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Henry Ford Health System	**CONSENT TO PARTICIPATE IN A RESEARCH STUDY** (HFH IRB form rev: 12/7/2018)	DATE: MRN: NAME:
APPROVAL PERIOD Oct 28, 2021 – Oct 27, 2022 INSTITUTIONAL REVIEW BOARD	**PROJECT TITLE:** **Use of blood flow restriction (BFR) therapy in peri-operative rehabilitation following anterior cruciate ligament tear**	

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1. INTRODUCTION

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. More detailed information is provided after the box. No research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document.

Key Information for You to Consider
Voluntary Consent. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
Purpose. The purpose of this research is to evaluate the effect of blood flow restriction therapy (BFR) on rehabilitation following ACL tear.
Duration. It is expected that or your participation will last one year. You will not require any clinic or therapy visits outside the usual number of visits following ACL reconstruction.
Procedures and Activities. You will be asked to participate in an experimental rehabilitation program as an addition to your usual rehabilitation. This will not require additional visits, however the content of your therapy visits will be changed.
Risks. Some of the foreseeable risks or discomforts of your participation include blood clot, blood clot traveling to the lungs, pain from the pressure cuff. More detailed

information can be found in the "*What Are The Risks, Discomforts, And Inconveniences Of The Study?*" section in the Consent Form.

Benefits. Some of the benefits that may be expected include less pain following surgery, faster strength and range of motion recovery, faster return to sport

Alternatives. As an alternative to participation, you could participate in usual physical therapy protocols.

2. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST

The investigator(s) in this study are also healthcare providers. They are interested in the knowledge to be gained from this study and are interested in your well-being. Investigators may obtain salary or other financial support for conducting the research.

3. WHY IS THIS RESEARCH BEING DONE?

You have been asked to take part in a research study because you have an ACL tear. The purpose of this research study is to determine if an alternative rehabilitation method (BFR) is beneficial in helping patients regain strength and function following ACL reconstruction. BFR has the benefit of limiting some blood flow to the leg to mimic a more intense exercise environment while using less weight and repetitions. Additionally we would like to determine if BFR will allow sooner return to sport.

A total of 34 people will be enrolled at Henry Ford Health System (HFHS).

4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

If you agree to take part in this study, your participation in this study will last a total of 1 year. As part of this study, you will not have any additional visits outside the usual ACL reconstruction protocol. Your only commitment outside of the usual protocol will be undergoing functional test and return to sport tests at the end of your recovery period. This will be done during usually scheduled therapy visits.

There will be two groups in the study. You will be randomized into one of the study groups described below. Randomization means that the group you are assigned to will be chosen by chance, (like

flipping a coin). A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

If you are in group 1 (often called "Arm A"), you will use BFR during your therapy regimen. The goal of the BFR cuff is to mimic a low oxygen environment which will potentially allow for increased muscle growth with lower weight and repetition. You will be trained before surgery on how to use the BFR cuff in order to perform a daily 15 minute home exercise program prior to surgery that will require no equipment. You will also be educated on the potential risks of the BFR cuff and warning signs to stop using the cuff at home. You will be tested in the clinic to ensure you are safe to use the cuff at home. If you experience any numbness/tingling of the leg, severe pain, calf pain, lower extremity swelling or shortness of breath you should stop using the cuff and contact our office immediately. Following surgery, the BFR cuff will be administered by a physical therapist who has undergone additional training in the use of this cuff. The BFR will be performed by inflating the pressure cuff around the leg during your therapy exercises. The exercises will be provided by the surgical team to the physical therapist. These will be the same exercises as the control group, however they will be performed with the cuff inflated. The procedure will be performed by the physical therapist only, and this will be done during each therapy session. Therapy sessions will typically last about 45 minutes. The use of the pressure cuff will only be carried out due to your participation in the study and while there is some early research demonstrating the safety of the cuff, the study group is still experimental and not the current standard of care. Your leg strength will be measured at each follow up clinic visit adding no more than five minutes to the visit.

If you are in group 2 (often called "Arm B"), you will undergo the same 15 minute daily home exercise program without the use of a cuff. Following surgery you will be placed in physical therapy as usual per previous Henry Ford protocol. Your leg strength will be measured at each follow up clinic visit adding no more than five minutes to the visit.

In summary a timeline for your participation is as follows:

- Daily 15 minute home exercise program for two weeks leading up to surgery
- Following surgery, you will have a 45 minute therapy session 1-2 times weekly guided by your physical therapist for at least three months. Therapy will consist of a structed exercise program

that we currently use for ACL reconstruction patients that takes you through graduated activity at the direction of the surgeon.

- As with all ACL reconstructions, you will have a post-operative visit at two weeks, six weeks three months and six months. At these times we will also test your leg strength with a simple handheld test and measure your range of motion totaling five minutes of extra time. Additionally, we will conduct testing at the end of your therapy sessions to ensure you are prepared to return to sports. This will not require extra time outside of usual scheduled therapy visits.

5. WHAT ARE THE RISKS, DISCOMFORTS, OR INCONVENIENCES OF THE STUDY?

Likely: Discomfort due to the pressure cuff. However we will use a special wide cuff to minimize pain and some discomfort while strengthening the muscles is expected.

Rare but Serious: Blood clot in the leg, blood clot traveling to the lungs

The researchers will try to minimize these risks by taking a thorough history of any blood clotting or family history of clots. We will educate the patients and therapists on the signs and symptoms of blood clots and what to do if blood clot is suspected.

There may be additional risks or discomforts that are not known at this time.

Additional risks include a potential breach of confidentiality of your personal information. The measures taken to protect your personal information and any possible disclosure are described in the section below titled "*How will my personal information be protected?*"

A possible inconvenience may be the time it takes to complete the study.

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. If you are currently in another study, took part in one recently, or if you consider another study in the future, please inform the research staff right away.

6. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

The benefits of participating in this study may include faster return to preoperative level of strength following surgery.

7. WHAT OTHER OPTIONS ARE THERE AND WHAT ARE MY ALTERNATIVES?

Participation is voluntary. You do not have to participate in this study.

Your other choices may include participating in rehabilitation as usual.

Talk to your doctor about your choices before you decide if you will take part in this study.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

Research records will not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. The researchers will label research records with a unique code and keep any master key that links your name and data and/or specimens in a separate location. The researchers will maintain all study records (including any codes) in a locked, secure location. Your research will not be made a part of your regular medical record. If the researcher orders any tests, the order and results may become part of your regular medical record. All electronic files containing identifiable information will be password protected and only the members of the research staff will have access to the passwords. If researchers share your data and/or specimens with others, the information will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. The researchers will maintain any data described in this paragraph in accordance with the security provisions of this paragraph until destroyed by the researchers. Records will be kept until study publication or if the data is unused for six months.

You should also know that the HFHS Institutional Review Board (IRB) and IRB Administration Office may inspect study records as part of its auditing program, but these reviews only focus on the researchers. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

9. WHAT IF I GET SICK OR I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study.

By signing this consent form, you do not give up any of your legal rights in the event of an injury.

10. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Dr. Moutzouros MD, or his/her staff member has explained this research study and has offered to answer any questions. If you have any additional questions about the study procedures, or to report an injury you may contact Dr. Moutzouros MD by phone at 248-325-1000 or by email at vmoutzo1@hfhs.org. Medical treatment is available to you in case of an injury.

If you would like to discuss your rights as a research participant, discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research, you may contact the Henry Ford Health System IRB Administration Office by phone at (313) 874-4464 or by email at research_admin@hfhs.org. The IRB is a group of people who review the research to protect your rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

11. DO I HAVE TO PARTICIPATE IN THIS STUDY?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. Inform the research staff/study doctor if you are thinking about stopping or decide to stop. There are no penalties or loss of benefits to which you are otherwise entitled if you decide that you do not want to participate.

If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue

being in the study. You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.

12. WHO ELSE CAN STOP MY PARTICIPATION?

The PI, sponsor, or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

13. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

14. WILL I BE PAID TO PARTICIPATE?

There is no compensation available to you for your participation in this study.

DOCUMENTATION OF CONSENT

By signing this form, I agree that I have read and understand this form and that I agree to participate in the research project described above. I have been given enough time and opportunity to ask about the details of the research study and to decide whether or not to participate. Its general purposes, the particulars of my involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time without giving any reason without my medical care or legal rights being affected. My signature also indicates that I have received a copy of this consent form.

Signature of Subject	Date	Time

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_____

Printed Name of Subject

_____ _____ _____

Signature of Parent/Guardian of Subject Date Time

_____

Printed Name of Parent/Guardian of Subject

_____ _____ _____

Witness to Signature Date Time

_____ _____ _____

Signature of Person Obtaining Consent Date Time

_____

Printed Name of Person Obtaining Consent