Department of Nutritional Sciences

CONSENT FORM

Validity and Reproducibility of Clinically Feasible Postprandial Testing

IMPACT OF COVID-19 ON THIS STUDY

This study has been approved to proceed in the context of COVID-19.
At the present time, there is increased risk of COVID-19 exposure with all activities located outside of your personal residence.
However, the researchers are committed to strong measures to lessen risk of COVID-19 spread during your participation in this study.

Should you choose to participate in this study, the following steps will be taken to decrease risk of COVID-19 spread:

- All participants will be screened via telephone prior to attending the laboratory.
- Temperature checks will be conducted on all researchers and participants upon entering the laboratory.
- All individuals will apply hand sanitizer and wear a mask upon entering the laboratory. Researchers will wear a mask, gloves and a laboratory coat.
- If you participate, you will be the only participant in the laboratory and there will never be more than 2 investigators in the laboratory with you.
- As much as possible, individuals in the laboratory will be at least 6 feet apart.
- Investigators will wash their hands or apply hand sanitizer before and after every procedure during your assessment.
- Prior to your arrival in the laboratory, all surfaces that you will contact will be disinfected. This will be repeated after each participant leaves the laboratory. We will also disinfect equipment after each specific test/procedure.

Background Information

You are invited to participate in a research study assessing the accuracy of a new abbreviated fat tolerance test (AFTT) for measuring the change in blood lipids after a meal. The change in blood lipids after a meal is a risk factor for cardiovascular disease (CVD). The primary study measurements of interest are metabolic values, especially blood lipids, obtained from blood samples. We will measure your response to an AFTT twice in order to determine if it is reliable. We will also measure your response to a typical and more time-consuming fat tolerance test twice, in order to compare it to the AFTT. Our goal is that one day the AFTT will allow for earlier, more sensitive detection of CVD risk.

We ask that you read this form and ask any questions you may have before agreeing to enroll in the study. Your participation is entirely voluntary.

To be eligible to participate in this study, you must:

- Be age 18-69 years
- Have healthy fasting metabolic values (as determined by a fasted blood draw)
- Have a Body Mass Index (BMI) between 18.5 and 34.9 kg/m^2

In addition, to be eligible you must **not**:

- Have an existing cardiometabolic condition, such as diabetes or coronary artery disease
- Be pregnant
- Use tobacco products or illicit drugs
- Use medications that lower triglycerides, such as statins or fibrates

This study is being conducted by: Christina M Sciarrillo, Department of Nutritional Sciences; Bryant H Keirns, Department of Nutritional Sciences; Kara L Poindexter, Department of Nutritional Sciences; under the direction of Sam R Emerson, PhD, Department of Nutritional Sciences.

Procedures

***Overview of Study*: If you participate, you will report to the laboratory on five occasions: a screening/initial assessment and four meal assessments.**

Overview of Screening Assessment: The screening assessment will consist of paperwork (health history and physical activity questionnaires), height and weight measurement, blood pressure, and a finger prick for a metabolic panel to determine study

eligibility. If you have healthy fasting metabolic values, we will conduct a body composition scan using dual energy X ray absorptiometry (DEXA).

If you qualify for the study, you will complete four meal assessments, each separated by ~1 week. You will complete the AFTT twice and a "standard in lab" oral fat tolerance test (SL) twice. The order of the tests will alternate. You will complete the four trials in one of the two following orders: *AFTT, SL, AFTT, SL* or *SL, AFTT, SL, AFTT*.

Overview of AFTT trial: You will arrive in the lab having followed a 10-hour fast. First, a fasting blood draw is made via single venipuncture. Next, you will consume a hypo-allergenic milkshake. You are then free to leave the laboratory for several hours. You will return ~4 hours after finishing the meal for a follow-up blood draw.

Overview of SL trial: You will arrive in the lab having followed a 10-hour fast. An intravenous (IV) catheter will be placed in a forearm vein and a baseline blood draw will be taken. Next, you will consume a standard high-fat shake in 20 minutes or less. After consumption of the meal, you will remain in the lab for 6 hours while your post-meal response is monitored. Blood draws will occur 1, 2, 3, 4, 5, and 6 hours post-meal. Besides the blood draws, you will be free to relax, read, work on your computer, watch movies, or engage in other sedentary activities during your 6-hour post-meal period in the lab.

Screening Visit Specific Procedures:

Blood pressure: We will measure your blood pressure using an automatic cuff on the upper-arm 2-3 times.

Finger prick: A lancet will be used to draw a few drops of blood from your finger once at the screening visit in order to perform a basic metabolic panel. We will take this blood sample to determine whether you qualify for the study based on your fasting metabolic values.

Body composition: If you qualify for the study, we will measure your body composition using a method called dual-energy X ray absorptiometry (DEXA). DEXA is the gold-standard technique for assessing body composition and fat distribution. DEXA works by scanning your body with a very low-dose X ray beam. The DEXA scan takes about 3 minutes.

Meal Assessment Specific Procedures:

Physical activity assessment: An activity tracker will be attached to your non-dominant wrist, which we will ask you to wear for the three days prior to each meal assessment.

Dietary assessment: Prior to your first meal assessment, you will be administered and asked to complete a 3-day food record for the 3 days prior to the assessment. For each subsequent meal session, we will provide you with a photocopy of your original food record and ask you to generally replicate your dietary pattern.

Phlebotomy (single needle sticks): During the AFTT trials, a 21-gauge needle will be used to draw blood from a forearm vein twice (baseline and 4 hours post-meal). We will draw ~5 mL pre- and post-meal. Therefore, we will draw a total of ~10 mL over the course of the visit.

IV placement and saline infusion: A catheter will be inserted into a forearm vein and connected to an IV line that will slowly infuse saline (0.9% NaCl solution) in order to keep the line clear. We will use a small diameter needle that will cause minimal discomfort. IV catheters allow us to make repeated blood draws from the same port without needing to continually poke participants with a needle. The catheter will be held firmly in place with film dressing, allowing you to move about the lab comfortably. There is no risk associated with saline infusion – it is 99.1% water and 0.9% salt. We will draw ~40 mL of blood each SL trial.

High-fat shake consumption: You will consume the same high-fat shake in all 4 meal trials. The shake will consist of **coconut milk**, **chocolate syrup** and **protein powder**. The amount of shake you consume will be based on your body mass: 9 Calories per kilogram of body mass. Water will be available to you during the meal and throughout the post-meal period.

Participation in the study involves the following time commitment:
Screening visit: ~1 hour
AFTT visit 1: ~5 hours (~1 hour in the lab, ~4 hours out of the lab)
AFTT visit 2: ~5 hours (~1 hour in the lab, ~4 hours out of the lab)
SL visit 1: ~7 hours
SL visit 2: ~7 hours
Total time commitment for study: ~23 hours
Total time commitment for study in the laboratory: ~17 hours

Biospecimen Sampling for Research:
We will be collecting blood samples to measure metabolic markers. Metabolic markers will be measured in whole blood. Then these blood samples will be centrifuged and we will extract the serum (watery portion). Your red blood cells will be discarded.

The type of specimens that will be stored and where they will be stored: De-identified serum samples will be stored in a freezer in a room that is locked after hours.

The length of time your biospecimen will be stored until they are destroyed: No more than 5 years.

Because your samples will not be linked to your name after they are stored, you cannot withdraw your consent to the use of the samples after they are taken.

Risks and Benefits of Study Participation

The only foreseeable risks involved in this study are related to *DEXA scan*, *finger prick*, *phlebotomy* (single needle sticks in the AFTT trials and catheter insertions in the SL trials), and *breach of confidentiality*. These risks are described in the dedicated sections below. In order to assist with the offset of these risks, we are utilizing the most participant-friendly procedures possible to address our research aims. In case of serious injury or illness, we would call 911 and emergency medical treatment will be available through transportation to the nearby student health center or hospital by emergency response professionals. However, this outcome is highly unlikely. No funds have been set aside by Oklahoma State University to compensate you in the event of illness or injury.

DEXA Scan:
If you choose to participate in this study, you will be exposed to radiation from a DEXA scan (which uses X ray). This radiation exposure is necessary to obtain the research information desired related to body composition. You will not be exposed to this radiation if you choose not to participate in the study. The amount of radiation from a DEXA scan is less than 1% of the amount of radiation to which an X-ray technologist is permitted to be exposed in one year. Additionally, a whole-body DEXA scan is equivalent to approximately 3 hours of background radiation (radiation to which we are naturally exposed during daily living). The risk from radiation exposure increases over your lifetime as you receive additional exposure to radiation. If you are a female participant of childbearing potential, a urinary pregnancy test will be provided prior to the DEXA scan to confirm you are not pregnant. You cannot participate if you are pregnant.

Finger Prick:
There is a minor risk associated with this project in that you may experience slight pain when we pierce the skin on your finger; however the puncture and blood collecting equipment are part of the commercially available **s**ystems that have been approved by the FDA. Drawing blood from a finger stick may, in rare cases, cause discomfort, bruising, prolonged bleeding and infection at the site of puncture. To minimize risk, we will swab the site of puncture with alcohol to disinfect the area, use disposable lancet and capillary tubes to collect blood and apply pressure to the puncture site following the blood draw to minimize bruising. We will cover the puncture with an appropriate dressing and provide you with information on how to monitor for signs of infection.

Phlebotomy:
Risks of phlebotomy include slight pain/discomfort upon needle insertion, and potential redness and bruising at the site of the insertion. A blood draw may lead to lightheadedness or fainting in some individuals. In order to minimize these risks, we will wipe the site of the blood draw with alcohol to disinfect the area, use disposable sterile needles and tubes to collect blood, and apply pressure to the site following the blood draw to minimize bruising. To protect against infection, we will also provide instructions on how to care for the puncture site and watch it for signs of infection. The longer an IV catheter is left in place, the more common it is for redness or infection to develop. It is important to know that these blood tests performed in the study are strictly for research purposes. The researcher using your blood sample is not a physician and therefore not qualified to make clinical recommendations. Furthermore, no physicians will review the results of these blood tests, as the researchers are not using this test to make a diagnosis.

Breach of Confidentiality: The risk of breach of confidentiality and our efforts to minimize this risk are stated in the "Confidentiality" section on the following page.

The benefits to participation are: Your metabolic and body composition results can be shared with you, if desired. Some individuals find this personal health information very interesting. However, we cannot guarantee or promise that you will find this study or its associated information beneficial.

Compensation

For participating in this study, you will be compensated $100. This will be distributed to you in cash at the conclusion of your final meal assessment.

Confidentiality

The information that you give in the study will be handled confidentially. **Your information will be assigned a code number.** Your name will not be used in any report, nor will it be used alongside your study data. Despite these considerations, there is always a risk of breach of confidentiality.

How we will protect your data/information: We will collect your information through paper surveys and metabolic assessments. Coded paper surveys and data sheets will be stored in a locked filing cabinet in a locked laboratory. Data will be stored electronically on a password-protected program on a password-protected laptop that does not leave the locked laboratory, and backed up on an encrypted and password-protected external hard drive. This informed consent form will be stored in a separate locked office, in a locked filing cabinet. It will be kept for 3 years after the study is complete, and then it will be destroyed. Your data collected as part of this research project, will not be used or distributed for future research studies.

It is unlikely, but possible, that others responsible for research oversight may require us to share the information you give us from the study to ensure that the research was conducted safely and appropriately. We will only share your information if law or policy requires us to do so.

Voluntary Nature of the Study

Your participation in this research is voluntary. There is no penalty for refusal to participate, and you are free to withdraw your consent and participation in this project at any time. The alternative is to not participate. On the questionnaires, you can skip any questions that make you uncomfortable and can stop at any time.

Termination of Participation:

Your participation may be terminated by the investigator without regard to your consent in the following circumstances:

- Your fasting metabolic panel at the screening visit reveals that you have elevated metabolic values.
- You do not comply with lifestyle controls (i.e. fasting) prior to meal assessments.

Contacts and Questions

The Institutional Review Board (IRB) for the protection of human research participants at Oklahoma State University has reviewed and approved this study. If you have questions about the research study itself, please contact the Principal Investigator at 405-744-2303, sam.emerson@okstate.edu. If you have questions about your rights as a research volunteer or would simply like to speak with someone other than the research team about concerns regarding this study, please contact the IRB at (405) 744-3377 or irb@okstate.edu. All reports or correspondence will be kept confidential.

You will be given a copy of this information to keep for your records.

Statement of Consent

I have read the above information. I have had the opportunity to ask questions and have my questions answered. I consent to participate in the study.

Indicate Yes or No:

I give consent to be contacted for follow-up in this study or future similar studies:

___Yes ___No

Signature: _____ Date: _____

Signature of Investigator: _____ Date: _____