RUTGERS
Robert Wood Johnson Medical School

Department of Orthopaedic Surgery
Rutgers, The State University of New Jersey
51 French Street, MEB 422
New Brunswick, NJ 08901-0019

Charles J. Gatt, Jr., MD – Chairman

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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Conservative Treatment of High Ankle Sprains
Principal Investigator: Charles J. Gatt, Jr., MD, Principal Investigator
Eric Nussbaum, MEd, LAT, ATC Study Coordinator

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 study the long term impact of high ankle sprain. If you take part in the research, you will be asked to complete a brief survey, and undergo 4 xrays to determine the amount of joint erosion and functional disabilities. Your time in the study will take approximately 5-10 minutes to complete the online survey, and 15 minutes to complete 4 standard xrays.

Possible harms or burdens of taking part in the study may be a small exposure to radiation from the ankle xrays, but this risk is minimal and equivalent to about 6-8 hours of normal sunlight exposure. Other than signing your name on the consent form, all data collected will be de-identified and offers no more than minimal risk to you.

An alternative to taking part in the research
Your 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 acknowledge 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. Eric Nussbaum, MEd, LAT, ATC is serving as the study coordinator and he may be reached at ericn@uognj.com, 908-300-5833 (cell). Charles J. Gatt, Jr., MD may be reached at 732-537-0909, gattcj@rutgers.rwjms.edu.

The Principal investigator or another member of the study team will also be asked to acknowledge this informed consent and a copy will be emailed to you to keep.

Why is this study being done?

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This study is being done to look at the long-term impact of high ankle sprains and evaluate the initial treatment that was employed for your injury. .

Who may take part in this study and who may not?
Only individuals who suffered high ankle sprains while participating in athletics and who underwent a standardized rehabilitation protocol may participate in the study. Those who did not, may not participate. .

Why have I been asked to take part in this study?
You are being asked to participate because a record review noted that you suffered a high ankle sprain and underwent conservative treatment as an athlete at Rutgers University or Hillsborough High School 15-20+ years ago. .

How long will the study take and how many subjects will take part?
Participation in the study should take less than 30 minutes to complete. The online survey may be completed online at your home, while the xrays will be arranged at University Orthopaedic Associates.

What will I be asked to do if I take part in this study?
You will be asked to complete and acknowledge the online consent, a brief online survey (5-10 minutes to complete) and undergo 4 standard xrays of your ankles (10-15 minutes) which will be completed at UOA without any cost to you or your insurance. .

What are the risks of harm or discomforts I might experience if I take part in this study?
You will be subjected to no more than minimal risk by participating in this study. Use of an Xray does involve a small amount of radiation that is equivalent to 6-8 hours of sun exposure in a normal day. The xray technicians will make every effort to prevent un-necessary exposure by limiting the field of exposure and with use of protective draping. .

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 minimal to you personally, but the information we gather from this study will help to influence care of HAS for other patients in the future. However, it is possible that you may not receive any direct benefit from taking part in this study. We will provide a $15 VISA gift card to you as a token of our appreciation for your participation in the 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?

We will alert you to any significant findings we make during the study. We will share a copy of our results after all volunteers have been enrolled and findings have been analyzed.

Will There Be Any Cost To Me To Take Part In This Study?
There will be NO cost to you to take part in the study.

Will I Be Paid To Take Part In This Study?
You will receive a $15 VISA gift card as a token of our appreciation for participating 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. When you agree to take part in the study, you are automatically given an ID number which is utilized for all review of data in order to keep the data de-identified. .

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?

- 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. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by acknowledging 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. Any data that has already been collected cannot be withdrawn because there may not be any identifiers to link the data with you.

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, Chairman, Department of Orthopaedic Surgery, Rutgers, Robert Wood Johnson Medical School, gattcj@rutgers.rwjms.edu.: You can also contact the study coordinator, Eric Nussbaum, MEd, LAT, ATC, ericn@uognj.com, 908-300-5833.

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?

- Responses to a survey (SEFAS, PROMIS-10, Demographics)
- Xray review (K-L Score, TFCS, TFO, Talar Tilt)

Who May Use, Share or Receive My Information?
(Required Text)
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

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 him or her of your decision. Charles J. Gatt, Jr., MD, Chairman, Department of Orthopaedic Surgery, CAB, 1 Rutgers Plaza, New Brunswick, NJ. gattcj@rutgers.rwjms.edu

How Long Will My Permission Last?
Your permission for the use and sharing of your health information will last until the study is closed and any information presented/or published. (approximately 1-2 years)

AGREEMENT TO PARTICIPATE

Subject Consent:

Please print out this consent form if you are 18 years of age or older and have read and understand the information. I agree to take part in the research.

Subject Name (Print):_____

Subject contact information:_____

Date:_____ Time:_____

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: _____