Science for a Quality Life
AUBURN UNIVERSITY
COLLEGE OF HUMAN SCIENCES

AUBURN UNIVERSITY
COLLEGE OF EDUCATION

NOTE: DO NOT SIGN THIS DOCUMENT UNLESS AN IRB APPROVAL STAMP WITH CURRENT DATES HAS BEEN APPLIED TO THIS DOCUMENT.

Informed Consent

For a Research Study Titled:

"Peanut protein supplementation to augment muscle growth and improve markers of muscle quality and health"

A description of this clinical trial is available https://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 Web site at any time.

General information	You are asked to take part in a research study. This study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described in this document.
Purpose	The purpose of this study is to examine skeletal muscle adaptations that occur over 10 weeks of weight training with or without peanut protein powder supplementation. **You cannot participate if you are allergic to peanuts.**
Duration and visits	You will visit the School of Kinesiology for a consent visit, 2 longer testing sessions, and 20 training sessions. This will total about 30 hours over 11 weeks.
Overview of procedures	1) Report to the School of Kinesiology to provide written consent, and fill out a medical history questionnaire (~30 min) 2) Report to the School of Kinesiology after an overnight fast to perform baseline testing (called T1-1) (~2 hours) where you will perform low-dose radiation x-ray tests and other tests to assess muscle mass, and consume milliliter amounts of heavy D2O water 3) Report to the School of Kinesiology for a visit 24 hours following T1-1 (and again overnight fasted) to donate your first muscle biopsy and blood sample, donate a stool sample, complete your first exercise bout, and donate a saliva sample (~2 hours) 4) Report to the School of Kinesiology for a visit 48 hours following T1-1 to donate a 2nd muscle biopsy, and donate a saliva sample (~30 minutes) 5) Report to the School of Kinesiology 2 times weekly over 10 weeks to perform whole-body weight training workouts (~60 minutes each) 6) Report to the School of Kinesiology for a visit 72 hours following your last workout complete post-intervention assessments including low-dose radiation x-ray tests to assess muscle mass, donate a 3rd and final muscle biopsy from your leg, donate a 2nd and final blood draw, and donate a 2nd and final stool sample (~2 hours)
Risks	1) low risk that an adverse event can occur during exercise 2) discomfort or bruising from muscle biopsies 3) discomfort or bruising from blood draws 4) exposure to low-dose x-rays
Benefits	You may enjoy strength training.
Alternatives	The alternative is to not participate in this study.

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Screening protocol and other details related to COVID-19 (added 7-28-2020)

****Constructed to be in line with Auburn IRB COVID-19 Guidance March 27, 2020 (updated April 22, 2020 and June 4, 2020)*

Note, on your medical history form are questions related to COVID-19. We have already asked you these questions over the phone prior to this face-to-face visit, but ask that you answer these questions in writing as well.

Throughout the study, we will continue to ask as to whether or not any of those conditions apply to you.

Also note that there are other precautions taking place to mitigate your exposure to COVID-19. These precautions will be highlighted throughout this document.

If you have questions related to your risk of contracting the virus, please ask a staff member and they will be happy to answer questions.

Additionally, please visit https://cws.auburn.edu/ovpr/pm/irb-covid19-precautions for more details regarding safety precautions being taken by research staff throughout this study.

You are invited to participate in a research study to evaluate the adaptations in skeletal muscle that occur in response to 10 weeks of weight training with or without peanut protein supplementation.

You were selected as a potential participant because:

1) are a male or female between the ages of 18-30 years with a body mass index (body mass/height squared) less than 35 kg/m2
2) **do not have a known peanut allergy**
3) have not been actively participating in resistance training for more than 2 days/week
4) are free of metal implants that will interfere with x-ray procedures
5) have not had any medically necessary radiation exposure in the last six months (except dental x-ray)
6) are free of any known overt cardiovascular or metabolic disease
7) have a blood pressure averaging less than 140/90 mmHg (with or without medication)
8) are free of any medical condition that would contradict participating in an exercise program, giving blood or donating a skeletal muscle biopsy (i.e. blood clotting disorder or taking blood thinners)
9) are not pregnant or trying to become pregnant

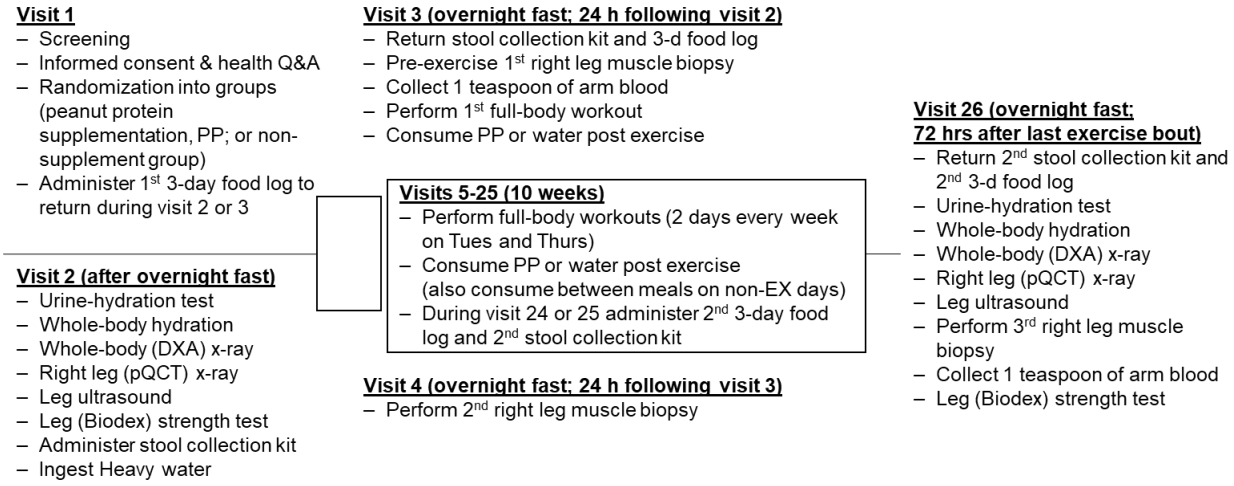
Initials: _____

What will be involved if you participate?

If you decide to participate in this research study as a participant, you will be asked to visit the School of Kinesiology on 26 separate occasions for a total hour commitment of approximately 30 hours.

A schematic of the study timeline is provided on the next page and, following the schematic, specific information pertaining to each individual visit is provided.

Figure 1. Study schematic for study. Abbreviations and testing procedures are noted on the next pages.



Details related to COVID-19

****Constructed to be in line with Auburn IRB COVID-19 Guidance March 27, 2020 (updated April 22, 2020 and June 4, 2020)*

All visits will involve close interaction between you and staff due to testing procedures.

We ask that you wear a cloth face covering during these visits (see the www.cdc.com for guidance on cloth face coverings for reference.)

Research Personnel that come within 6 feet of you will be wearing gloves, a face shield or goggles, and a surgical mask. We will be disinfecting testing equipment surfaces between participants with either 10% bleach or 0.5% hydrogen peroxide.

Finally, we will ensure that all Research Personnel do note present symptoms related to COVID-19 prior to their dealings with you as a research participant during these visits.

Initials: _____

Visit #1 (~30 min): consent and pre-screening

You will report to Kinesiology Building room 260 for:

An initial consent, medical questionnaire (room 260). During this session you will consent to or decline participation. If you consent, you will fill out a brief medical history questionnaire and the PI or a lab member will explain the sequence of testing events for the study. If you are a female, you will be asked to complete a urine-based pregnancy test because DXA and pQCT could be harmful to a baby in utero.

***Group assignment, and conversation regarding study design and instructions*:**
Prior to leaving, we will tell you whether you will be assigned to the peanut protein powder supplementation group or non-supplementation group. The non-supplementation group will receive a 10-week supply of peanut protein powder after completion of the study. A staff member will also speak with you regarding the study design and scheduling. You will then sign up for available times to train between the hours of 5:00 AM – 8:00 AM, or 4:00 PM to 7:00 PM on Tues and Thurs. It is critical to understand that you are committing to complete ***all*** training sessions, and missing more than 3 training sessions or committed times is grounds for complete removal from the study.

***Stool collection kit and 3-day food log (to return during Visit #3)*:**
We will give you a stool collection kit that you will use the day before Visit #3. The kit contains a device that attaches to the toilet lid and a tube with an attached spoon to collect the sample. Immediately after collection, you will place the sample tube in a bag and into your home freezer until Visit #3.
We will also give you a 3-day food log to fill out and return during Visit #3. We ask that you record all food and drinks consumed during the 3 days prior to collecting your stool sample. For example, if Visit #3 is on a Thursday, you will record the food log for Sunday through Tuesday, collect the stool sample on Wednesday, then bring the frozen sample and food log to Visit #3 on Thursday.

Visit #2 (~2 hours): Pre-testing or "T1-1"

You will report to Kinesiology Building room 260 after an overnight fast for:

Height & weight (room 260). You will be asked to remove your shoes and your height and weight will be measured using a standard balance scale.

Urine hydration testing (room 260). You will then be given a disposable cup and be instructed to proceed to the restroom and urinate in the cup. You will then leave the cup on the urinal and a lab member will go into the bathroom and retrieve it to analyze the specific gravity using a refractometer. The purpose of this test is to ensure adequate

Initials: _____

hydration for the body composition testing. Rarely are subjects inadequately hydrated. However, if you do present a urine gravity value of >1.030, then we will ask that you consume 20 fluid ounces of water (provided from a drinking fountain), and we will re-test your urine within a 30-minute window."

Whole-body hydration and body fat testing (room 260). Following urine specific gravity testing, you will undergo a method of body composition measurement calculated by analyzing the rate at which a small, harmless amount of electrical current travels through your body while standing on a scale and holding two hand-held attachments.

Whole-body x-ray scan for body composition testing (DXA) (room 125). You will then be walked downstairs to KINE room 125 and will have your body composition tested using a 'DEXA scanner'. The scan requires you to remain still for 7-10 minutes. During the scan, a low-dose x-ray beam will pass through the entire body. According to the scientific literature, the total radiation exposure is less than that of an airline flight from California to New York and back.

Please note these DXA scans are NOT being conducted for clinical purposes which means they are not designed to assess any medical condition you may have. They are being conducted for research purposes only and are not designed to reveal any existing disease or pathology. If however your scan reveals any unexpected findings given your medical history, it will be reviewed by a physician and he will communicate to you if there is a need to follow up with your preferred physician.

Right-leg x-ray scan (or pQCT) (room 128). You will then be asked to undergo a pQCT scan of your upper right leg (thigh region). Prior to being positioned in the scanner, a trained technician will explain the scan which you will undergo and ask if you have any further questions. All that is required of you is to sit as still as possible with your leg positioned inside the scanner. During the scan, a low-dose x-ray beam will pass through a very small section of your leg. This scan allows us to measure certain properties of your bone, muscle and fat. This scan will take approximately 5 minutes to complete.

Please note the pQCT scan is NOT being conducted for clinical purposes which means they are not designed to assess any medical condition you may have. They are being conducted for research purposes only and are not designed to reveal any existing disease or pathology.

Ultrasound assessment for muscle thickness (room 260). Following the pQCT test, you will be escorted to KINE room 260 for ultrasound testing. This test will require you to lie down on an athletic training table in supine body position (i.e., face facing up), whereby ultrasound pictures will be taken of the outside portion of the right thigh. This is done by placing a hand-held ultrasound probe on top of the skin and using a small amount of hypoallergenic transmission gel.

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Biodex strength testing of the legs (room 136). You will perform a brief series of force production assessments where you will be seated, and fastened to a seat with expressed comfort and asked to produce as much force as possible during knee extension or leg kicking exercise.

Heavy Water (D_2O). Upon completion of the BioDex you will be given Deuterium Oxide (Heavy Water) dosed in the amount of 0.5 ml/kg of fat-free body mass. Heavy water is an isotope of water that is in fact already present in small amounts within drinking water (~0.02%). It Is called heavy water because it is approximately 10% more dense than normal water; 20 fluid ounces of heavy water will weigh 22 ounces instead of 20 ounces. There are no health risks associated with heavy water. Almost half of your body water is replaced on a weekly basis, so after you stop consuming heavy water it will take ~20-30 days to for your body water to return to its normally very low Deuterium Oxide levels. You will be required to drink about 2.5 cups of Deuterium Oxide water during Visit #2. To ensure proper enrichment of the Deuterium Oxide in the body, you will be required to donate saliva samples during the next 2 visits. Potential side effects, although rare, are reports of feeling dizzy within the first 2-3 hours of consuming the product and this generally declines over time (within 2-3 hours of consumption). The purpose of drinking heavy water is to determine your muscle's ability to synthesize muscle proteins during the study. In particular, the heavy water that you consume will be used as a "tracer" which integrates in muscle proteins that are actively being synthesized. We believe that this tracer will indicate that resistance training increases muscle protein synthesis rates and that peanut protein might further increase this rate.

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Visit #3 (~2 hours): Biopsy and 1st Workout or "T1-2"

You will report to Kinesiology Building room 260 after an overnight fast. We ask that you return your stool sample to study personnel. Thereafter you will complete the following tests:

Blood draw (room 260). You will be asked to sit in a phlebotomy chair, or lie down on an athletic training table, and have blood drawn from a vein in the front of your elbow. Approximately 1 teaspoon (6 milliliters) of blood will be collected using sterile supplies and techniques. The site will be cleaned and bandaged following the blood draw and you will be given instructions to minimize bruising or discomfort. In addition, in the extraordinarily rare event that you require medical care following the blood draw, you will be referred to go to the on-campus medical clinic or a clinic in the Auburn area.

Muscle biopsy collection from the right upper/outer thigh region (room 260). Next, a skeletal muscle biopsy will be performed in order to determine your muscle fiber type (e.g., predominantly fast or slow fibers) and size. The person collecting the biopsies (Dr. Roberts) will explain the procedure. Dr. Roberts will then prepare your right middle/outer thigh for the collection of a muscle specimen. Below outlines the events involved with this procedure:

1. You will lie on a training table and the outer aspect of the respective mid-thigh will be shaven with electronic clippers.
2. The person collecting the biopsies will then garb in a clean lab gown and sterile gloves.
3. 4 'dots' will be drawn with a Sharpie marker on the respective leg to denote where the injection and incision sites are to be made (this will be referred to as the 'collection field').
4. The shaven portion of the leg will be cleansed with sterile, single-use alcohol swabs.
5. 0.5 cc of 2% Lidocaine will then be injected subcutaneously within the collection field to de-sensitize pain receptors using a very small needle. During this time, you may feel a slight 'burning' sensation due to the Lidocaine entering the sub-dermal layer. This agent will be allowed to take effect for 5 min.
6. 0.5 cc of 2% Lidocaine will then be injected deeper within the collection field to further de-sensitize pain receptors. This agent will be allowed to take effect for 5 min. During this time, the collection field and 2 inches beyond the collection field will then be swabbed with a sterilizing solution (Hibiclens).
7. A sterile drape will then be placed atop the leg.
8. After the 5-min waiting period a sterile/single-use no. 11 blade will be used to make a 1 cm incision (the width of your pinky nail) in the center of the collection field in order to facilitate the procedure. Any immediate bleeding will be swabbed with

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sterile gauze, although excessive bleeding in this area of the leg usually does not occur. After use, the blade will be placed in a sharps biohazard container and the soiled gauze pads will be placed in a biohazard container.

9. A sterilized biopsy needle (attached to a 60cc syringe with polyethylene tubing) will then be inserted into the pilot hole and will be pierced through the fascia (total depth ~2 inches, or 5 cm). Once the needle breaches the fascia, Dr. Roberts will apply an upward and downward motion to the needle which excises ~200-300 mg of muscle tissue (which is roughly the size of a no. 2 pencil eraser). During this aspect of the biopsy, you should not feel sharp pain due to the administered lidocaine and will only feel pressure from the biopsy needle which is akin to a muscle cramp. This portion of the procedure typically lasts 2-3 seconds.
10. The needle will be removed from the leg, large sterile gauze pads will be placed atop the pilot incision, and pressure will be held by the investigator for up to 10 min.
11. Following pressure application on the collection field, the pilot incision will be pinched shut and a butterfly bandage will be applied to keep the pilot incision closed.
12. Triple antibiotic will be applied around the incision site, sterile gauze will be placed atop the butterfly bandage, and a large adhesive bandage will be placed atop the collection site.
13. Dr. Roberts or a staff member will hand you a biopsy care sheet to abide by in order to optimize wound closure from the procedure and ***ask that you return to the laboratory 24 hours after your testing session so that they can examine the collection sites (5 min visit)***.

The muscle biopsy procedure possesses imminent discomfort, but very minor health risks. Dr. Roberts has collected an estimated ~1,000 muscle or fat biopsies since 2014 under Auburn University IRB-approved protocols. Based upon Dr. Roberts' experience of performing the procedure at Auburn University, the following observations have been made:

a. All participants will sense 2-3 seconds of moderately uncomfortable pressure in the quadriceps muscle during the procedure (Wong-Baker scale rating 4-6 on the scale below).
b. After the lidocaine wears off (2-3 hours following the procedure), all participants will feel like he/she has a deep bruise at the collection site for up to 12 hours following the procedure (scale rating 2-4).
c. 19/20 participants have reported a pain scale of "0" the next day when the site is examined, and bandages are replaced.
d. 1/19 participants still report the feeling of a bruise at the collection site that lasts up to 48 hours (scale rating 2-4).

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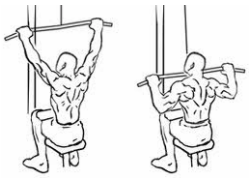
Following your biopsy you will then perform your first full-body workout which will consist of the following exercises:

Exercise	# of sets	# of repetitions per set
Bench press	3	8-12*
Cable-bar pull-down	3	8-12*
Leg press	3	8-12*
Leg extension	3	8-12*
Leg curl	3	8-12*

*indicates that the last repetition per set is challenging to complete

Exercises are pictured below:


Bench press


Cable-bar pull-down


Leg press


Leg extension


Leg curl

Immediately after the exercise bout your will be given 72 grams of peanut protein supplement to consume with water (if you are in the PP group), or you will consume water from a drinking fountain (if you are in the non-supplement group).

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Visit #4 (~30 min): 2nd Biopsy or "T1-3"

You will report to Kinesiology Building room 260 after an overnight fast. We ask that Thereafter, you will donate a 2nd muscle biopsy out of your right leg as discussed above.

Visits #5-25 (~60 min each): workouts and supplementation

On Tuesdays and Thursdays between 5:00 AM to 8:00 AM, or 4:00 PM to 7:00 PM we will ask that you report to the School of Kinesiology for your workouts.

Workouts will include the following:

Exercise	# of sets	# of repetitions per set
Bench press	3	8-12*
Cable-bar pull-down	3	8-12*
Leg press	3	8-12*
Leg extension	3	8-12*
Leg curl	3	8-12*

*indicates that the last repetition per set is challenging to complete

Workouts will be twice per week over a 10-week period. If you miss more than 3 workouts we will have to remove you from the study due to non-compliance and issue partial compensation described below.

If you are in the peanut protein supplementation group, you will be asked to mix 72 grams (2 of the provided scoops) with 10-24 ounces of water, which contains 32 grams of protein and 280 total calories. You will need to consume the protein supplement following each workout (on workout days), and between meals during all other days of the week. Study staff will administer 1-2 week supplies of peanut protein powder to you on a routine basis throughout the study as you report to training sessions.

Finally, a 2nd 3-day food log and materials for a 2nd stool collection will be given to you during the last week of training to complete and return during post-intervention testing described below.

Visit #26 (~2 hours): Post-testing or "T2"

You will report to Kinesiology Building room 260 72 hours following your last workout after an overnight fast. We ask that you return the 2nd stool sample kit and 2nd 3-day food log. You will then perform the following tests as described above:

- ***Weight (room 260)***
- ***Urine hydration testing (room 260)***

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- ***Whole-body hydration and body fat testing (room 260)***
- ***Whole-body x-ray scan for body composition testing (DXA) (room 125)***
- ***Right-leg x-ray scan (or pQCT) (room 128)***
- ***Ultrasound assessment for muscle thickness (room 260)***
- ***Biodex strength testing of the leg (room 136)***
- ***Muscle biopsy and blood draw (room 260)***

Answers to potential questions

Are there any risks or discomforts? The risks associated with participating in this study are:

1) The chance of a hematoma (bruise) formation from the muscle biopsy procedure or venipuncture.
2) Mild discomfort (i.e., pressure) from the muscle biopsy procedure or venipuncture.
3) There is a very rare chance that muscle biopsy can lead to dull pain beyond the day of testing, become infected, or produce non-stop bleeding. To this end, hundreds of studies have been performing this procedure, and many of these studies have been performed on non-medical campuses. Furthermore, Dr. Mike Roberts is an expert of this procedure, and have performed hundreds using sterile techniques without any complications. It should be also noted that Highstead et al. (J Appl Physiol. 2005 Apr;98(4):1202-6) reported that only 18/1,301 participants experienced a hematoma after collection, only 2/1,301 participants experienced a persistent bleeding/oozing, only 4/1,301 participants experienced pain longer than 3 days after collection, and 0/1,301 participants experienced infection. Additionally, Dr. Roberts has performed hundreds of muscle and fat biopsies on Auburn's campus and has reported no adverse events or complications from this procedure. Hence, this procedure presents minimal risk to the participant when done using sterile techniques and the subject does not present blood clotting issues. **Please be upfront on the medical history questionnaire about being on blood-thinning medications and/or having a condition which prevents blood clotting and verbally let an investigator know that you are on them.**
4) There is the risk that an allergic reaction may occur to lidocaine or peanut protein. **To reduce this risk, we will ask that you are upfront about all allergies in the medical history questionnaires and verbally tell the investigators any allergies that you may have.**
5) Mild discomfort (i.e., muscle soreness) from resistance training. Delayed onset muscle soreness is a likely consequence of exercise training and is not unusual. The muscle soreness is not considered a risk, but a nuisance that resolves itself over time. If muscle soreness from training becomes unbearable you will be allowed to discontinue the study at any time.

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6) The Biodex machine is a form of exercise testing. There is an extraordinarily low risk that an adverse event can occur during exercise testing. To this end, and according to the 2009 ACSM Guidelines for Exercise Testing and Prescription, the risk of death associated with exercise testing is 0.05 percent of 10,000 people in a healthy population.
7) You will be exposed to radiation during DEXA and pQCT scans which are low-dose x-ray procedures. This research study involves exposure to radiation from 3 DEXA scans and 4 pQCT scans. This radiation is not necessary for medical care and is for research purposes only. Participants will receive radiation exposure of approximately 0.003 mSv from each DEXA whole body scan and 0.002 mSv for each pQCT leg scan for a total of 0.01 mSv. Critically, this amount which is less than the radiation received in ~2 days from natural background radiation (~ 3 mSv/yr), such as naturally occurring radioactivity in soil. Furthermore, when a person receives radiation as part of a research study at Auburn, their extra radiation dose is limited by Auburn University to 1 mSv, which is the annual regulatory limit for the general public set by the U.S. Nuclear Regulatory Commission. Any risk from this amount of radiation is too small to measure directly, and is small when compared to every day risks. Although the amount of radiation received in this study is minimal, it is important for you to be aware that the risk from radiation exposure is cumulative over a lifetime. **To reduce the risk of too much exposure, we ask that you be upfront about x-ray exposure in your health history questionnaire.**

Are there any benefits to yourself or others?
You may enjoy the workout regimen.

This study will benefit the scientific community and sports performance practitioners by obtaining data which supports or refutes using a peanut protein supplement for enhancing resistance training adaptations.

Will you receive compensation for participating? To thank you for your time you will receive $500 upon completion of the study.

If you miss more than 3 workouts (which would equal less than a 90% compliance rate to the protocol) then you will be disqualified from the study.

Partial compensation will be allowed as follows:
-Completion of baseline testing (T1-1), but discontinuation of study: $100
-Completion of T1 and 2-8 weeks of training before dropping the study: $200

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Are there any costs for participating? If you decide to participate, you will not be monetarily charged for anything. In the unlikely event that you sustain an injury from participation in this study, the investigators have no current plans to provide funds for any medical expenses or other costs you may incur.

If you change your mind about participating, you can withdraw at any time during the study. Your participation is completely voluntary. If you choose to withdraw, your data can be withdrawn as long as it is identifiable. Your decision about whether or not to participate or to stop participating will not jeopardize your future relations with Auburn University or the School of Kinesiology.

Your privacy will be protected. Any information obtained in connection with this study will remain confidential. Information obtained through your participation may be published in a professional journal and presented at a professional scientific meeting. However, you will be assigned a participant code upon agreeing to partake in the study and any discussion regarding your data will be associated with your participant code. Only de-identified data will be used to disseminate scientific results, and no one will use this data for commercial use (i.e., marketing).

If you have questions about this study, please ask them now or contact:
Morgan Smith at mas0216@auburn.edu or Casey Sexton cls0087@auburn.edu or Krissy Smith at kss0034@auburn.edu or Drew Frugé at adf0003@auburn.edu

A copy of this document will be given to you to keep. If a copy is not offered to you, please verbally request a copy from the PI or a lab member.

If you have questions about your rights as a research participant, you may contact the Auburn University Office of Research Compliance or the Institutional Review Board by phone (334)-844-5966 or e-mail at IRBadmin@auburn.edu or IRBChair@auburn.edu.

HAVING READ THE INFORMATION PROVIDED, YOU MUST DECIDE WHETHER OR NOT YOU WISH TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES YOUR WILLINGNESS TO PARTICIPATE AND AGREEMENT TO ADHERE TO THE PROTOCOL AS DESCRIBED.

_____	_____
Participant's signature Date	Investigator obtaining consent Date
_____	_____
Printed Name	Printed Name

Initials: _____

Information on COVID-19 For Research Participants

Auburn University recognizes the essential role of research participants in the advancement of science and innovation for our university, community, state, nation, and beyond. Therefore, protection of those who volunteer to participate in Auburn University research is of utmost importance to our institution. As you are likely aware, COVID-19 references the Coronavirus that is being spread around the world including in our country, state, and community. *It is important that we provide you with basic information about COVID-19 and the risks associated with the virus so that you can determine if you wish to participate or continue your participation in human research.*

How is COVID-19 spread? COVID-19 is a respiratory virus that is spread by respiratory droplets, mainly from person-to person. This can happen between people who are in close contact with one another. It is also possible that a person can get COVID-19 by touching a surface or object (such as a doorknob or counter surface) that has the virus on it, then touching their mouth, nose, or eyes.

Can COVID-19 be prevented? Although there is no guarantee that infection from COVID-19 can be prevented and no vaccine is currently available, there are ways to minimize the risk of exposure to the virus. Examples include but are not limited to, "social distancing" where individuals physically distance themselves from others (a minimum of 6 feet is often used as a standard distance); using effective barriers between persons; wearing personal protective equipment like masks, gloves, etc.; washing hands with soap and water or sanitizing hands after touching objects; disinfecting objects touched by multiple individuals, etc.

What are the risks of COVID-19? For most people, COVID-19 causes only mild or moderate symptoms, such as fever and cough. For some, especially older adults and people with existing health problems, it can cause more severe illness. While everyone is still learning about this virus, current information suggests that about 1-3% of people who are infected with COVID-19 might die as a result.

Who is most at risk? Individuals over age 65 and those with chronic conditions such as cancer, diabetes, heart or lung or liver disease, severe obesity, and conditions that cause a person to be immunocompromised have the highest rates of severe disease and serious complications from infection.

What precautions should be taken? Based on the proposed research, precautions for the risk of COVID-19 will be addressed on a project by project basis. You will be provided with information about precautions for the project in which you may participate. Any site where research activities will occur that are not a part of Auburn University (offsite location) are expected to have standard procedures for addressing the risk of COVID-19. It is important for participants to follow any precautions or procedures outlined by Auburn University and, when applicable, offsite locations. Further, participants will need to determine how best to address the risk of COVID-19 when traveling to and from research locations. The US Center for Disease Control and Prevention has issued recommendations on types of prevention measures you can use to reduce your risk of exposure and the spread of COVID-19.

Auburn University is continuing to monitor the latest information on COVID-19 to protect our students, employees, visitors, and community. Our research study teams will update participants as appropriate. *If you have specific questions or concerns about COVID-19 or your participation in research, please talk with your study team.* The name and contact information for the study team leader, along with contact information for the Auburn University Institutional Review Board for Protection of Human Research Participants, can be found in the consent document provided to you by the study team.

Initials: _____