Study Title: Functional Resistance Training to Improve Knee Function after ACL Reconstruction

NCT Number: NCT03282565

This version of the consent Document was finalized on **May 13, 2020**

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CAUTION: IF YOU HAVE PRINTED THIS CONSENT FOR USE WITH PARTICIPANTS, IT IS NOT THE IRBMED APPROVED VERSION. Access the approved/watermarked consent from the Documents Tab in the main study workspace. The approved/watermarked document *will not* contain this cover page and *will* have the approval watermark present in the header.

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INSTRUCTIONS FOR EDITING THIS DOCUMENT

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
   - **Consent - Tracked**
   - **Consent -** *Concise Subtitle* **– Tracked** (provide a subtitle when there are multiple consents associated with the study)
   - **Assent - Tracked**
   - **Parental Permission/Assent - Tracked**
   - **Parental Permission – Tracked**

NOTES:
Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as**:** **Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be stacked on the previously uploaded track changes version.

DO NOT delete any documents or stacks of documents from eResearch; these are retained for historical and regulatory reference purposes.

DO NOT upload a clean version of the consent**.**

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Study ID: HUM00133860 / Continuing Review ID: CR00083084

Approval Date: 5/12/2020

Document Finalized: 5/13/2020 8:26 AM

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You (or your child) may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study. *From this point forward in the document, the use of the word you may also refer to your child.*

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:

Functional Resistance Training during Gait: A Novel Intervention to Improve Knee Function after ACL Reconstruction

1.2 Company or agency sponsoring the study: National Institutes of Health

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Riann Palmieri-Smith, PhD, ATC, School of Kinesiology, University of Michigan
Chandramouli Krishnan, P.T., Ph.D., Department of Physical Medicine and Rehabilitation, University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose: Thigh muscle weakness and activation deficits (i.e., inability to fully contract the muscles) are common after anterior cruciate ligament (ACL) injury. Loss of thigh muscle strength reduces its ability to serve as a shock absorber during physical activity. This can lead to increased loads on the knee and deterioration of the joint (such as osteoarthritis). This research study is being done to determine if we can improve rehabilitation following ACL surgery using functional resistance training (resistance or load is applied via an external device while a person is walking) to determine if we can better improve muscle strength and function.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you/your child are otherwise entitled.

3.1 Who can take part in this study?

There are two parts to this study. For this part of the study, persons between the ages of 14-40 who have undergone ACL-reconstruction surgery can participate. They should be willing to participate in testing and training sessions as outlined in this document. Additionally, all subjects in the study may not:

1) have suffered a previous ACL injury;
2) have undergone previous major surgery to either knee;
3) have a history of recent significant knee injury (other than ACL) or lower-extremity fracture;
4) have a history of uncontrolled diabetes or hypertension;
5) be pregnant or plan to become pregnant;
6) have metal implants in the head;
7) have electronic devices in their ear or heart (e.g., cochlear implants or cardiac pacemakers);
8) have unexplained recurrent headaches;

9) have a recent history of seizures;
10) be taking drugs that reduce seizure threshold;
11) have a history of repeated fainting spells

Before you sign this consent form and we bring you in for testing, we will ask you a series of questions that helps us to determine whether you meet these criteria.

3.2 How many people (subjects) are expected to take part in this study?
We expect 116 total subjects to take part in this research study. For this part of the study, we anticipate 70 subjects participating.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
If you choose to participate, you will be randomly assigned (e.g., like a flip of a coin) to one of the two groups:

- If you are in Group 1, you will receive functional resistance training using a device that applies resistance (i.e. producing a force against your leg/knee) while you are walking on a treadmill.
- In you are in Group 2, you will wear a device that does not apply any resistance while you are walking on a treadmill.

Regardless of the group you are in you will be asked to report for training up to 3 times per week for 8-12 weeks. You will report for study treatments 6-12 weeks post-ACLR. During your initial visit, we will ask you to fill out several questionnaires about your general health, physical activity level, and any pain you may experience in your knee. You are free to skip any questions that you do not wish to answer. Then we will do some basic physical tests. For example, we may move your legs manually, measure how far you can bend your joints, check the looseness of your knee joint, and check for any swelling in your knee. It is recommended that you do not workout heavily or consume alcohol 24 hours prior to your participation in testing or training sessions as it minimizes confounding effects or any unforeseeable risks.

Study Testing Measurement Sessions
Study-related measurements may be performed before, during, and immediately after 8-12 weeks of training.
In this part of the study, we will test

- your thigh muscle strength
- your ability to fully contract your muscles during strength testing
- your brain and spinal cord excitability and responses to magnetic stimulation
- your ability to walk and climb stairs

All testing procedures may be performed on both legs in a pre-determined order.

Picture 1. Person set up for muscle strength testing

Muscle Strength and Activation Testing

- First, if you would like to warm-up your muscles, you will be provided with an opportunity to do some light exercise (e.g. exercise bike or stretching).
- After which, we will clean your skin with alcohol wipes and may place electromyographic (EMG) electrodes (small stickers) on the skin over your thigh and leg muscles. The electrodes are similar to EKG sensors that doctors use for heart exams. You will not feel the electrodes working.
- You will sit on a chair attached to a system that measures the strength of your leg muscles (Picture 1).Your leg will be attached to the system through a series of straps.

- We will place additional electrodes on the top and bottom of your thigh muscles. These electrodes will send electrical pulses into your muscles, causing them to contract. We will send only as much electricity as necessary to result in a complete muscle contraction.
- You will then practice kicking/pulling against the device at 50-100% of your perceived maximum effort.
- You will rest for one or two minutes, and then you will kick/pull your leg muscles as hard as you can several times.
- We will send electrical pulses into your muscles during and directly after each kick. Throughout the testing, we will regularly ask about your comfort, please let us know if you are having any issues.
- These procedures may take about 1 hour during each testing.

Measures of brain output

In our lab, we have a system that allows us to measure brain excitability in a noninvasive manner. To measure this, we will use a device called as transcranial magnetic stimulation (TMS) (Picture 2). Essentially, this device stimulates the nerves in the brain with a magnetic field. Because the device uses a magnetic field, the procedure is of minimal discomfort to you.

Picture 2. Magnetic stimulation unit

- First, we will place EMG sensors and have you sit on the strength testing device and firmly secured to it using several straps. We may then attach reflective markers on your head and place an apparatus on top of your head.
- Using a moderate magnetic stimulation level, we will then find the best position to simulate the brain area that controls your muscles. During this procedure you will fell you muscle twitching, but should not feel any pain.

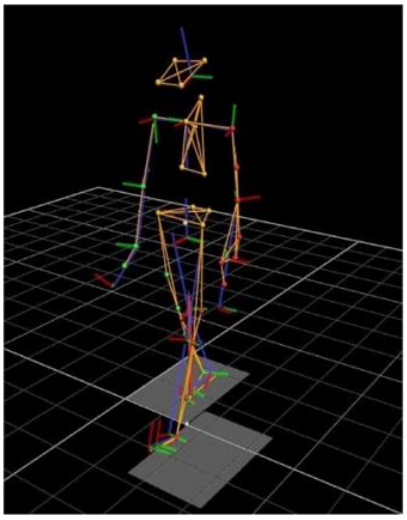
- Once the best stimulation area (hotspot) is found we will mark it using our camera system or a pen marker with washable ink.
- We will then stimulate your brain using different levels of magnetic stimulation while exerting a small contraction.
- You will then receive several stimulations while you make a muscle contraction. During this procedure you will feel your leg muscles twitching, and also may have some twitching in the face muscles due to stimulation. Throughout the testing, we will regularly ask about your comfort, please let us know if you are having any issues.
- These procedures may take about 2 hours.

Measures of spinal cord output

- For these tests we will obtain measures of brain and spinal cord function known as the H-reflex and M-wave.
- One small area, on both legs cleaned with isopropyl alcohol. Four round stickers (electrodes) will be applied to this area and an additional electrode will be applied to the bone on the inside of your ankle
- Next, you will be given a small round disc to place near your groin. A diagram will be provided to demonstrate the correct placement. Additionally, we will ask you to place a large rubber electrode on your buttocks.
- Several measurements will be taken while you are lying down. These measurements include a 1-millisecond shock. The intensity of this shock will vary depending on which response is being elicited. Lower intensities will be needed to obtain an H-reflex where higher intensities are needed to elicit an M-wave. The shocks in this study feel similar to a shock of static electricity, like when you are walking across a carpet and then touch a door knob, except the voltage is much lower (A shock of static electricity can provide up to thousands of volts of electricity).
- These procedures may take about 40 minutes

Walking and Stair Climbing

- Your walking and stair climbing pattern will be assessed using motion capture. Motion capture allows us to understand the forces that are applied across your knee as well as the position of the knee while you move.
- Prior to testing, round balls will be placed on the skin overtop of bones and muscles located on the lower half of your body. The balls will be held on your skin with double-sided tape and stretchy tape. The balls will allow cameras located in the laboratory to track the position of your body during testing.
- Small electrodes will will be attached to your skin over muscles in the leg (no electricity comes from these electrodes). Prior to attachment of these, your skin will be cleaned with alcohol. The electrodes will be connected to a series of wires and then to a computer that allows us to record muscle activity during movement.



Picture 3. Output from motion capture while a person walking.

- Your will now be asked to walk or climb a set of stairs. As you walk, we will collect information using cameras and force platforms (similar to a scale which will measure forces). The force platforms will be located in the ground, the staircase, or in a treadmill and the cameras will be located around the lab. The cameras in the room will not allow the researchers or others to see/record your face or body, they simply track the markers that have been placed on your skin (Picture 3). You will be asked to wear your own running shoes during testing.
- These procedures may take about 1.5 hours.

Questionnaires
We will provide you with a series of questions about how your knee feels and how you feel about performing activity. We will allow you to fill these out on your own while in the laboratory or we can read them to you and you can answer the questions verbally. It will take you approximately 20 minutes to answer the questions.

Training for Group 1 (Functional Resistance Training)

If you are assigned to Group 1, you will be trained to strengthen your thigh muscles during walking. You will need to report to the lab for training, up to 3 times per week for 8-12 weeks, beginning between 6-12 weeks after your ACL surgery. When you report for each training session you can expect the following:

- First, we will apply a brace, cuff or band to your leg that provide resistance (force). It will be similar to a knee brace that you may have worn after your operation or may be a cuff that attaches to your leg with exercise tubing.
- You will then be asked to warm up with the brace/cuff by walking on a treadmill for about 2 minutes wearing the brace/cuff where no resistance is applied.
- Following warm-ups we will ask you to walk on the treadmill for about 30 minutes while the brace/cuff applies resistance/force. This 30 minutes will be broken up into 5 minute blocks. After 5 minutes, you will be given a chance to rest. Once you have walked 6, 5-minute blocks, training for the day will be over.
- Each training session will last about 1-hour and will be repeated up to 3 times per week for 8-12 weeks.

Training for Group 2

If you are assigned to Group 2, you will perform everything identical to Group 1, except that the brace/cuff will not apply resistance while you walk.

4.2 How much of my time will be needed to take part in this study? Your participation in this study will last for approximately six months to a year and will involve up to 48 visits (up to 36 training sessions and up to 12 testing sessions (3 strength/activation, 3 stair climbing/walking, 3 spinal cord output, 3 brain output)). The actual number of testing and training sessions may vary depending on your availability. For example, the number of testing visits could reduce if we perform multiple tests during a single session. Testing sessions could last up to 4 hours, depending on the amount of testing we perform in each session. Training sessions will be about an hour each.

4.3 When will my participation in the study be over? Your participation in the study will be over after the last testing session. You may stop participating at any time if you wish to do so.

4.4 What will happen with my information and/or biospecimens used in this study? Your collected information may be shared with the National Institutes of Health. Your collected information may also be shared with other researchers, both here or around the world, or with companies. Any sharing is subject to contractual obligations with the Sponsor. Additionally, without your additional consent, your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks? The known or expected risks and the procedures that the researchers will used to minimize these risks are stated below:

- **Transient headache or scalp discomfort (Likely):** There is also a small risk of temporary

headaches after TMS. However, these are momentary and typically go away after the completion of the procedure.

- **Discomfort from electrical pulses (Common):** You may feel some discomfort from the electrical pulses we send into your muscles. These electrical pulses are similar to those that patients experience during rehabilitation. A researcher will be present during all study procedures, so you can tell us if you're feeling any discomfort. We will stop the electrical pulses or other procedures any time you ask us to.
- **Clicking noise and muscle twitching (Common):** You may feel twitches in your arms, face, and leg muscles. A loud clicking noise may be heard during the stimulus. You will have the opportunity to wear foam earplugs that can minimize this discomfort.
- **Allergic reactions (Infrequent):** You may experience allergic reactions from the application of electrode paste and adhesive tapes necessary for attaching electrodes or markers. We will use hypoallergenic tapes to minimize allergic reactions. If redness or excessive itching occurs, the area will be monitored closely by study staff and testing will be ended at their discretion or in accordance with your wishes.
- **Skin irritation (infrequent):** You may experience some skin irritation from the tapes and sensors attached to your body, especially when removing them. This should be temporary and should usually go away by applying skin lotion. You may decide to shave your legs before the study visit.
- **Muscle or Joint Discomfort and Swelling (Infrequent):** During or following the experiment, you may feel temporary or persistent muscle aching or joint pain, swelling, or general fatigue. We will provide appropriate rest breaks during the experiment. The level of soreness should not be greater than what would be experienced following a regular exercise session.
- **Lightheadedness/dizziness (Infrequent):** Although not common, you may experience lightheadedness, dizziness or fainting. In the event of such symptoms, the experiment will be stopped. You will have the ability to stop the study at any time by asking the study team to either give you rest or if necessary, remove the device. If willing, we will resume at a later time. Please let us know if you are prone to get fainting spells as that would exclude you from the study.
- **Knee looseness (Rare):** It is possible that exercising with the brace or cuff could increase knee looseness or laxity. Prior research indicates that high-intensity exercise training is safe for individuals with ACLR. However, there is a very small risk that knee looseness/laxity could be increased.
- **Muscle Strain, Ligament Sprain, or patellar fracture (Rare):** There is a small risk of injury during repeated muscle contractions, electrical stimulation, or walking/stair climbing. Current literature indicates that there is a rare chance of patellar fracture in ACL-reconstructed individuals with patellar-tendon graft during activation testing. However, we are only aware of a single-case and this person had been experiencing pain in the kneecap and didn't inform the researchers. Please let us know if you experience unusual pain in your kneecap during testing.
- **Seizures (Rare):** Rare cases have reported the development of seizures during or immediately after magnetic brain stimulation, but these are particularly for repetitive transcranial magnetic stimulation protocols (where burst of TMS pulses are used to modulate cortical excitability). To be extra-cautious, if you have had a recent history of seizures (< 6 months), you will be evaluated for the study participation in consultation with the physician on this study and would be excluded from this research study if recommended. Further, if you are taking any medications, a doctor will review them to make sure that none of them are known to increase the risk of seizures.
- **Breach of Confidentiality (Rare):** Confidentiality refers to the researchers' agreement to handle, store, and share research data to ensure information about you is not improperly revealed. We will only share data among the study team members listed in this consent form. All data that is associated with you will be identified with a study ID number and only the study team will have the file that links you with your study ID. Once the study is complete, we will destroy the file that links you to your data. All data will be transferred and stored on secure

devices and servers.

- **For women of child-bearing potential:** It is unknown if transcranial magnetic stimulation can pose a risk to fetuses. To minimize this risk: You will be asked during screening whether you are pregnant or are trying to become pregnant; you should not take part in this study if you are. Sexually-active women of child-bearing potential are asked to use a reliable birth control method for the duration of this study.
- **Unforseeable Risks:** As with any research study, there may be additional risks that are unknown or unexpected. If you have any questions or are unsure about anything outlined below please do not hesitate to ask the study team.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have? Your only option is not to participate.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished? No harm will come to you if you decide to leave the study early.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.

- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
You will receive $25 per training session and $10 per hour for each testing session in which you participate. You will receive the payment upon the completion of study participation. If you receive payment of greater than $100 for taking part in this study, the University of Michigan accounting department will collect your name, address, social security number, payment amount, and related information. The information collected will be used for tax reporting purposes if you participate in additional studies and the total amount of study payment exceeds $600 in a calendar year. In this situation the University of Michigan accounting department is required for tax reporting purposes to submit this information to the Internal Revenue Service (IRS).

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of the study. Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

- In any publications that result from this research report, neither your name, nor any information from which you may be identified will be published without your consent.
- Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you.
    - Personal identifiers will be removed from the data before we share any of this information with anyone else.
    - Only the research investigators of this study will have access to the list that

connects identifying information with your information. This will be kept in a locked cabinet in the PIs' offices or labs.

- This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

  The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

  The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal information
- Other information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.

- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Co-Principal Investigator: Riann Palmieri-Smith, PhD, ATC
Mailing Address: 401 Washtenaw Avenue, Ann Arbor, MI 48109
Telephone: 734-615-3154

Co-Principal Investigator: Chandramouli Krishnan, PT, PhD
Mailing Address: 325 E. Eisenhower Parkway, Suite 3013, Ann Arbor, MI - 48108
Telephone (Cell): 734.936.4031

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
- Other (specify):_____
-

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

For use only if required by sponsor:

Date of Birth (mm/dd/yy): _____

ID Number: _____

Parent Permission

Subject Name:

_____

Parent:

Name:

_____

Signature: _____

Address: _____

Date of Signature (mm/dd/yy): _____

Reason subject is unable to consent: _____

For use only if required by sponsor:

Date of Birth (mm/dd/yy): _____

ID Number: _____

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.

Assent for using photographs/videos to be used in presentations/publications

I consent for using my photographs/videos to be used in presentations or publications, including medical journals, textbooks, and electronic publications. I understand that the image may be seen by members of the general public, in addition to scientists and medical researchers that regularly use these publications in their professional education. I also agree for my photographs or videos to be shown for teaching purposes.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Parental consent for using photographs/videos to be used in presentations/publications

I consent for using my child's photographs/videos to be used in presentations or publications, including medical journals, textbooks, and electronic publications. I understand that the image may be seen by members of the general public, in addition to scientists and medical researchers that regularly use these publications in their professional education. I also agree for my photographs or videos to be shown for teaching purposes.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____