RUTGERS
Robert Wood Johnson Medical School
DEPARTMENT OF ORTHOPAEDIC SURGERY

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Does Scoring on the TAMPA Scale of Kinesiophobia Impact Single-Leg Balance for ACL Surgery Patients?
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: investigate the relationship between TSK scores and performance on a single-leg balance test results in ACL reconstruction patients. If you take part in the research, you will be asked to complete a brief Patient Reported Outcome Measure (PROM) called the Tampa Scale of Kinesiophobia (TSK). Additionally, patients will perform two single-leg balance tests at 3 and 6 months post operatively. The balance test is performed by standing on one leg and timing the duration of balance. Participants will engage in a comprehensive physical therapist evaluation which is part of your normal rehabilitation program. This functional assessment is standard procedure and will occur at 6 months following your surgery. The functional assessment will including the Single-Leg Hop Test, Triple Hop Test, Triple Crossover Test, Timed 20m Hop on a Single Leg, and strength testing using the MicroFET device. All information, including TSK scores, single-leg balance results, and strength measurements, will be systematically logged into a secure database. Your time in the study is anticipated to be 1 year when we ask you to complete another round of PROMs to assess your recovery.

Possible Harms or Burdens of Participation:

Discomfort during Assessments: Participants may experience discomfort or fatigue during physical assessments, such as the single-leg balance tests and strength measurements, potentially causing temporary discomfort.

Possible breach of confidentiality.

Possible Benefits of Participation:

Enhanced Rehabilitation Strategies: Participants may benefit from a more comprehensive understanding of their recovery process, potentially leading to personalized and targeted rehabilitation strategies.

Improved Clinical Care: Findings from the study could contribute to advancements in clinical care for ACL reconstruction patients, potentially improving overall recovery outcomes.

Contribution to Scientific Knowledge: Participants have the opportunity to contribute valuable data to the field of sports medicine, aiding in the understanding of the relationship between kinesiophobia, balance, and strength in the context of ACL reconstruction.

An alternative to taking part in the research study
An alternative to taking part in the research study is choosing not to participate. Patients who opt out of the study can follow the standard rehabilitation protocols and treatments prescribed by their healthcare providers for ACL reconstruction without participating in the additional assessments and evaluations outlined in the research study.

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. If you are under the age of 18, your parent or guardian must give consent for you to participate. 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. Charles J. Gatt, Jr., MD may be reached at 2 Worlds Fair Dr, Somerset, NJ 08873, 732-537-0909.

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 wants to understand how people feel about moving after they've had knee surgery. We're particularly interested in those who may be afraid of moving too much (kinesiophobia). We're going to ask participants to do some simple balance tests and answer questions about how they feel. By doing this, we hope to find better ways to help patients recover from knee surgery and make sure they feel confident and comfortable moving again. The study will look at how fear of movement might affect balance and overall recovery after knee surgery.

Who may take part in this study and who may not?
Inclusion Criteria:
Patients 14-64 years and older with a confirmed ACL tear who undergo ACLR Surgery.
Those under the age of 18 will require consent from their parent or guardian.

Exclusion Criteria:
Elderly patients >age 64, prior history of ACL tear, patients with other pre-existing physical conditions in which single-leg balance would put them at risk of harm

Why have I been asked to take part in this study?
You are invited to take part in this study because you recently experienced a knee injury and chose to undergo surgery, specifically for ACL reconstruction. We're interested in understanding how patients feel about moving after their surgery. Your experiences can help us figure out better ways to support patients during their recovery.

How long will the study take and how many subjects will take part?
We are hoping to have around 25 participants like yourself take part in the study. Each person's involvement will last for 1 year.

What will I be asked to do if I take part in this study?

2. PROMS (Patient Reported Outcomes Measures)
We will ask to complete a questionnaire about your feelings and functional activity.

3. Single leg balance test:
You'll be asked to stand on one leg to assess your ability to balance. This test will be performed twice at 3 & 6 months after your surgery. It's a simple and safe activity that will be performed postoperatively and supervised by your therapist.

4. Your Regular Rehabilitation:
You will continue with your regular rehabilitation and medical care during this study. We're just adding two balance checks to assess your progress.

5. Overall Duration:
Your involvement will last 1 year.

If at any point you're uncomfortable or want to stop, you can let us know. Your well-being is our top priority.

What are the risks of harm or discomforts I might experience if I take part in this study?
Possible risks may include knee and leg discomfort due to physical therapy. However, this is a common and normal discomfort during physical rehabilitation with standard therapy.

Are There Any Benefits To Me If I Choose To Take Part In This Study?
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.

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?
All participants will have access to the study results at the conclusion of the study.

Will There Be Any Cost To Me To Take Part In This Study?
There will be no cost in participating in the study.

Will I Be Paid To Take Part In This Study?
You will not be paid to take part in this 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 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

What Will Happen To My Information—data, recordings and/or images—And Biospecimens Collected For This Research After The Study Is Over?
- The information collected about you for this research will not be used by or distributed to investigators for other research.

What Will Happen If I Am Injured During This Study?
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 Dr., Somerset, NJ 08873.

Who Can I Contact If I Have Questions?
If you have questions, concerns or complaints about the research, wish more information, you can contact the Principal Investigator: Charles J. Gatt, Jr. MD, Department of Orthopedic Surgery Rutgers RWJMS, 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?
- Medical history or treatment
- Survey results or questionnaires
- Results of balance and functional testing

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

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 Dr., Somerset, NJ 08873.

How Long Will My Permission Last?
There is no set date when your permission will end at this time.

AGREEMENT TO PARTICIPATE

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:_____

Parent or Guardian – (Print) _____ Date:_____

Parent or Guardian Signature: _____

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 Name (Print):_____

Signature:_____ Date: _____