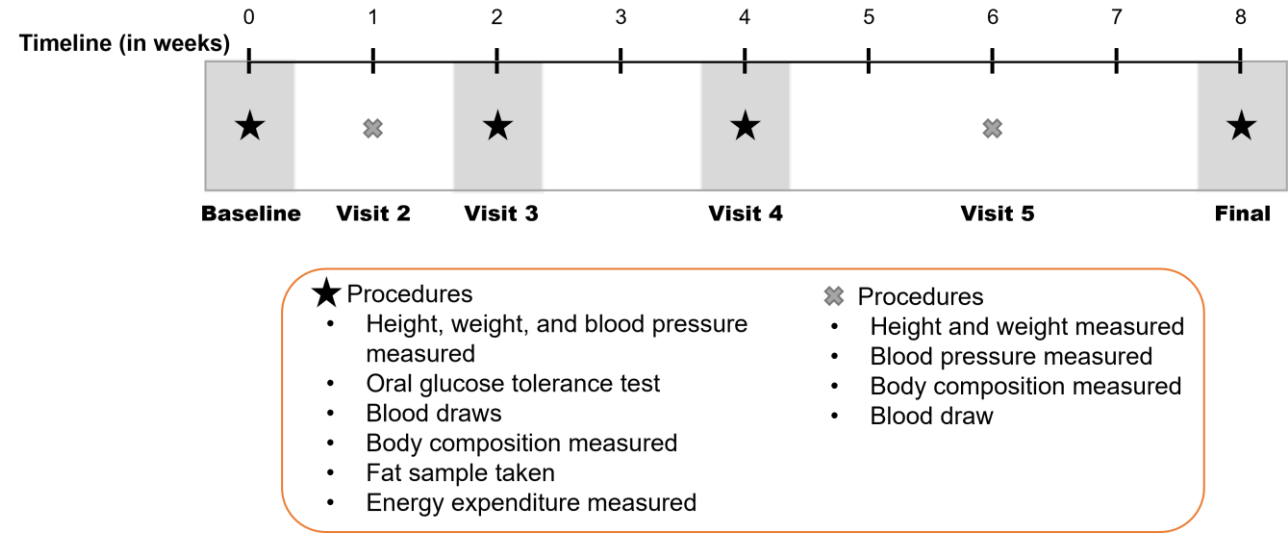
You are being asked to participate in this study because you have a risk for elevated testosterone concentrations in your blood. The reason we are studying women with higher testosterone concentrations is to understand how excess testosterone affects health. Your testosterone concentrations do not necessarily signify an underlying condition at this time. We think that a BMI of  $\geq 25$  kg/m<sup>2</sup> with high testosterone also results in abnormally high insulin concentrations. Our goal is to understand how these two hormones work together in a woman's body.

If you decide to participate, you will come to the University of Missouri for six additional visits, in addition to today's screening visit. During these visits, you will fill out questions/surveys, have your body weight and height measured, have body composition assessed using a machine called a DEXA, have a small amount of blood drawn, and have a fat sample taken. Today, using this consent form, we will explain each of the procedures and risks. We will only include you in this study if you give us your permission first by signing this consent form.

**WHAT WILL HAPPEN DURING THE STUDY?**

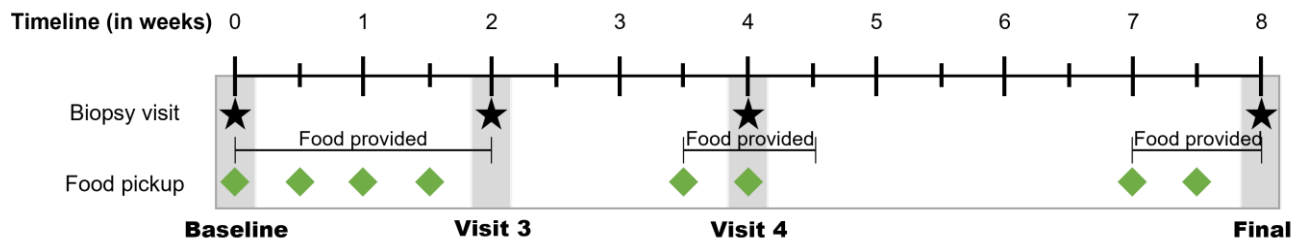
About 6 people will take part in this study. Women who have testosterone concentrations greater than 20 ng/dL but less than 200 ng/dL and a BMI more than 25 kg/m<sup>2</sup> but less than 50 kg/m<sup>2</sup> are being recruited to participate. Blood samples, height, weight, and blood pressure measurements will be taken at today's screening visit. If the results of this screening visit show you are eligible, you will have the opportunity to take part in the eight-week study. As shown in **Figure 1**, the study will start with an initial (baseline) fat sample taken and an oral glucose tolerance test (OGTT). After which, you will be sent home with your first set of prepared meals to initiate the weight loss. At weeks 2, 4, and 8 you will return to the research unit to have repeat fat and blood samples taken. At weeks 1 and 6, you will return for a blood draw and weight measurement. During the study, you will meet with a registered dietitian who will help you adjust your diet to promote weight loss. The study diet will begin on the day you undergo your first OGTT and you will stay on this diet for eight weeks.

Figure 1: Study Protocol



In **Figure 1**, the black stars indicate the visits in which you will have a fat sample taken (biopsy) and will consume a sugar-sweetened beverage as part of the OGTT. Blood will be drawn through an IV periodically during each visit to measure blood sugar levels and insulin concentrations. The gray Xs in **Figure 1** indicate the visits in which blood and body weight measures will be collected. When you start the diet, you will pick up study meals at the research kitchen in Gwynn Hall every three days. The food in this diet is made fresh and packaged in coolers specifically for you. The food comes with instructions for you to heat it up in a microwave or oven. The periods in which you will be given food are indicated on **Figure 2** below.

Figure 2: Schedule of when food is provided



Below are details of the study visits.

Screening Visit

During the screening visit, if you decide to join this study, you will sign this consent form and then you will complete the screening measurements to further check if you are eligible to be included. Even though you are signing the consent form today, the final decision to enroll you in the study happens after your screening blood results are available. The screening measurements, listed below, won't cost you anything:

- Height, weight, waist circumference, and blood pressure taken.
- Blood Tests: We will take about 6 teaspoons of blood (30 ml) from a vein in your arm to test for blood markers like glucose and testosterone.
- OGTT: You will drink a sugar sweetened beverage and we will evaluate your body's response to glucose.
- Surveys and questionnaires related to wellbeing, menstrual cycle, weight, and food preferences.

After the screening visit, you will be sent home with a food record to document the typical foods you eat on three days (two weekdays, one weekend day).

Once the results of the blood tests are available, if we find any clinically important information, we will inform you as soon as possible. For instance, if your blood pressure is too high (>180/110 mm Hg), or if a diabetes marker (HbA1c) is too high, you would not be eligible. We will give you the results of the tests so you can share them with your regular doctor.

If the results of these tests show that you can be in the study, we will work with you to schedule a morning to come in and complete your first visit. You will then send the food record to the research dietitian ahead of your baseline visit. The food record will help us determine how much and what foods to provide to you during the study.

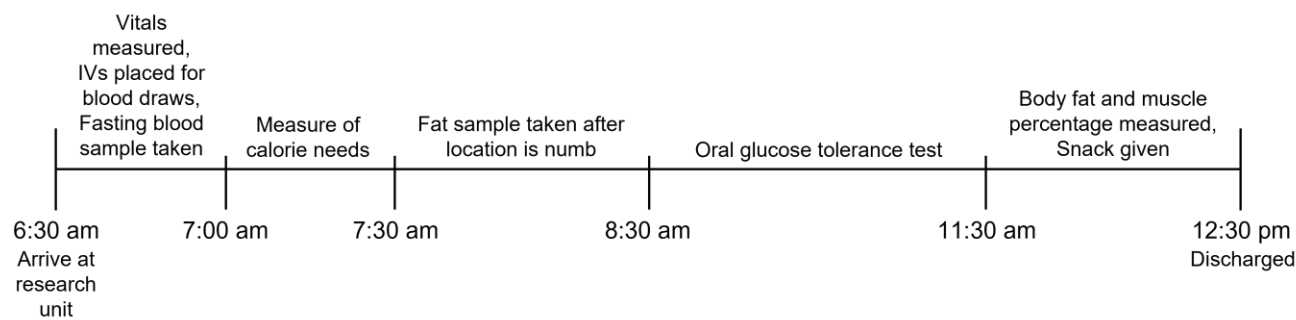
**Baseline Visit**

On the morning of this visit, you will come to the research center, which could be at the MU Hospital or another research center on campus. You will be fasted overnight for this visit. Please do not exercise on the morning of this visit. When you arrive, your blood pressure, waist size, and body fat percentage will be measured. You will also have a test of your body’s calorie needs. You will then be prepped for the fat sample procedure. During this procedure we will take a small sample of fat from your abdomen or buttocks after cleaning and numbing the site. After we have taken the fat, the site will be cleaned with antiseptics and bandaged.

During the baseline visit, we will take about 5 teaspoons (26 ml) of blood from an IV placed in a vein in your arm. The blood draws will occur before and after you consume a sugar-sweetened drink as part of the OGTT. You will also be given some questionnaires to fill out. Your body’s fat and muscle percentage will be measured using the DEXA. The DEXA uses a small amount of radioactivity to complete the measurement, similar to an x-ray. We will administer a urine pregnancy test first to be sure you are not pregnant before the DEXA scan. The scan may affect unborn babies. For this reason, pregnant women cannot take part in this study. At the end of this test, you will be given a snack, after which you will be discharged and may leave. An example timeline of this visit is given in **Figure 3** below.

The baseline visit lasts about six hours and when we are done, we will give you the first batch of research meals to consume for the rest of the day and the next three days. We will ask you to document your physical activity for the next four days and to document if any of the foods we provide are not eaten or are prepared differently than specified. This will help us monitor your response to the meals and also your general day-to-day exercise activities.

Figure 3: Example timeline of baseline, visit 3, visit 4, and final visit



**Pick-up of study meals**

As shown in **Figure 2** above, you will be asked to pick-up study meals eat throughout the study. You will consume only the research provided foods (meals and snacks) during this time and no other foods. To ensure

food freshness, coolers with the packaged food will be given every 3-4 days during the food provided weeks. Study staff will be in communication with you to arrange a pick-up time that is convenient for you.

**Visit 2 (Week 1)**

During your first follow-up visit, you will come to a research center to have your blood drawn. At this visit we will take 2.5 teaspoons (12 mls) of blood during a single stick blood draw. We will also measure your blood pressure, weight, and body composition at this appointment.

**Visits 3 and 4**

During these follow-up visits, you will come to a research center and repeat the tests from the baseline visit (biopsy and glucose test). We will take blood (5 teaspoons, 26 ml) from an IV. We will also measure your blood pressure, weight, body composition, and waist/hip circumference at these appointments.

**Visit 5 (Week 6)**

This visit is a repeat of visit 2, the procedures that occur during this visit include a blood draw and a weigh-in.

**Final visit (Week 8)**

This visit will be a repeat of the baseline visit. You will complete surveys, the OGTT, a fat biopsy, blood draws (6 teaspoons, 30 mL) and body composition measures. At the end of this visit, you will be done with the study and can resume your normal diet.

**HOW LONG WILL I BE IN THE STUDY?**

The total amount of time you could be in this study is about ten weeks – from the time we first discuss the project with you – to finishing the eight-week diet and follow-up testing.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

There are some outcomes that may be beneficial to you as a result of your participation. We anticipate that participants in this study will lose weight, which may be of value to you. Additionally, you will be meeting with a registered dietitian who will provide individualized and personalized nutrition recommendations and counseling. We will provide all lab results to you which you may choose to share with your health care provider.

**WHAT ARE THE POSSIBLE RISKS FOR PARTICIPATING IN THIS STUDY?**

There are risks to taking part in any research study and you should discuss these with the researchers. Because this study is testing the effects of weight loss, we do not anticipate there to be major side effects. However, there could be some side effects we do not know about yet. To help lower possible risks we will screen you before the study to ensure that you are an appropriate candidate for enrollment. We will closely monitor you for side effects. You need to tell the study Investigators immediately if you have any problems, side effects, or changes in your health. You will be monitored for any signs of discomfort during the procedures.

If we learn about new important risks and side effects, we will tell you. We will also tell you about any new information we learn that may affect your decision to continue taking part in the study. Our research staff in Dr. Parks' lab will be available during the study visits, as well as by telephone [(573) 884-2014] at other times, for you to ask questions. Talyia Fordham's cell number is (801) 828-0048 and Dr. Parks' cell is (682) 433-9012. You may call at any time.

**Below is a list of the procedures and the potential risks for each of the procedures**

**Blood draws:** For your screening, baseline, and follow-up visits, you will have blood drawn through a needle. The total blood drawn over the duration of this study will not exceed  $\frac{3}{4}$  cup (180 mL).

**Risks:** Blood drawing is associated with a small risk of inflammation of a vein (called phlebitis), bruising and minor pain. Antiseptic technique is used by the staff who are experts in phlebotomy. If phlebitis occurs, it will

be treated conservatively with heat. You should refrain from donating blood in public blood drives or performing other research that requires a blood draw during your participation in this project.

**Fat biopsy:** This procedure involves lying on your back on a hospital bed or exam table for ~30 minutes. During this time, trained research staff will thoroughly clean a few inches of skin on your stomach around your bellybutton. A numbing agent, lidocaine, will be administered into the sterilized area. The lidocaine injection can have a stinging sensation. After waiting ~15 minutes for the lidocaine to take effect, staff will ensure that the site is numb by touching and applying pressure to the area. If you still have sensation, staff may administer more numbing agent until the site is numb to the touch. A small incision (~ ¼ in) will be made in the skin. A biopsy needle will be inserted into the area below your skin to acquire the fat sample. After insertion, the needle will be pulled out at least three times to ensure we get enough fat to study (about 1 gram). You may feel pressure at the site, but should not feel pain. The site will be cleaned with antiseptics and bandaged. If we are unable to get sample from your stomach, we may try the buttocks area. The procedure will be the same as outlined above but the location will be different. You will be asked to lay on your stomach and the area on the buttocks will be cleansed, the sample taken, and the site cleaned and bandaged after. **Risks:** You may have a small scar at the biopsy site. The process might be uncomfortable but should not be painful. The site may be tender or sore for 24-48 hours following the procedure. You may experience redness or bruising around the biopsy site and there is a small chance of infection. A lump may occur at the biopsy site, this is a collection of blood under the skin that will be reabsorbed by the body with time. A dip at the biopsy site may occur later but will return to normal with time and site massages. *If you have a known allergy to lidocaine, tell the researchers now.* The research team will choose a different anesthetic to use.

**Food intake:** The foods consumed as part of the diet are purchased from a local grocery store (HyVee). The meals are made fresh. They will be given to you fresh or frozen, for you to heat up by yourself. You will need to eat no other food than what is provided you during the study. You may be asked to modify your beverage intake, such as reducing sodas. You will be asked to keep a record of any leftover, uneaten study food. We will work with you to make meals that mirror some of your food preferences. **Risks:** We anticipate no risks associated with these meals although for some people, stress may occur due to the limited food choice that will occur for the durations of the diet interventions.

**DEXA to measure body fat:** This procedure involves lying on a table for 20-30 minutes while a moving arm on an x-ray machine passes over your body. Although you will need to lay very still and quiet, you will feel no discomfort. **Risks:** DEXA radiation exposure is equivalent to about two percent of the average radiation dose from all sources (natural background radiation, consumer appliances, radon gas, medical tests, etc.) that a person in the United States receives each year. A urine pregnancy test is administered before the DEXA. The effects of the DEXA scan on the female reproductive system or on a developing fetus are unknown but could cause harm. For this reason, it is necessary to avoid getting pregnant while you are a subject in this study. You must also inform the Investigator if you become pregnant. If you have any questions about the reproductive issues or about preventing pregnancy, please discuss them with the Researcher or your doctor.

**Measurement of your weight, and other characteristics:** There are no known risks for measuring your weight, height, waist circumference, and blood pressure.

**Calorimetry:** This test measures how many calories your body uses. The test requires resting quietly on your back for 15 to 30 minutes under a large, clear, plastic hood. You will breathe room air normally and your breath goes into an analyzer to measure the air that you breathe out. **Risks:** The test is painless; however, persons who are uncomfortable in confined spaces may find this test stressful. You will be given a chance to practice this test to see how you feel.

**Questionnaires and surveys:** During your participation, you will fill out questionnaires and surveys to assess your eating habits. Some participants may feel uncomfortable answering some of these questions. You will not have to answer questions that you do not wish to.

**Loss of confidentiality:** Any time information is collected; there is a potential risk for loss of confidentiality. Every effort is made to keep your information confidential; however, this cannot be guaranteed. The information collected includes your date of birth, sex, ethnicity/race, lifestyle patterns (food intake, family history of disease, quality of life), height, weight, blood pressure, body fat, pregnancy status, blood test results (e.g., glucose and cholesterol), and social security number (for the purpose of us paying you). Finally, you should understand that the Researcher is not prevented from reporting information to authorities in order to prevent serious harm to you or to others.

**WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO BE IN THIS STUDY?**

You are not required to be in this study. You can simply choose not to participate. You can look for other research projects you may be interested in instead of this study. The research team can share other options with you.

**WHAT WILL BE MY RESPONSIBILITIES DURING THE STUDY?**

While you are part of this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.
- Tell the researchers before you take any new medication, even if it is prescribed by another doctor for a different medical problem or something purchased over the counter.
- Report to the researchers any injury or illness while you are on the study even if you do not think it is related.

**WILL I RECEIVE COMPENSATION FOR TAKING PART IN THIS STUDY?**

Yes, for your time and effort, you will be paid. You will be paid as you go through the study, with a check written after each visit. You will receive a total of \$750 for completion of the study; this will be broken down as follows: \$100 for the completion of the baseline visit, \$75 for visits 2 and 5 (blood draws and weight checks), \$125 for visit 3 (week 2), \$150 for visit 4 (week 4), and \$225 for the completion of the final visit (week 8). If you choose to withdraw from the study before completion, you will be paid a partial amount according to the length of time you participated.

We will need your Social Security Number in order to pay you. Any payment may need to be reported as income on your tax return. If you are not a resident/citizen (non-resident alien) of the United States, you will need to work with the MU Nonresident Tax Specialist at (573) 882-5509.

**ARE THERE ANY COSTS TO BEING IN THE STUDY?**

You should not expect any additional costs by participating in this study. The study will pay for all research tests and procedures. You and/or your health plan/insurance will not be billed for tests and procedures that are done for the research only. You should discuss any questions about costs with the researchers before agreeing to participate. If you have any questions, a social worker and financial counselor are available to discuss concerns with you. Please let the research staff know if you would like to visit with them and an appointment will be made.

**WILL INFORMATION ABOUT ME BE KEPT PRIVATE?**

The research team is committed to respecting your privacy and keeping your personal information confidential, including health information. We will make every effort to protect your information to the extent allowed by law. Your records will be given a code number and will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a separate, secure location. When the results of this research are shared, we will remove all identifying information so it will not be known who provided the information. Your information will be kept as secure as possible to prevent your identity from being disclosed. FDA may inspect the records since the study is FDA regulated.

What we collected from you as part of this research will not be used or shared for future research studies. It will only be used for purposes of this study.

The results of this study may be published in a medical journal or used for teaching purposes. However, your name or other identifying information will not be used in any publication or teaching materials without your specific permission.

**PERMISSION TO USE YOUR PROTECTED HEALTH INFORMATION**

State and federal privacy laws (called HIPAA) protect the use and release of your health information. If you decide to take part in this study, you also give us your permission to use your private health information that directly relates to whether you are eligible to participate, including the health information in your medical records and information that can identify you. You have the right to refuse to give us your permission for us to use your health information. However, doing so would mean that you could not take part in this study.

The following identifiers will be obtained from your health records:

- |   |  |
|---|--|
| <input checked="" type="checkbox"/> Name                                  | <input checked="" type="checkbox"/> Address                  |
| <input checked="" type="checkbox"/> Dates related to you                  | <input checked="" type="checkbox"/> Telephone number(s)      |
| <input type="checkbox"/> Fax Number                                       | <input checked="" type="checkbox"/> Email Address            |
| <input type="checkbox"/> Social Security Number                           | <input checked="" type="checkbox"/> Medical Record Number    |
| <input type="checkbox"/> Health Plan Beneficiary Number                   | <input type="checkbox"/> Account Numbers                     |
| <input type="checkbox"/> Certificate or License Numbers                   | <input type="checkbox"/> Any vehicle or device serial number |
| <input type="checkbox"/> Web Address (URL)                                | <input type="checkbox"/> Internet Protocol (IP) Address(es)  |
| <input type="checkbox"/> Biometric Identifiers (finger/voice print)       | <input type="checkbox"/> Photographic images                 |
| <input type="checkbox"/> Any other characteristic that could identify you |  |

The following is the type of protected health information that will be used in the study:

- |  |  |
|--|--|
| <input type="checkbox"/> Radiology Images                            | <input type="checkbox"/> Discharge Summaries   |
| <input type="checkbox"/> Radiology Reports                           | <input type="checkbox"/> Health Care Billing or Financial Records  |
| <input type="checkbox"/> EKG Recordings/Reports                      | <input type="checkbox"/> Consultations   |
| <input type="checkbox"/> Progress Notes                              | <input checked="" type="checkbox"/> Medications  |
| <input checked="" type="checkbox"/> History and Physical Exams       | <input type="checkbox"/> Emergency Medicine Reports  |
| <input type="checkbox"/> Operative Reports                           | <input type="checkbox"/> Dental Records  |
| <input checked="" type="checkbox"/> Demographics (age, race, etc.)   | <input checked="" type="checkbox"/> Laboratory Reports   |
| <input checked="" type="checkbox"/> Questionnaires, Surveys, Diaries | <input type="checkbox"/> Photographs/Video Recordings  |
| <input type="checkbox"/> Audio Recordings                            | <input checked="" type="checkbox"/> Social Security Number (This is only collected for billing/payment purposes and will not be shared with the study sponsor) |

We may give out your personal information if the law requires it. We may share any of this information with the following:

- Authorized members and staff of the University of Missouri Institutional Review Board (IRB) – the committee that monitors research participant safety.
- Study monitors and auditors who make sure that the study is being done properly.

- Government agencies and public health authorities, such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), and the Office for Human Research Protections (OHRP)

Any research information shared with outside entities will not contain your name, address, telephone, email address, social security number, or any other personal identifier unless it is necessary for review or required by law. The people who get your health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission. Your permission for us to use and/or release your information will not expire unless you cancel your permission. You can cancel your permission at any time by writing to:

Investigator's Name: Dr. Elizabeth Parks

Institution: University of Missouri, Columbia

Department: Nutrition and Exercise Physiology

Address: Medical School Building, Room NW406, Columbia, MO 65212

After we receive your letter, the information we have already collected may still be used for this research study, but we will not collect any more information. You have the right to access your protected health information that is obtained or created during this research project until the end of study ends. If you have not already received a copy of the University of Missouri Healthcare Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights, you may contact the Privacy Officer at (573) 882-9054.

#### **WHAT IF I AM INJURED DURING THE STUDY?**

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri.

In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

#### **WHERE CAN I GET MORE INFORMATION ABOUT THIS STUDY?**

A description of this clinical trial will be available on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). This Web site will not include information that can identify you. In the years to come the Web site will include a summary of the results. You can search this Web site at any time.

#### **WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS?**

If you have questions about this study or experience a research-related injury, you can contact Talyia Fordham at (801) 828-0048.

If you have questions, you may also contact the University of Missouri Institutional Review Board (IRB) if you:

- Have any questions about your rights as a study participant;
- Want to report any problems or complaints; or
- Feel under any pressure to take part or stay in this study.

The IRB is a group of people who review research studies to make sure the rights of participants are protected. Their phone number is (573) 882-3181 and their email is [muresearchirb@missouri.edu](mailto:muresearchirb@missouri.edu). If you want to talk privately about your rights or any issues related to your participation in this study, you can contact University of



Missouri Research Participant Advocacy by calling (888) 280-5002 (a free call), or by emailing [MUResearchRPA@missouri.edu](mailto:MUResearchRPA@missouri.edu).

**DO I GET A COPY OF THIS CONSENT?**

You will receive a copy of this consent for your records. Please keep it where you can find it easily. It will help you to remember what we discussed today. We appreciate your consideration to participate in this study.

**CONSENT TO PARTICIPATE - SIGNATURES**

**SIGNATURE OF STUDY PARTICIPANT**

By signing my name below, I confirm the following:

- I have reviewed this entire consent form.
- All of my questions were answered to my satisfaction.
- The study’s purpose, procedures, risks and possible benefits were explained to me.
- I voluntarily agree to take part in this research study. I have been told that I can stop at any time.

|                            |             |             |
|----------------------------|-------------|-------------|
|                            |             |             |
| <b>Subject’s Signature</b> | <b>Date</b> | <b>Time</b> |

**SIGNATURE OF PERSON AUTHORIZED TO OBTAIN CONSENT**

I have explained the purpose of the research, the study procedures (identifying those that are investigational), the possible risks and discomforts and potential benefits of the study and have answered questions regarding the study to the best of my ability.

|   |             |             |
|---|-------------|-------------|
|   |             |             |
| <b>Signature of Person Authorized to Obtain Consent</b> | <b>Date</b> | <b>Time</b> |