CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Effects of Blood Flow Restriction training on rotator cuff and proximal shoulder musculature in post-operative repairs and shoulder arthroplasty
Principal Investigator: Charles J. Gatt, Jr., MD

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to: see if blood flow restriction therapy (BFR) provides additional benefits when used with physical therapy for post-operative rehabilitation after rotator cuff tear repair surgery. BFR is performed by the supervising physical therapist who apply a blood pressure cuff just below your shoulder and act like a tourniquet. The cuff will be inflated to <50% of your resting blood pressure while you perform rehabilitation exercises. You will be randomly (independently selected by the supervising physical therapist) assigned to one of two groups: one group will have BFR done with physical therapy and the other group will only receive physical therapy. If you are enrolled into the experimental group, you will also under go BFR twice a week starting 6 weeks into rehabilitation therapy. This would be done along with your prescribed physical therapy by your physical therapist. You would also have your shoulder range of motion, flexion strength, and endurance measured. These measurements are taken at 6 weeks and 14 weeks after starting physical therapy. You will also fill out a pain scale and a survey called Quick Disability of Arms, Shoulder, and Hand (Quick DASH) which will take 5 to 10 minutes to complete. Your time in the study will take a total of 14 weeks.

Possible harms or burdens of taking part in the study if enrolled to the group undergoing BFR include delayed muscle weakness, bruising, numbness, dizziness, and muscle breakdown. Possible benefits of taking part may be recovering muscle function, strength, and endurance quicker or better compared to physical therapy alone.

An alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?
Charles J. Gatt, Jr., MD is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Charles J. Gatt, Jr., MD may be reached at 732-537-0909 or cjgatt@rutgers.edu

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?

This study is being done to see if blood flow restriction therapy when combined with standard physical therapy can offer quicker and more effective rehabilitation after rotator cuff repair surgery.

Who may take part in this study and who may not?
Those who may be included in the study are adults age 18 years and older with a small to medium-sized rotator cuff tear that requires surgery. Those who are not included in the study are those with a prior history of shoulder surgery, history of complex regional pain syndrome after surgery, medical history of unstable hypertension, heart and lung disease, blood clots, and blood vessel disease. Those who do not speak English will be excluded as well.

Why have I been asked to take part in this study?
You have been asked to participate in this study because you have met the inclusion and exclusion criteria for this study. Your participation in this study can help better determine if BFR therapy can help patients who underwent shoulder surgery are able to recover faster.

How long will the study take and how many subjects will take part?
The study will take 14 weeks for you to complete. We aim to enroll a total of 26 subjects in total.

What will I be asked to do if I take part in this study?
When enrolled in the study we will collect demographic information that includes your name, date of birth, race, gender, and email. This contact information is used in REDCap to send you the Quick DASH survey. While you are in this study, you will have measurements taken starting 6 weeks into physical therapy and after completing physical therapy at 14 weeks. You will also be messaged to complete an online Quick DASH survey. If you were chosen to be in the BFR group, you will also complete BFR therapy alongside the prescribed physical therapy. BFR is performed by the supervising physical therapist who will apply a blood pressure cuff just below your shoulder. The cuff will be inflated to <50% of your resting blood pressure while you perform rehabilitation exercises Details of the measurements taken are listed below:

Measurement: shoulder range of motion
• Description: Your shoulder range of motion determined by measuring the angles of shoulder movement in all directions.

Measurement: endurance test
• Description: Muscle endurance will be tested by seeing how many repetitions of muscle contraction you can do before feeling fatigued.

Measurement tool: Shoulder flexion strength
• Description: A handheld device will be used to measure the maximum strength you have during shoulder use.

Evaluation tool: Quick DASH Survey
• Description: Patient survey that evaluates the impact of your disease on your quality of life which will be sent out through REDCap and takes 5 to 10 minutes to complete.

	Before Surgery	Surgery	Week 6 of PT	Week 14 of PT
Demographics	x	[redacted]		
Range of Motion (degrees)			x	x
Muscle Strength (kg)			x	x
Muscle Endurance			x	x
qDASH score			x	x

What are the risks of harm or discomforts I might experience if I take part in this study?
The use of blood flow restriction therapy carries a risk of developing late-onset muscle soreness, numbness, dizziness, and developing bruises under where the blood pressure cuff is placed. Muscle breakdown has also been reported in 0.008% of cases.

Are there any benefits to me if I choose to take part in this study?
The benefits of taking part in this study may be recovering shoulder function, strength, and endurance quicker if assigned to the BFR group. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?
Your alternative is not to take part in this study. In which case, you will not be enrolled and continue to receive standard of care per your attending physician.

How will I know if new information is learned that may affect whether I am willing to stay in the study?
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will I receive the results of the research?
In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. The findings of this study are expected to be collated for publication to medical journals and possibly presented at medical conferences.

Will there be any cost to me to take Part in this study?
This study will not incur any additional cost on top of the standard of care that is provided.

Will I be paid to take part in this study?
You will not be paid to take part in this study.

Who might benefit financially from this research?
The study personnel for this trial do not have any vested financial interests in the outcomes of this study. No one will receive financial compensation for their role in this research study.

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. The data collected will be stored on encrypted files on UOA servers that only research personnel will have access to.

The research team may use or share your information collected or created for this study with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

A description of this clinical trial will be available on 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.

What will happen to my information—data, recordings and/or images—and biospecimens collected for this research after the study is over?
After information that could identify you has been removed, de-identified information collected for this research may be used for other research we conduct without obtaining additional informed consent from you.

What will happen if I am injured during this study?
Subjects in this study will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which include a risk of developing late-onset muscle soreness, numbness, dizziness, and developing bruises under where the blood pressure cuff is placed. Muscle breakdown has also been reported in 0.008% of cases. These injuries are relatively minimal and should resolve when the cuff is removed and/or within 24-48 hours. In addition, it is possible that during the course of this study, new adverse effects of the use of BFR that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Charles J. Gatt, Jr., MD at 2 Worlds Fair Drive, Somerset, NJ 08873. At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.

Who can I contact if I have questions?
If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Charles J. Gatt, Jr., MD with the department of orthopaedic surgery at Robert Wood Johnson Medical School. He can be contacted by phone at 732-537-0909 or via email at cjgatt@rutgers.edu.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects

Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?
You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?

- Name
- Date of birth
- Race
- Gender
- Phone number
- Email

Who May Use, Share or Receive My Information?
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved in the Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Hospital Personnel as Necessary For Clinical Care:

- University Hospital
- Robert Wood Johnson University Hospital
- Barnabas Health

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I Be Able To Review My Research Record While The Research Is Ongoing?
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision: Charles J. Gatt, Jr., MD at 2 Worlds Fair Drive, Somerset, NJ 08873.

How Long Will My Permission Last?
There is no set date when your permission will end. Your health information may be studied for many years.

AGREEMENT TO TAKE PART IN RESEARCH

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____