

## Combined Consent and Authorization to Participate in a Research Study

### **Novel actions of metformin to augment resistance training adaptation in older adults**

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

You are being invited to take part in a research study attempting to identify new ways to improve muscle mass and strength gains during a resistance exercise program through the use of metformin, a common drug used for diabetes. You are being invited to take part in this research study because you are the age of 65 or older, are considered healthy, and have not participated in a resistance training program in the last year. If you volunteer to take part in this study, you will be one of about 40 people to do so at the University of Kentucky and about 60 people to do so at the University of Alabama at Birmingham.

#### **WHO IS DOING THE STUDY?**

The persons in charge of this study are Charlotte Peterson, PhD, and Philip Kern, MD of the University of Kentucky, College of Health Sciences and College of Medicine. They are being assisted by Douglas Long, M.S., also in the College of Health Sciences. There also may be other people on the research team assisting at different times during the study.

#### **WHAT IS THE PURPOSE OF THIS STUDY?**

Muscle mass and strength help determine a person's quality of life and functional independence. Older individuals often suffer losses of muscle mass and strength. Exercise training by lifting progressively heavier weights over time (progressive resistance exercise training, PRT) is the most effective intervention identified to improve muscular strength, and protect against the loss of muscle during the aging process. In addition, unlike younger people, the muscle's response to exercise is reduced and more variable in older people.

By doing this study, we hope to learn whether a commonly prescribed drug called metformin, can enhance the benefits seen during resistance exercise such as increased muscle mass and strength. Metformin is an approved drug by the Food and Drug Administration (FDA) for use in people with Type 2 diabetes. However, its intended use in this project is investigational and has not been approved by the FDA.

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

You should not take part in this study if you are under the age of 65, have participated in any formal strength training program within the last year, or have any of the following conditions:

- Obesity
- Diabetes
- Impaired kidney function
- Chronic aspirin or NSAID (e.g., ibuprofen) use (unless it can be safely stopped prior to the biopsies), and any other use of an anticoagulant (e.g., Coumadin, Warfarin, Heparins, Lovanox, Angiomax, Rivaroxaban, Dabigatran) or history of bleeding.
- History of alcoholism or liver disease.
- Currently receiving androgen or anabolic therapy.
- Any severe medical condition such as heart failure, uncontrolled hypertension, inflammatory bowel disease.
- Any condition that would prevent you from completing resistance training and all performance tests.
- Any other medical condition that would interfere with testing or increase one's risk of complications during exercise, as judged by the study physicians.
- Lidocaine or metformin allergy (1% lidocaine is the local anesthetic used during the muscle biopsy procedure).
- Known hypersensitivity to metformin.
- History of regular resistance training within the past year (>2x per week consistently).

You will also be examined by one of our study clinicians who may have other concerns that could prevent your participation in the study.

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

The research procedures will be conducted in different departments at the UK Medical Center including the CCTS (Center for Clinical and Translational Science) and the Human Performance Lab (MultiDisciplinary Science Building). You will need to come to the CCTS outpatient research clinic one time for screening to make sure you are eligible for the study. If you are eligible, you will be required to come into the research clinic for an additional 2- 3 visits to complete pre-study procedures. While we anticipate that testing will take two or three visits, unforeseen circumstances may require extra visits to complete all of the testing. Each of these visits will last approximately two or three hours or less. You will also be required to come into the Human Performance Lab to complete 3 days of resistance exercise training per week with a trainer (Monday, Wednesday, Friday) for 14 weeks that will last approximately 1 hour. After training, you will then complete post-study procedures over 2-3 visits lasting approximately two hours. Thus, the total amount of time you will be asked to volunteer for this study is approximately 60-65 hours over the next 4.5 months. Additionally, you may be asked to come into the Human Performance Lab for some follow up testing after your training has finished.

## **WHAT WILL YOU BE ASKED TO DO?**

After an initial phone or web based screen to gather information about your health history, you will be asked to meet with the research team on approximately 2-3 separate occasions to provide and perform the following screens and tasks in the CCTS.

## Screening

### Onsite Clinical Evaluation and Physician Clearance

The onsite clinical evaluation will be used to confirm eligibility into the study based on inclusion/exclusion criteria. You will be seen by either the study physician or study PA to complete a physical exam and additional medical history including questionnaires. This physician clearance must be obtained to assure you do not have any unstable medical conditions or a condition made worse by mild exercise. Previous injuries that may affect exercise will also be reviewed. As part of this exam, you will also have the following which will determine your final eligibility for the study.

1. Resting ECG- electrodes will be placed on your chest to monitor your heart rate and rhythm.
2. Fasting Blood Draw- A standard blood panel similar to what you would have done for a physical will be drawn to look at your glucose, insulin, electrolytes, liver enzyme levels, and other routine tests. We will also use some of your blood for cell isolations.
3. Physical Function Testing

### Study Procedures

#### Short Form 36 (SF-36), Physical Activity Survey, and PROMIS

These surveys are multi-item scales designed to assess health related quality of life and physical activity.

#### Physical Function Testing

You will perform three timed standing balance tests, a timed 4-meter walking speed test, and a timed chair stand test where you will be asked to stand from a chair five times.

#### Oral Glucose Tolerance Test (OGTT)

You will be asked to drink a sweet liquid (sugar water), which contains 75 grams of glucose, followed by blood draws at 30 minute intervals for 2 hours. The total amount of blood drawn will be about 1 tablespoon. This test will determine your tendency towards diabetes.

#### Body Composition- DXA and Circumferences

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. You will also have various areas on your body assessed for the distribution of fat on your body. This will include circumferences (the length around different parts of your body) at your waist, abdominal, and hip.

### Computed Tomography Scan (CT)

A very limited CT scan of your upper leg will be performed to assess the amount of fat and muscle in your thigh. This will involve one of the research assistants making an mark on your mid-thigh with a pen and lying on a table for about 10 minutes or less. The testing done in this study is for research purposes only. Our tests are not diagnostic tests that can rule out any disease. If you have any health concerns, you should raise them with your doctor. The CT scans will be very narrow in scope and will be used to assess the amount of muscle and fat in your leg. Therefore, these scans will not be interpreted by a physician and should not be regarded as medical diagnostic tests. These results will not be provided to you.

### Muscle Biopsies

A small piece of your muscle and/or fat tissue will be removed from your thigh. The 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 (Lidocaine) and a small ¼ inch incision will be made in the skin. A needle or conchotome will then be briefly (lasting just a couple of seconds) inserted into the muscle to remove a 0.005 ounce piece of muscle (about the size of a pencil eraser). Prior to the muscle biopsy, some fat tissue surrounding your muscle may also be removed. The incision will be pulled closed with a bandaid after the site is cleaned with an alcohol preparation and your leg will be wrapped snugly with an elastic bandage. You will be provided with some easy take home biopsy care instructions. The procedure will last approximately 30 minutes.

You will also be assessed in exercise labs located in the College of Health Sciences to perform the following:

### Muscle Strength and Power Testing

You will be assessed for the maximum amount of weight that can be lifted one time with proper form. You will be asked to do this for eight separate exercises using exercise machines: the chest press, leg press, leg curl, leg extension, lat pull down, seated calf raise, triceps pushdown, and bicep curl. Warmup will be given and proper form and breathing will be shown to accustom you to each exercise.

You will also be assessed for the maximum amount of force that you can generate from thigh muscles on a different exercise machine. Muscle strength will be determined in your leg muscle while you are in a seated position. To minimize the use of muscles other than your thigh muscles, you will be stabilized with two shoulder straps, and a waist strap. Your muscle strength will be the highest force generated during three trials of knee extension held in a static position for 3-4 seconds each. Rest periods will be given between each trial. Following this test, your leg power will also be assessed by using a certain percentage of the maximum force you generated during your strength test.

### Dietary and physical activity monitoring

You will be asked to maintain your normal dietary intake throughout the study period. Your food intake and nutrient composition will be assessed by 4 day diet records in which you will tell us what foods you ate over two weekday and two weekend days. Over this same period,

you will be asked to wear a physical activity monitor on your wrist which will record your daily activity.

### **Resistance Exercise Training Intervention**

This study is composed of 2 pre-determined or random groups in which you will have a 50/50 chance of being in either group. One group will receive a common medication used in the treatment of diabetes called metformin (one pill taken twice per day) while the other group will receive a placebo or “fake” medication. You will receive this treatment for two weeks prior to beginning the resistance exercise so that we may investigate its effect on your body. You will continue taking the treatment throughout the remainder of the exercise program. No matter which group treatment you receive, you will complete a progressive exercise program designed to increase muscle strength and size. It will require visiting the College of Health Sciences Human Performance Lab three times per week for 14 weeks.

### **Medication Schedule**

You will be placed into either a metformin or a placebo (nonmetformin) group. Neither you or your trainer will know which group you are in. Each capsule will be 850 mg and you will start by taking increasing doses for two weeks as follows: 1 capsule (850 mg) per day for 7 days, 2 capsules per day (1700 mg) for 7 days, if tolerated. You will continue this dose (1700 mg) throughout the 14 weeks of training. In some subjects, the dose increases may be slower and may not reach 1700 mg/day due to GI side effects. The placebo or nonmetformin capsules will look identical to the metformin capsules, but will contain inert substances, and the escalating dose schedule will be the same.

Progression of Medication	
# of capsules (dose)	Amount of time
1/day (850 mg)	7 days
2/day (1700 mg)	7 days
2/day (1700 mg)	14 weeks

### **Progressive resistance exercise training (PRT)**

The 14 weeks of PRT (42 sessions) will be supervised by trained personnel (exercise physiologists, or senior level physical therapy or athletic training graduate students under the supervision of an exercise physiologist). You will be instructed on proper techniques and continuously monitored so that you can progress. You will be required to train three days per week on Monday, Wednesday, and Friday. Each training session will consist of a warm-up, and 8 exercises to train all major muscle groups (leg press, leg extension, one legged squat, seated calf raise, chest press, lat pull down, biceps curl, and triceps pressdown). On Mondays and Fridays, your intensity will be higher where you will complete 3 sets of 8-12 repetitions at a specified level with rest in between each set. On Wednesdays, resistance loads will be lower and concentrate more on faster movements. Your trainer will work with you to accommodate your schedule. We will also ask that you complete at least three training sessions in a row before completing your follow up testing. Thus, we may ask you to complete some extra sessions or may even give you the flexibility to finish your training a little early if needed.

Long term follow up

If willing, you may be asked to come back to the Human Performance Lab at approximately 26 and 52 weeks after the start of the study to re-evaluate your muscle strength and power, physical function, quality of life, and physical activity levels.

A summary and timeline of all testing procedures has been provided here:

Time Point	Physical Function Testing, Physical Activity Monitoring	CT and Circumferences	Blood draw (20 ml)	Oral Glucose Tolerance Test	Body Composition and Muscle Biopsy	SF-36, PASE, PROMIS modules	Strength and power testing	4 Day Diet Record
Pre-treatment	X	X	X	X	X	X	Familiarization	X
<b>2 weeks of metformin or placebo treatment only (prior to progressive resistance training, PRT)</b>								
Wk 2 (pre-PRT)			X		X		X	
Wk 4							X	
Wk 9 (mid-PRT)			X (CMP only)				X	
Wk 16 (post-PRT)	X	X	X	X	X	X	X	X
Long Term Follow-Up	X					X	X	

## 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

### Oral Glucose Tolerance Testing

You will drink a standard 75 g glucose drink, followed by blood draws through a catheter over 2 hr. There is minimal risk or discomfort from this. Rarely a catheter inflammation/infection can occur.

### Physical Function Testing

The risks involved in motor control testing are minimal and involve the potential for falls. You may wear a gait belt around your waist and will be closely guarded during all physical performance testing. Members of the research team will be present to minimize potential falls.

### Muscle Biopsy

With the muscle 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.

<b>Possible Risk/Side Effect</b>	<b>How often has it occurred?</b>	<b>How serious is it?</b>	<b>Can it be corrected?</b>
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 rarely can lead to a hematoma (deep tissue collection of blood)	Can be treated and 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 will occur	Does not impact your overall health	Can persist

#### Strength and Power Testing/Resistance Exercise

Muscle strength testing and resistance training may be associated with some risk. These risks include muscle tightness, soreness or stiffness, fatigue, and could possibly result in a strained muscle. However, these symptoms are no different than what would normally result as part of any resistance strength testing and are temporary and recoverable. You may experience some temporary discomfort from exertion during exercise. Although this form of exercise is not a severe cardiovascular stress, there is a remote possibility of the feeling of chest pain or even a heart attack.

#### Total Body Dual-Energy X-ray Absorptiometry (DXA) and CT Scan

These research procedures involve 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. The single slice CT scan will impose approximately 23 additional mrem. Although the dose is small, accumulated radiation from medical x-rays can theoretically increase the risk of cancer.



### Metformin/Placebo Treatment

Metformin is generally well-tolerated and causes few adverse side effects, the most common being stomach upset, which we will try to avoid by gradual dose increases over the first 2 weeks which will reach a maximum of 1700 mg/d. The most common side effect of metformin is diarrhea, which usually goes away with continued use. The study physician is an Endocrinologist who use metformin routinely in their clinical practice and is experienced in coaching patients in the use of metformin. Nevertheless, some people may have trouble tolerating metformin, or cannot tolerate a significant dose. If you are experiencing difficulty with the drug, we will slow the pace of dose escalation. If you cannot take at least 850 mg/day, then you may be dropped from the study. The placebo pills contain inert substances and no risks are foreseen.

Continued use of metformin may also cause lactate acidosis, a condition that is very rare and occurs in approximately 0.03 cases per 1000 patients per year. Lactic acidosis is a condition that is described by low pH levels in the blood due to your cells receiving less oxygen than they should which creates higher lactate levels in your blood. It is more common in people with kidney disease. Symptoms of lactic acidosis include nausea, vomiting, hyperventilation, abdominal pain, anxiety, hypotension, and irregular heart rates.

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

### **WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?**

There is no guarantee that you will get any benefit from taking part in this study. However, resistance training is the best intervention to help maintain muscle mass and improve muscle strength and will ultimately improve function and independence. Thus, you have the chance of significantly improving your function within daily life. The risks presented to you in this proposal are minimal and the information that will be obtained from this project will be useful in assessing an effective intervention to maximize muscle size and strength gains in an older age group.

### **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 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. You may, however, decide to participate in your own exercise program outside the University of Kentucky.

## **WHAT WILL IT COST YOU TO PARTICIPATE?**

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.

## **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 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. 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.

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, NIH, or the FDA may look at or copy pertinent portions of records that identify you in the event of an audit.

## **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 procedures and the study intervention and medication will no longer be provided by the investigator and may not be accessible commercially. This may occur if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of scientific reasons.

## **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](mailto:delong2@uky.edu)) immediately and he will contact the medical supervisor. The medical supervisor for this study is Dr. Philip Kern, M.D and can be contacted at 859-218-1394.

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 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 receive \$300 for completing all research procedures as part of this study (all procedures and resistance exercise program). This will be prorated if you decide to withdraw from the study before finishing the resistance exercise program and completing the follow up procedures. You will receive \$75 for initial screening and testing and will receive \$100 for completing the exercise program. If you complete all follow up procedures, you will be paid an additional \$125.

### **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.

## POTENTIAL FUTURE USE

### Banking of tissue and blood specimens

The investigators would like to keep some of the unused or leftover blood and muscle samples collected during this study. No additional blood or tissue will be taken. If you agree, the blood and muscle samples will be stored for an indefinite amount of time and may be used in future research.

Please read each sentence below and think about your choice. After reading each sentence, mark "yes" or "no." 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 blood and muscle samples, you may still take part in this study. If you answer yes to either choice below you also give your authorization for your accompanying health information acquired during this study to be used and disclosed along with the blood and muscle samples. Your protected health information such as your name will be de-identified or coded so that others will not know your identity.

1. Do you give permission for your blood and muscle samples to be kept by the investigators of this study in a central location/specimen bank 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

The blood and fat samples 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.

If you later decide to withdraw your permission for the banking of leftover samples, please contact Charlotte Peterson, PhD; 105B 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.

### Contacting Research Subjects for Future Studies

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

☐ Yes      ☐ No      \_\_\_\_\_ Initials

## WHAT ELSE DO YOU NEED TO KNOW?

There is a possibility that the data/tissue/specimens/blood collected from you may be shared with other investigators in the future. If that is the case the data/tissue/specimen/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.

NIH is providing financial support for this study. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

## **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 (Height, Weight, Age, Gender, Race etc.)
- Screening information from initial evaluation (health history, physical function etc.)
- Results from all questionnaires (SF-36, physical activity, quality of life, diet etc.)
- Results from all physiological exams (blood, OGTT, muscle biopsy, DXA, CT etc.)
- Results from all strength tests (leg extension strength and power, 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
- National Institute of Health (NIH)
- Investigational Drug Service (IDS)
- Center for Clinical and Translational Science (CCTS)
- University of Alabama Birmingham research staff collaborating with this project (UAB)
- Food and Drug Administration (FDA)

The researchers agree to only share your health information with the people listed in this document.

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 or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.**

\_\_\_\_\_  
Signature of research subject or \*research  
subject's legal representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of research subject or  
\*research subject's legal representative

\_\_\_\_\_  
Representative's relationship to  
research subject

\*(If, applicable) Please explain Representative's relationship to subject and include a description of Representative's authority to act on behalf of subject:

\_\_\_\_\_  
Name of [authorized] person obtaining informed consent/HIPAA authorization

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Principal Investigator or Sub/Co-Investigator