Document Coversheet

Study Title: Exercise-induced Skeletal Muscle Exosomes Promote Adipocyte Lipolysis

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	3/17/2022
NCT Number:	NCT04500769
IRB Number	43910
Coversheet created:	8/3/2023

Consent and Authorization to Participate in a Research Study

KEY INFORMATION FOR Training Induced Muscle Exosome Release (TIMER)

We are asking you to choose whether or not to volunteer for a research study about certain molecules that may play a role in physiological adaptation after exercise. We are asking you because you are generally healthy and not currently performing structured exercise. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn how small molecules communicate between different tissues in your body ad how exercise may alter these molecules. Your participation in this research will require approximately 7- 8 hours divided over 4 research visits.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By participating in this study, you are helping the investigators find biomarkers that may predict those people who do not respond to exercise as effectively, based on fitness or age. In addition, you will be given information about your health and physical function as it relates to this study. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

The key reasons why you would not want to volunteer for this study are mainly related to the time required and to the study procedures. The samples that we collect for this study are blood, muscle, and fat tissue which require a needle procedure. Thus, if you are scared of needles or scar easily, you may not want to volunteer. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or class grade(s).

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Douglas Long, research coordinator, at delong2@uky.edu or Charlotte Peterson (Principal Investigator, PI) of the University of Kentucky, Department of Rehabilitation Sciences at cpete4@uky.edu

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study to determine the time course of certain molecules called microRNAs that are released from your muscle in vesicles and are circulating in your bloodstream after an acute exercise bout that may end up in your fat tissue causing increased fat metabolism. Aging differences in muscle tissue repair following resistance exercise will also be studied. You are being invited to take part in this research study because you are between 18 and 39 or 65 years of age and older and are considered healthy. If you volunteer to take part in this study, you will be one of about 120 people to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Charlotte Peterson, PhD, of the University of Kentucky, College of Health Sciences. She is being assisted by Douglas Long, M.S., who is also in the College of Health Sciences. They are researchers at the University of Kentucky. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

New evidence suggests that certain molecules called micoRNAs may play an important role in your health and adaptations to exercise. However, information is lacking on how these molecules communicate between different tissues and the time course in which they are altered by exercise. By doing this study, we hope to learn how circulating microRNAs can serve as biomarkers of exercise related traits. In addition, the muscle's ability to repair itself after exercise may be diminished with aging. By studying the differences between old and young muscle, we hope to learn how impairments in the ability of cells to divide may play a role.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

You should not take part in this study if you are under 18 or between the ages of 39 and 65, have uncontrolled blood pressure, smoke, or have been seen by your doctor for any cardiovascular, neuromuscular, or metabolic problems (diabetes). If you are allergic to Betadine or Xylocaine HCL, or have an extreme fear of needles, you will not be able to participate in this study. If you are pregnant or think you may be pregnant, you will also be excluded from the study. Although there are no data that testing while pregnant is harmful, we do not want any additional risks for the participants. If you have any signs of active infection such as headache, fever, chills, or chest congestion with shortness of breath, you should also not participate. Finally, you should not take part in this study if you are currently taking any medication that could affect the outcome of the study including medications that cause excess bleeding such as aspirin, Warfarin, Plavix etc or any steroid or beta-blocker (unless they can be safely stopped).

Your information will be reviewed by our study physician to be sure it is safe for you to participate.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at both the inpatient and outpatient units of the CCTS (Center for Clinical and Translational Science) located in the UK Chandler Medical Center and at the Human Performance Lab located in the Multidisciplinary Building. You will need to come to the CCTS unit located on the 3rd floor (C wing) of the UK Medical Center 3 times for the study and could decide to come for an optional 4th visit. These visits will take approximately 1-3.5 hours.

WHAT WILL YOU BE ASKED TO DO?

You will be required to meet with the research team for approximately seven hours over 3 visits to provide a brief medical history and blood, complete some questionnaires about your normal physical activity, test your strength, perform a leg resistance exercise bout, and provide fat and muscle samples. An optional fourth visit would take approximately 1 additional hour.

Medical Health Questionnaire
You will be asked to fill out a questionnaire that will be used to ask questions about general health, personal and family health history, smoking, and exercise habits. It will also be used to screen for any evidence of cardiovascular, metabolic, neuromuscular disease, or pregnancy. This information may be reviewed by the study physician.

Fasting Blood Draw
An IV line or needle will be inserted and approximately 10-20 ml of blood (2-3 teaspoons) will be taken to perform blood chemistries which will include blood glucose and labs, as well as to isolate for vesicles containing microRNAs. It is required that you arrive without having any food or drink except water for at least 8 hours. The samples that you contribute are the property of the University of Kentucky and any patents or inventions that come indirectly from your samples are also the property of the University of Kentucky. You will receive no monetary compensation from any patents or inventions that might result in part from material that you have donated for the purposes of this research.

Physical Activity Assessment
The International Physical Activity Questionnaire (IPAQ) is a designed to capture and assess occupational, active transport, household, and leisure activities typically performed. You will also be given a physical activity monitor that you will wear over the course of a week which will record your daily physical activity level by how many steps you take.

Body Composition- DXA:
A Dual-energy X-ray absorptiometry (DXA) scan will be performed to determine the bone mineral content and density of your bones and to measure your body composition (amount of muscle and fat you have). This will involve lying on a table for approximately 10-15 minutes. During this time, the investigators will take a scan of your total body. These scan results will serve to allow the research team to consider your performance measures in relation to your body's lower body muscle mass and strength. In addition, you may have a copy of your scan results to share with your physician or health care providers. If you are a woman of child bearing potential, a pregnancy test will be given to ensure that you are not pregnant prior to conducting this procedure.

Lower and Upper Body Muscle Strength
1 Repetition Assessment (1RM):
You may be assessed for the amount of weight that you can lift with your legs and arms one time with proper form. You will be asked to do this for four exercises: squat, leg extension, and leg press as well as lat pulldown. Warmup will be given and proper form and breathing will be shown to accustom you to the exercise.

Resistance Exercise Bout
You will be asked to perform a single resistance exercise session on the same exercise machines. You will be given a warmup that includes cycling and body weight squats and stretching if desired before being asked to perform any lifts. You will perform three sets of eight repetitions and a fourth set until failure with 90-120 seconds of rest in between sets.

Additional Blood Draws
From an IV line, you will have 2-3 teaspoons of blood drawn immediately following your exercise bout and at 30, 60, and 90 minutes following the completion of the exercise. There is the possibility that there may be more if an initial attempt to draw the blood fails.

Fat Biopsy
A small piece of your fat will be removed from your lower abdomen and/or thigh at 2-3 different timepoints, one before and 1-2 after an exercise session. The abdomen fat biopsy requires approximately a 1 inch incision on your lower abdomen to remove approximately 0.5-1g of fat tissue and you will receive the same anesthetic used for the thigh biopsy procedure (described below). The thigh fat will be removed from the same incision made for

the muscle biopsy. A suture will be used to close the incision. You will be provided with some easy take home biopsy care instructions and can have your sutures removed in 7 days on your next visit. The procedure will last approximately 30 minutes.

Muscle Biopsy
Muscle tissue will be taken from your vastus lateralis muscle which is located on the outside of your thigh and will be taken about one hand width above your knee. A 1 inch by 1 inch portion of hair will possibly need to be shaved if necessary. You will then have the area of your thigh numbed with an injected anesthetic (Xylocaine) and a small ¼ inch incision will be made in the skin. A needle will then be briefly (lasting just a couple of seconds) inserted into the muscle to remove a .005 ounce piece of muscle (about the size of a pencil eraser). The incision will be pulled closed with a bandaid after the site is cleaned with an alcohol preparation and your leg will be wrapped snuggly with an elastic bandage. You will be provided with some easy take home biopsy care instructions. The procedure will last approximately 30 minutes. COVID-19 testing may be a requirement prior to a biopsy procedure depending on local guidelines.

Use of specimens for future research
Some blood will be stored indefinitely in the laboratory and may be used in future research approved by the University of Kentucky Medical Institutional Review Board. These samples will be labeled with a code number and not with a name and thus any investigator who may study your sample will not be able to identify you. These blood samples may be used to study biomarkers, such as RNAs, proteins and and/or muscle damage markers.

Your participation requires multiple abdomen fat samples and muscle biopsy samples for this protocol. By initialing and dating the option below you agree to proceed with this sample collection.

Please initial / date only one item:
• You agree to allow a sample of fat to be taken from the abdomen and also agree to allow muscle to be taken from your leg during this research protocol.
Initial _ Date _

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You have been told that the study may involve the following risks and/or discomforts:

Blood Draw
During venipuncture, there may be some slight discomfort experienced from the insertion of the needle into the vein. In addition, with needle insertion, potential infection, soreness, pain, bleeding, bruising, and fainting may occur. This pain and soreness may last up to 24 hrs following the procedure.

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Soreness	It occasionally occurs	Can be easily treated	Yes
Pain	It occasionally occurs	Does not impact your overall health	It will go away within 24 hrs
Bleeding	It occasionally occurs	Can be easily treated	Yes, by applying pressure
Bruising	It occasionally occurs	Can be easily treated	Yes
Fainting	It is uncommon	Can be easily treated by lying down with the legs elevated	Yes, usually in 20 minutes
Infection	It is very uncommon	Can be treated	Yes

Muscle/Fat Biopsy. With the biopsy procedure, there is a risk of bleeding, bruising, soreness, pain, infection, and scarring of the skin. Bleeding could rarely result in development of a hematoma (deep tissue collection of blood). Pain and soreness usually resolves within 24-48 hrs post-procedure. Numbness of the skin near the biopsy site may occur and is usually temporary, but this numbness may persist indefinitely. An allergic reaction to the anesthetic also may occur but is rarely seen. If a COVID-19 test is required, this may also cause some discomfort.

Possible Risk/Side Effect	How often has it occurred?	How serious is it?	Can it be corrected?
Soreness	It usually occurs	Can be treated	It will go away with or without treatment within 24-48 hrs in most cases
Pain	It often occurs	Does not impact your overall health and can be treated	It will go away within 24-48 hrs in most cases
Bleeding	It occasionally occurs and sometimes can lead to a hematoma (deep tissue collection of blood)	Can be treated and hematoma will resolve on its own	Yes, by applying pressure
Bruising	It occasionally occurs	Treatment is not required	Yes, it will fade on its own
Fainting	It is uncommon	Can be easily treated by lying down with the legs elevated	Yes, usually in 20 minutes
Infection	It is very uncommon	Can be treated	Yes
Numbness at the biopsy site	It occasionally occurs	Does not impact your overall health and treatment is not required	Can persist in rare cases
Scarring	It occasionally occurs	Does not impact your overall health	Can persist

Total Body Dual-Energy X-ray Absorptiometry (DXA)
This research procedure involves exposure to a small amount of radiation. As a part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 200 to 300 millirem (mrem) each year. The effective dose from the DXA x-ray procedure is about one (1) mrem. Although the dose is small, accumulated radiation from medical x-rays can theoretically increase the risk of cancer.

Resistance Exercise
It is expected that you will experience some degree of generalized muscular fatigue as a result of the max exercise tests. As with any moderate to high intensity activity, muscle fatigue, joint pain, cramps, feeling of light headedness or dizziness, cardiorespiratory distress, and even death are all possible situations that could arise. In adults without a known history of heart disease, the risk of heart attack or death from maximal or sub-maximal exercise bouts is rare (occurs in less than 6 per 10,000 tests). Since you are performing the test fasting, there is also a greater chance of hypoglycemia. A snack and a beverage will be provided to you following the testing.

Other risks. There is always the possibility for unexpected events, and the medical staff will attend to these. There are no anticipated psychological, financial, legal, or other potential risks associated with the proposed research.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not receive any benefit from taking part in this study. However, finding biomarkers may help us in determining those who do not respond to exercise as effectively, based on fitness or age.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on the quality of medical care you receive.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

All procedures as part of this study are considered research only. The only cost you will experience is your time for participation and travel expenses (gas and mileage) to the University of Kentucky. Parking in the Kentucky Clinic will be validated for all study visits. Therefore, there will be no costs associated with parking for you as long as you park in the Kentucky Clinic parking lots and have your ticket validated by the research team.

The University of Kentucky may not be allowed to bill your insurance company, Medicare or Medicaid for the medical procedures done strictly for research. Therefore, these costs will be paid by the research team.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep private all research records that identify you to the extent allowed by law. Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private. We will collect your social security number for payment purposes only.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is (i.e.,blood results, fitness information). All data will be stored either in locked file cabinets and on secured password protected computers. You will be identified using only a study identification number and the investigators of this study will keep private all research records that identify you. Only personnel associated with this study will have access to the data and to keep information confined. Please be aware, while we make every effort to safeguard your data once received on our servers via REDCap, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still in route to us.

In certain circumstances however, you should know that we are required by law to disclose your information to a court of law as part of an audit or if information is received that may require us to do so. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child being abused or if you pose a danger to yourself or someone else. Additionally, officials of the University of Kentucky may look at or copy pertinent portions of records that identify you in the event of an audit.

Certificates of Confidentiality (CoC):

To help us protection your privacy, this research has a Certificate of Confidentiality. The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

- you have requested us to provide, for instance, to your insurance company or doctor;
- to the sponsor (e.g., National Institutes of Health) or agency auditing the research (e.g., Food and Drug Administration);
- about child or elder abuse, neglect, or harm to yourself or others; and
- about you if it involves a reportable disease.

This policy does not prevent you from releasing information about your own participation in this study.

CAN YOUR TAKING PART IN THE STUDY END EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study. The individuals conducting the study may need to withdraw you from the study if you no longer meet the criteria necessary for

participation. Should this happen you will no longer be asked to participate. This may occur if you are not able to follow the directions they give you or if they find that your being in the study is more risk than benefit to you. It should be known that if you decide to withdraw, any data collected up to that point can remain in the study database and will not be removed.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study as long as there are no medications or physical activity as part of the protocol that would affect the outcome of this study. It is important to let the investigator know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should first call Douglas Long at 859-323-5438 (email delong2@uky.edu) immediately and he will contact the medical supervisor. The medical supervisor for this study is Dr. Philip Kern, M.D. It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. The medical costs related to your care and treatment because of research related harm or information such as cardiopulmonary follow up exams will be your responsibility. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study. You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will be paid $40 for the exercise bout and blood draws during this study, $50 per abdomen biopsy, and $50 per muscle biopsy. Payment will not be received unless you have fulfilled all the requirements of each part of this study. In order for payment to be processed, you must provide your social security number to the research team. This information must be provided in order to be paid in this study. If you make over $600 in research compensation, you may need to report this for tax purposes. Total compensation for this study (including the optional visit) is $400.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, please contact the research coordinator Douglas Long, at 859-323-5438 or 614-313-4835 (cell) or the principal investigator of this study, Charlotte Peterson, at 859-218-0476 for more routine questions. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. We will provide you with individual research results such as data from baseline blood draws, exercise response, or body composition results.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

Do you give your permission to be contacted in the future by Charlotte Peterson and her research staff regarding your willingness to participate in future research studies about muscle health?

☐ **Yes** ☐ **No** **Initials**

WHAT ELSE DO YOU NEED TO KNOW?

There is a possibility that the data/blood/fat/muscle collected from you may be shared with other investigators in the future. If that is the case the data/blood will not contain information that can identify you unless you give your consent/authorization or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.
By signing below, you acknowledge that you have been able to ask questions and express concerns which have been satisfactorily responded to by a member of the research team. You understand the purpose of this study, benefits and risks, and hereby give your informed and free consent to be a participant in this study.

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information or samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers if you allow us to do so.

STORING AND SHARING YOUR INFORMATION OR SPECIMEN SAMPLES FOR FUTURE USE:

The purpose of the bank is to collect and store samples of (tissue, blood, and/or other biologic specimens), along with health information for research purposes. Researchers can then use the stored materials for future research studies to learn more about muscle health. The bank provides a ready supply of samples, so researchers do not have to look for donors for each new study. The goal of the bank is to ask participants of ongoing research projects if they would like to participate. Having samples from many people allows the researchers to identify trends and discover better ways to diagnose, prevent, and treat many conditions. Neither the bank nor researchers who access samples or information from the bank will contact you about future research, unless you agree to allow them to do so below.

WHERE WILL INFORMATION OR SPECIMEN SAMPLES BE STORED AND FOR HOW LONG?

If you agree, the blood and muscle tissue will be stored for an indefinite amount of time in the Center for Muscle Biology Tissue Bank in a lab on the 4th floor in the College of Health Sciences Wethington Building and may be used in future research.

ARE THERE RISKS FROM ALLOWING YOUR INFORMATION OR SPECIMEN SAMPLES TO BE STORED FOR FUTURE RESEARCH?

The investigators would like to keep some of the unused or leftover blood and muscle tissue collected during this study. No additional blood or tissue will be taken and thus, there is no additional physical risk. There is a risk that someone could get access to the stored information or samples. In spite of the security measures and safeguards we will use, we cannot guarantee that your identity will never become known. With genetic testing, even without your name or identifiers, genetic information is unique to you making it possible for someone to trace it back to you. The results of genetic research apply to both you and your family members. Genetic information used improperly to discriminate or support negative stereotypes could cause you or your family distress.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). Generally, GINA makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that GINA does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of an already known genetic disease.

There also may be risks that at this time are unknown. As technology advances, there may be new ways of linking information back to you that we cannot foresee now.

HOW WILL WE SHARE YOUR INFORMATION OR SPECIMEN SAMPLES WITH OTHER RESEARCHERS?

All identifiable information such as your name, medical record number, or date of birth will be removed from the information and samples collected by this bank. After we remove all identifiers, the information and samples may be used for future research or shared with other University of Kentucky (UK) researchers and researchers outside of UK, without your additional informed consent.

WHAT IF YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR INFORMATION OR SPECIMEN SAMPLES?

If you later decide to withdraw your permission for the banking of leftover samples, please contact Charlotte Peterson, PhD; 439 Charles T. Wethington Building, 900 S. Limestone, Lexington, KY 40536-0200 to inform her of my decision and request that your leftover samples be discarded after this protocol is completed.

WILL YOU RECEIVE ANY COMMERCIAL PROFIT FROM FUTURE RESEARCH DISCOVERIES?

The blood and muscle/fat tissue that you are giving will no longer belong to you and might be used in studies that lead to new products for research, diagnosis or treatment. There is no plan to keep you informed of findings from these studies. These products might have some commercial value but there are no plans to provide financial compensation to you should this occur.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE FUTURE RESEARCH TESTS?

Tests done for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information.

If you have questions, please talk to the investigator or staff. Remember, no matter what you decide to do about the storage, and future use of your tissue, you may still take part in this study. If you answer yes below you also give your authorization for your accompanying health information acquired during this study to be used and disclosed along with the tissue. Your protected health information such as your name will be de-identified or coded so that others will not know your identity. Your samples may be shared with UK researchers or those outside of UK and while there is no direct benefit to you, the knowledge gained from additional research may help others in the future.

1. Do you give permission for your blood and/or muscle tissue to be kept by the investigators of this study in labs of the PI located in the Wethington Building at the University of Kentucky, indefinitely or until they are used up for use in future research to learn more about muscle health and disease?

☐ **Yes** ☐ **No** **Initials**

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

I allow (or authorize) Charlotte Peterson, PhD. and her research staff at the University of Kentucky to create, access, use and release my health information for the purposes listed below.

My health information that may be used and released includes:

- Demographic Information (name, initials, sex, race, ethnicity, age, height, weight, address, phone number, study number, social security number)
- Screening information from initial evaluation (health history, labs etc.)
- Results from all questionnaires (physical activity, etc.)
- Results from all physiological exams (blood, muscle, fat, fitness assessment etc.)

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity.
- Law enforcement agencies when required by law.
- University of Kentucky representatives.
- University of Kentucky Medical Center
- Center for Clinical and Translational Science (CCTS)
- Quest Diagnostics
- Other researchers at the University of Kentucky
- Other researchers outside the University of Kentucky

The researchers agree to only share your health information with the people listed in this document and it will never include any protected health information such as your name, DOB, or address with researchers using banked samples for future research.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws. You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the form, it will not affect your:

- **Current or future healthcare at the University of Kentucky**
- **Current or future payments to the University of Kentucky**
- **Ability to enroll in any health plans (if applicable)**
- **Eligibility for benefits (if applicable)**

After signing the form, you can change your mind and NOT let the researcher(s) release or use your health information (revoke the Authorization). If you revoke the authorization:

- I will send a written letter to: Charlotte Peterson, PhD 105B Charles T. Wethington Building, 900 S. Limestone, Lexington, KY 40536-0200 to inform her of my decision.
- Researchers may use and release my health information **already** collected for this research study.
- My protected health information may still be used and released should I have a bad reaction (adverse event).
- I may not be allowed to participate in the study.

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Mon-Fri at: (859) 323-1184.

You are the subject. You have read this information, and you will receive a copy of this form after it is signed.

Signature of research subject _____ Date

Printed name of research subject _____

Name of [authorized] person obtaining informed consent/HIPAA authorization _____ Date

Signature of Principal Investigator or Sub/Co-Investigator _____