Document Coversheet

Study Title: Success of Long-acting Anti-inflammatories After Anterior Cruciate Ligament and Meniscal Injury

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Consent to Participate in a Research Study

The Effect of Various Strength Training Protocols in ACL Reconstructed Participants

When we say “you” in this form, we mean you or your child; “we” means the doctors, researchers and other staff.

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

You are being invited to take part in a research study about the effect of two types of blood flow restriction training on rehabilitation. You are being invited to take part in this research study because you are between the ages of 15-40, and have had an anterior cruciate ligament (ACL) tear. If you volunteer to take part in this study because you have had an ACL tear within the past 10 weeks, you will be one of about 60 people to do so.

WHO IS DOING THE STUDY?

The person in charge of this study is Brian Noehren, PT, Ph.D. of the University of Kentucky, College of Health Sciences, Department of Physical Therapy. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of the study is to determine how two different blood flow restriction training programs used in conjunction with standard rehabilitation affect your leg strength. By doing this study, we hope to learn if one program improves strength and function more than the other. We also hope to learn how the training affects the properties of muscle in patients who will or have had an ACL reconstruction. These results will help define how the training programs are working. The results of this study will be shared with the company, the Food and Drug Administration and other federal agencies, if required.

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

You should not participate in this study if you are not between the ages of 15-40 years, or have had a significant lower extremity surgery that affects your ability to exercise or walk, have a spinal fusion, unable to attend physical therapy or study visits, have varicose veins, are pregnant or have a history or an immediate family history of deep vein thrombosis.

You should not participate in the muscle biopsy (a needle is used to get a small sample of muscle) and magnetic resonance imaging (MRI – a special way of seeing the muscles in the thigh without radiation) portion of the study if you have had a knee surgery other than the one ACL reconstruction on one leg, lower extremity injury/s other than the one ACL, You should also not participate if you are diabetic or have uncontrolled hypertension, have a recent inflammation, bleeding disorders, active bleeding or infection within the lower limbs or are allergic to Betadine or Xylocaine HCL, taking warfarin/Coumadin or clopidogrel/Plavix, Rivaroxaban/Xarelto, Dabigatran/Pradaxa, apixaban/Eliquis, edoxaban/Savaysa, betrixaban or any other anti-coagulants that may cause excess bleeding. You should also not participate in the additional magnetic resonance imaging if you have metal pins, plates or clips in your body or have orthodontics [braces or dentures], have surgical implants such as pacemakers or cochlear implants, or if you have a BMI of 35 or greater. You should also not participate in the muscle biopsyif you are unable or do not discontinue the use of aspirin in the 5 days preceding and NSAIDS (Advil) 3 days prior to the scheduled date for the muscle biopsy, you should not participate in the study.

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

This study will be conducted at the University of Kentucky BioMotion Laboratory. You will need to come to the BioMotion Laboratory in the Multidisciplinary Sciences Building at 725 Rose Street 40536-0082 for the study. The initial data collection and follow up assessment at the end of the training will each take up to 6 hours (2 hours for MRI, 2 for muscle biopsy, 2 for muscle strength, movement mechanics and questionnaires). Your physical therapy visits will occur at the BioMotion laboratory. There will be no charge for your physical therapy visits as long as they are part of the study. The physical therapy visits will range from 60-120 minutes depending on your stage of recovery and the activities to engage in.

Training sessions will typically be held 3 days a week for approximately 4 weeks before surgery and 6-7 months after surgery. There will be a total of 4 data collections over 7 months. The first data collection will be used to capture baseline conditions of your knee and thigh muscles (muscle biopsy, MRI, strength). The second will occur right before surgery to assess your change during preoperative rehabilitation (strength and walking and step down mechanics). The third will occur 4-5 months after surgery and will be a complete re-evaluation of your thigh muscle and knee function (muscle biopsy, MRI, strength, gait, and step down). The last visit will occur 6-7 months after surgery and will involve an assessment of your thigh muscle strength, walking, step down, jogging/running and jumping form. In addition, depending on equipment availability and schedules some of the muscle strength assessments may occur at the Sports Medicine Research Institute at 108 Sports Medicine Research Institute, Sports Complex Drive, Lexington, KY 40506.

The muscle biopsy and magnetic resonance imaging portion of the study will occur in the outpatient unit of the Center for Clinical and Translational Science at the UK Medical Center and the MRI and spectroscopy center located on the medical center campus. The muscle biopsy will take an additional 15 minutes and the MRI up to two hours (1 hour per leg). There may be additional time needed to set up each procedure and in the case of the muscle biopsy, wait to have the physician arrive. Therefore, we expect that can take up to 4 hours total to complete both procedures. We will accommodate your preference for scheduling. The biopsy and MRI may occur on the same day or differing days depending on scheduling availability of the equipment and your time preferences. In addition, the quadriceps strength testing will occur on one of the days that you come for the biopsy and/or the MRI.

WHAT WILL YOU BE ASKED TO DO?

The following procedures may be performed. Some procedures may not be performed due to time constraints, availability of equipment, and/or by the decision of the investigator. Before we begin, you will be asked some questions including but not limited to the following: age, sex, level of activities, and expectations. You will also complete a Sports Activity Scale to determine your physical activity level.

TIMELINE OF STUDY

Visit One: Within 10 weeks of ACL injury

- Confirm ACL tear and meet study eligibility requirements
- Sign informed consent/assent documents
- Schedule pre-operative testing and training visits

Visit Two: Within 10 weeks of ACL injury and prior to starting 12 pre-operative physical therapy visits

- 3 day food record
- Fear and concerns survey
- Movement mechanics
    - Walking at self-selected pace and 1.5 m/s, if able
    - Step down
- Biodex Strength and Power Assessments
- MRI (Bilateral)
- Muscle Biopsy (bilateral)
- Blood Draw (about 2 teaspoons of blood)

Visit Three: Upon completion of 12 pre-operative physical therapy visits

- Fear and concerns survey
- 3 day food record
- Movement mechanics
    - Walking at self-selected pace and 1.5 m/s, if able
    - Step down
- Biodex Strength and Power Assessments

Visit 3A*: 1 week (+/- 3 days) post-surgery

- Blood Draw (about 2 teaspoons of blood)

Visit 3A: Two weeks (+/- 3 days) post-surgery

- Perform algometry testing
- 3 day food record

Visit Four: 4-5 months (+/- 3 weeks) following surgery

- Perform algometry testing
- 3 day food record
- Movement mechanics
    - Walking at self-selected pace and 1.5 m/s
    - Step down
- Biodex Strength and Power Assessments
- MRI (Injured leg only)
- Muscle Biopsy (injured leg only)
- Blood Draw (about 2 teaspoons of blood)

Visit Five: 6-7 months (+/- 3 weeks) following surgery

- Perform algometry testing
- Fear and concerns survey
- Movement mechanics
    - Walking at self-selected pace and 1.5 m/s
    - Step down
    - Jogging/running at self-selected pace and 3.0 m/s, if able
    - Drop vertical jump
- Biodex Strength and Power Assessments
    - Post Study Questionnaire for Participant

For the testing session, you will be asked to wear sports clothes (e.g. athletic shoes, shorts, and t-shirt).

Training sessions: We are comparing two interventions, one is the standard of care and the other is the standard of care plus an additional treatment. You have a 50/50 chance of receiving either treatment. You will be randomly assigned one of the two groups. Assignments to which group are determined by the investigator based upon subject number. The airbands will then be placed on your thighs and you will be doing a standardized exercise program that will vary depending on the stage of rehabilitation you are in and as determined by the study personnel. You will also complete a standardized course of physical therapy. Activities in physical therapy may include ice over the knee, range of motion exercises to maintain hip strength and gait training exercises as needed and the subject's impairments dictate. We will also provide an educational program at regular intervals on the injury and your recovery. We will also administer a scale at several intervals throughout physical therapy to help identify barriers, goals, and perceptions to physical therapy.

Quadriceps strength: You will sit in a seated position and a stabilizing strap will be placed around the thigh. A second strap will be placed around the bottom of your lower leg and attached to the isokinetic dynamometer (a muscle strength testing device) which will control movements and apply force at several different speeds and in an isometric mode. Upon completion of these tests, the dynamometer will also flex and extend your knee at a slow speed to determine how stiff the muscle is. You do not apply resistance during this test and we will use a small electrode placed on your quadriceps to monitor that the muscle stays relaxed.

Muscle power testing: You will sit in a seated position and a stabilizing strap will be placed around the thigh. A second strap will be placed around the bottom of your lower leg and attached to the isokinetic dynamometer (a muscle strength testing device). You will kick out 10 times against one-third of your maximum strength.

Pressure assessment: We will use a small device on your thigh after surgery to determine the point at which the feeling of pressure become pain. We will reassess this over the first 2 weeks after surgery.

3 Day Food Record: We will ask you to complete a 3 day food record of the food and drink you have consumed before the study starts, prior to and after the surgery, and 4-5 months following the surgery. You will record your diet using MyNetDiary, which is a website and phone application. You will be given an account login and password that is managed by study personnel. You will not incur any costs for the downloading, account or usage of this program. If you would like to utilize a written version of the diet recall instead, subjects may use a paper version of a food log.

Motion Analysis: Motion analysis will provide a means for evaluating motion of your hip, knee and ankle joints during walking and jogging/running on the treadmill. You will have reflective markers placed on certain landmarks of your legs and lower back to allow the motion analysis system to record your trunk, hip, knee, and ankle movements. Markers will be applied with sticky tape to the skin and if necessary, athletic tape to limit marker movement during activities. A stationary trial will be collected to help us identify anatomical landmarks. After this trial, some markers will be removed that won't be necessary for the activities you will later perform. Motion data will be collected for 10 seconds every minute. We will have you perform a series of jumps on both legs and on a single leg. In addition, we will have you go up and down step.

Treadmill Activity: You may walk on the treadmill as long as necessary to feel comfortable with it. Once you are ready you will walk at a self-selected warm up pace for 5 minutes. We will then gradually increase the speed to 1.5 m/s for 2 minutes. The speed of the treadmill will then be increased gradually to a self-selected comfortable jogging/running pace for 2 minutes. . You may also be asked to increase the jogging/running pace to 3.0 m/s and to jog/run at your self-selected speed for 2 minutes. You may request to stop at any time.

Muscle Biopsy: A small piece of your muscle tissue will be removed from both of your thighs. 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 (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 band aid after the site is cleaned with an alcohol preparation and your leg will be wrapped snuggly with an elastic bandage. The procedure will last approximately 15 minutes. The tissue samples will be used in the analysis process.

Blood Draws: In addition, we will collect about 2 teaspoons of blood from your arm for laboratory testing at both biopsy procedures and one week post-surgery. Samples will be stored and archived in the UK-Orthopaedics Serum repository for analysis.

Magnetic Resonance Imaging & Spectroscopy Center: When you first arrive for the study at the MRISC, you will be asked to complete a medical screening questionnaire that will ask specific questions about your health and medical history. This information will be used to determine eligibility to participate in the study. At this time, the procedures and risks involved in participating in the research study will be explained to you. You will also fill out a questionnaire asking whether you have any metal in your body as well as any other medical conditions that may need to be considered for you to enter the MRI scanner. The metal screening questionnaire will be reviewed by the individual operating the scanner and if any risks are identified, you may not be able to participate.

You will be taken to the MRI scanner by the experimenter. In the interest of your individual safety, the safety of others, and to prevent damage to the equipment itself, you will be asked to remove all jewelry, body piercings, hair accessories, belts, wallets, credit cards, and loose change and leave these items with the experimenter. You will then be instructed about specific MRI procedures, which include the need to remain still while in the scanner, the need to remain attentive and awake during the study, and how we will communicate with you while you are in the MRI scanner. The experimenter will then place you on the bed of the MRI scanner and will take a few minutes to make sure you are positioned correctly and are comfortable. You are then placed into the MRI scanner; the experimenter goes to the control room and communicates with you via an intercom system.

The magnetic resonance scanning will take approximately 60 minutes per leg. You will be asked to lie still during the DTI, T1 rho, T2, DIXON VIBE, CEST, and ASL scanning. After the DTI scanning is completed, you will be removed from the MRI device by the investigators.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Risks of strength training, and strength testing, are minimal and include muscle soreness similar to what you may experience after exercising. You will be given the option of icing, taping, and e-stimulation to reduce strength training and testing discomfort, pain, and/or soreness. You will be closely watched by the research team during testing to minimize the risk of fall. Also exercising with the compressive bands individuals may feel some discomfort in their thighs while they are on, the discomfort will go away once the session is over.

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, but may persist longer and be more severe in patients with fibromyalgia. 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.

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

MRI These are the possible risks:

Possible Risk/Side Effect from MR Scanning	How often has it occurred?	How serious is it?	Can it be corrected?
Claustrophobia	It occasionally occurs	Can be treated	Yes, volunteer is removed from the magnet
Loud noise	It is expected to occur	Not serious	Yes, participants wear ear protection

Blood draws. There is a risk of local pain, soreness, bleeding, bruising and swelling, as well as lightheadedness, dizziness and rarely, fainting and/or a local infection.

There is always a chance that any medical treatment can harm you, and the investigational treatment in this study is no different. In addition to the risks listed above, you may experience a previously unknown risk or side effect.

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. Your willingness to take part, however, may in the future, help clinicians better understand the potential role of different strength training programs. The MRI images are being used for research purposes only and will not be read for any clinical findings. Upon request at the time of taking the images we will supply you with a copy of your MRI images that you may take with you.

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 take part in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE? There is no cost to you to participate in this study, other than your travel costs to attend the training sessions.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep confidential 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. You will be assigned an identification number to protect your confidentiality. Hard copies of data will be stored in a locked filing cabinet. Electronic data will be stored on a password protected computer. Access to your information will be limited to the principal investigator and other team members. Collected data will be aggregated and presented without identifying information for individual subjects. Hard copies of the data and video tapes will be stored for six years following conclusion of the study at which time they will be shredded and disposed of properly.

You should know, however, that there are some circumstances in which we may have to show your information to other people. 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. Officials of the University of Kentucky and the Food and Drug Administration may look at or copy pertinent portions of records that identify you

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. 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.

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. 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 call Brian Noehren PT, Ph.D. at 859-218-0581 or 859-494-9518 immediately. The medical supervisor for this study is Darren Johnson, MD at 859-218-3131.

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. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study. The medical costs related to your care and treatment because of research related harm will be your responsibility.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY? We will compensate you a total of $200 for completing the data collections, MRI, biopsy, and function\biomechanics. You will be compensated $33 following the completion of the pre-operative training, $100 following completion of the study of the 4-5 month visit, and $67 following the completion of the 6-7 month follow up visit. In addition, we can reimburse you up to a 15 mile round trip, for study visits, at .585 cents per mile reimbursement rate if you are coming from outside of Fayette County. If you earn $600 or more by participating in any research, it is potentially reportable for tax purposes.

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, you can contact the investigator, Brian Noehren, PhD, PT at 859-218-0581. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity between the business hours of 8am and 5pm EST, Mon-Fri 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

Contacting Research Subjects for Future Studies

Do you give your permission to be contacted in the future by Brian Noehren PT, Ph.D. or a member of the research team regarding your willingness to participate in future research studies about how to prevent, detect, or treat knee injuries?

____ Yes_____ No _____Initials

WHAT ELSE DO YOU NEED TO KNOW? You will be told if any new information is learned which may affect your current or influence your willingness to continue taking part in this study. The National Institutes of Health is providing financial support for this study.

STORING AND SHARING YOUR INFORMATION OR SPECIMEN SAMPLES FOR FUTURE USE:
The researchers would like to store, use, and share your identifiable information for future research. Having information from many people helps researchers identify trends and discover better ways to diagnose, prevent, and treat many conditions. Researchers can use the stored information and samples to learn more about ACL rehabilitation or research additional scientific questions.

WHERE WILL INFORMATION OR SPECIMEN SAMPLES BE STORED AND FOR HOW LONG?
The information will be stored in a locked cabinet at Wethington 419 or B04 in the Multidisciplinary Sciences building for no longer than six years, after the conclusion of the study. If you agree, the 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 muscle tissue collected during this study. No additional muscle 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. 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 YOUR PRIVACY AND CONFIDENTIALITY BE PROTECTED?
Researchers will take careful steps to keep your information confidential.
Researchers will remove your name or other direct identifiers from your information or samples. We will label your information and muscle tissue with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code to you.

HOW WILL WE SHARE YOUR INFORMATION OR SPECIMEN SAMPLES WITH OTHER RESEARCHERS?
Your de-identified information or samples may be shared with other researchers without your additional informed consent, provided an Institutional Review Board (IRB) has approved this action. An IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human participants. If a researcher requests your information or samples with identifiable information, an IRB will decide if the research may be conducted with or without your additional consent.

WHAT IF YOU CHANGE YOUR MIND AND WANT TO WITHDRAW YOUR INFORMATION OR SPECIMEN SAMPLES?
You may withdraw your permission to allow your information or samples to be used for future research. To do so, you must send a written withdraw request to:

Brian Noehren, PT, Ph.D.
Assistant Professor
University of Kentucky Division of Physical Therapy
Wethington Building Room 105
900 S. Limestone
Lexington, KY 40536-0200

Any remaining information and samples will be destroyed. In addition, it may be possible to destroy the code that links you with your information and specimen samples. However, the information and samples that have already been used or shared may not be withdrawn.

WILL YOU RECEIVE ANY COMMERCIAL PROFIT FROM FUTURE RESEARCH DISCOVERIES?
The information and samples that you provide will no longer belong to you. The research may lead to new medical knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives 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.

OPTIONAL FUTURE USE:
Do you give permission for your identifiable information and leftover muscle tissue to be stored, used, and shared for future research?

☐Yes ☐No Initials _____

Remember, you can still be in the main study even if you even if you do not wish to allow your information and/or specimens stored or shared for future research

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 maybe accessed, used and/or released includes:

- Demographic information, medical history for inclusion/exclusion purposes, knee surgical procedure to be performed or performed, physical therapy notes for compliance with rehabilitation, radiographic data, and blood test results.
-

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.

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 will 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) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Brian Noehren to inform him of your decision.
  Brian Noehren PT, Ph.D.
  Assistant Professor

  University of Kentucky
  Division of Physical Therapy
  Wethington Bldg rm105
  900 S. Limestone
  Lexington, KY 40536-0200
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).
- You may not be allowed to participate in the study.
- You understand that you will not be allowed to review the information collected for this research study until after the study is completed. When the study is over, you will have the right to access the information.

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