Informed Consent Form

The Andrews Return to Sport ACL Score: A Developmental Study

RESEARCH PARTICIPANT INFORMATION, CONSENT FORM, AND HIPAA AUTHORIZATION FOR RESEARCH

TITLE OF PROJECT: The Andrews Return to Sport ACL Score: A Developmental Study

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INTRODUCTION:

To decide whether you wish to participate in this research study, you should understand why the study is being done, how the study will be run, the types of study procedures involved, your time commitments, and the possible risks and/or benefits associated with your participation to enable you to make an informed decision. This process is known as "informed consent."

Informed consent can be completed on paper, or electronically via REDCap. REDCap is a secure web application for building and managing online surveys and databases. While REDCap can be used to collect virtually any type of data in any environment (including compliance with 21 CFR Part 11, FISMA, HIPAA, and GDPR), it is specifically geared to support online and offline data capture for research studies and operations. The REDCap Consortium, a vast support network of collaborators, is composed of thousands of active institutional partners in over one hundred countries who utilize and support their own individual REDCap systems.

This written/electronic consent form and HIPAA Authorization provides detailed information about the research study. This consent form and HIPAA Authorization may contain words that you do not understand. Please ask the study doctor ("Investigator" or "Researcher") or the study staff to explain any words or information that you do not clearly understand. Before you decide to take part in this study, you may want to think about it more, or discuss it with family or friends. You can take a copy of this form home with you before making your decision. Your participation in this study is voluntary. You should not join this research study until all your questions are answered to your satisfaction.

If you wish to participate in this research study, you will be asked to sign/electronically sign this consent form and HIPAA Authorization. You must sign before any study procedures are done. You will be given a copy of this consent form and HIPAA Authorization to keep for your records.

PURPOSE OF THE RESEARCH STUDY:

The purpose of the study is to create a data-driven algorithm to assess competitive athletes' readiness to return to sport after ACL injury, surgery, and recovery safely.

WHAT IS RETURN TO SPORT?

Returning to sport refers to obtaining medical clearance to participate in competitive sports after recovery at each athlete's pre-injury level.

WHAT WILL HAPPEN DURING THIS STUDY?

Initially there will be a visit for the AREF Research Team to review inclusion criterion with you. At this time, the AREF Research Team will review and collect informed consent from each participant using the defined informed consent process (above). Visit two will occur three (3) months after each participant's ACL reconstruction surgery. At this time, a medical evaluation by the treating physician will occur along with functional movement assessment by a physical therapist and an MRI. Visit three will occur six (6) months after each participant's ACL reconstruction surgery. At this time, a medical evaluation by the leading physician will occur along with functional movement assessment by a physical therapist and an MRI. Visit four will occur nine (9) months after each participant's ACL reconstruction surgery. At this time, a medical evaluation by the leading physician will occur along with functional movement assessment by a physical therapist and an MRI. Visit five will occur twelve

(12) months after each participant's ACL reconstruction surgery. At this time, a medical evaluation by the leading physician will occur along with functional movement assessment by a physical therapist and an MRI. Visit six will occur eighteen (18) months after each participant's ACL reconstruction surgery. At this time, a medical evaluation by a leading physician will occur along with functional movement assessment by a physical therapist and an MRI. Visit seven will occur twenty-four (24) months after each participant's ACL reconstruction surgery. At this time, a medical evaluation by a leading physician will occur along with functional movement assessment by a physical therapist and an MRI. At each time point, the physician or the physical therapist performing the functional movement assessment can choose to limit the functional movement assessment if there are concerns that the patient may not be ready for the expected load of one or more elements of the functional movement assessment.

At each monthly time point after ACL reconstruction, patient reported outcomes measures (PROMs) will be collected by the research team to assist in assessing the overall health and confidence in Return to Sport for each athlete. The following patient reported outcomes will be collected in written or electronic format after informed consent has been obtained from each participant: Sports Participation, Reinjury, Tampa Kinesiophobia Scale, IKDC, PROMIS, SANE.

SELECTION OF PARTICIPANTS:

If you decide to be in this study, you will be one of one hundred pre-collegiate or collegiate competitive athletes in this research study. You must be between the ages of 14 and 24. You must consent to adhering to the above treatment schedule.

HOW LONG WILL I PARTICIPATE IN THIS STUDY?

The approximate duration of this study will be 36 months.

WHAT AM I RESPONSIBLE FOR?

After consenting to the study, you will be responsible for attending the scheduled appointments for the research study and completing the monthly Patient Reported Outcome Measures (PROMs). It will also be your responsibility to communicate openly with the research team during you monthly PROMs.

RESEARCH PROCEDURES:

If you agree to be in the study, we will ask you to do the following things:

Treatment Schedule:

1. Visit 1- Screening Visit (Consent, Inclusion/Exclusion)
2. Visit 2- (3 mo after ACL Reconstruction)
    a. Medical Evaluation, Strength/Functional Testing with a Physical Therapist, MRI
3. Visit 3- (6 mo after ACL Reconstruction)
    a. Medical Evaluation, Strength/Functional Testing with a Physical Therapist, MRI

4. Visit 4- (9 mo after ACL Reconstruction)-

    a. Medical Evaluation, Strength/Functional Testing with a Physical Therapist, MRI

5. Visit 5- (12 mo after ACL Reconstruction)

    a. Medical Evaluation, Strength/Functional Testing with a Physical Therapist, MRI

6. Visit 6- (18 mo after ACL Reconstruction)

    a. Medical Evaluation, Strength/Functional Testing with a Physical Therapist, MRI

7. Visit 7- (24 mo after ACL Reconstruction)

    a. Medical Evaluation, Strength/Functional Testing with a Physical Therapist, MRI

Patient Reported Outcomes: Monthly including Sports Participation, Reinjury, Tampa Kinesiophobia Scale, IKDC, PROMIS, SANE

RISKS AND DISCOMFORTS:

As with any research involving participants, there is the inherent risk of a breach in participant confidentiality though this will be minimized using participant code numbers and adherence to all HIPAA guidelines.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

In the unlikely event of an emergency, AREF will provide basic first aid medical treatment. However, if you were to require additional medical care because of participating in this study, you would need to contact your personal physician at your own expense.

The Investigators, the employers of the Investigators, and the Research Site do not have programs for compensating participants for injury or complications related to human participant's research. Any treatment will be at your expense.

ALTERNATIVES:

You do not have to take part in this study and can choose to proceed with your medical care without participating in this study.

BENEFITS:

What are the health benefits of participating in this study?

No benefits to participant health may be obtained from participation in this study, but it is hypothesized that the information obtained in this study will allow the orthopedic community to safely return competitive athletes to sport at their pre-injury level.

Will it cost me anything to be in this study?

There will be no cost to you for the MRIs, PROs, or Functional Movement Assessments.

Will I be paid for participating in this study?

Compensation will be provided to participants on a pre-set schedule. Each study participant will be provided with a total five hundred dollars ($500.00) by gift card for their participation in the study through the 24-month period. $100.00 gift card at Visit 2, $100.00 gift card at Visit 3, $100.00 gift card at Visit 5, $100.00 gift card at Visit 6, and $100.00 gift card at Visit 7. If a participant withdraws from the study the monetary benefits will not be dispersed after the withdrawal date.

Who is funding this study?
This study is being funded by the State of Florida Grant awarded to the Andrews Research & Education Foundation.

CONFIDENTIALITY:
All personal information is strictly confidential, and no names will be disclosed except as required by law. Your individual performance or results will not be reported; when/if this study is published, only the results of all participants as a group will be reported. During this study, your information will be de-identified and identified only by a participant number.

All information and data collected during this research will be recorded in an electronic data collection system. This data will not contain protected health information. The data will be stored in a secure password protected electronic system that only the study Investigators will have access to. Records related to this study will be securely retained in a secure location for a period of 3 years after the completion of the study or longer as required by law. At that time, all records will be properly destroyed.

HIPAA and PROTECTED HEALTH INFORMATION:
We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information, also called "PHI," or share it with others for research purposes.

You are being asked to sign this authorization allowing us to share your PHI for purposes of this research study. If you sign this authorization, you give permission to the Investigators to use or disclose your PHI for the research study described here. You can decide to sign or not to sign this authorization. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Any choice made will not effect your access to medical care.

The United States government has issued a privacy rule to protect the privacy rights of patients ("Privacy Rule"). This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your health information. Andrews Research and Education Foundation is required by law to protect your health information. By signing this document, you authorize Andrews Research and Education Foundation to use and/or disclose your health information for this research. Those persons who receive your PHI may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

During this study, the Investigators will need to use your PHI. PHI is information about you that could be used to identify you, such as your name, address, telephone number, date of birth, new and existing medical records,

or the types, dates, and results of various tests and procedures. This may also include information in your medical record and information created or collected during the study. We may also ask other health care providers to give us any information about your health status or your health care. If you sign this authorization, you are agreeing to allow the Researchers to use your PHI to carry out this study.

By signing this authorization, and solely for the purposes of completing this research, you allow the research staff to disclose your PHI to outside entities involved in completing the research project, such as people who review the research study, their staff, lawyers, government groups (such as the Food and Drug Administration), or safety monitors. The study data that the Researchers send to these entities will not include your name, address, or social security number, but instead, will be designated with a code number. However, your medical records can be reviewed or copied at the study site by regulatory authorities or other oversight bodies, including the Institutional Review Board. The purpose of these reviews is to make sure the study is being conducted properly and that the data is being collected correctly, or for other purposes allowed by law.

Your PHI may no longer be protected by the privacy rule once it is disclosed. Your PHI will be kept as confidential as possible under the law; however, absolute confidentiality cannot be guaranteed.

You may cancel this authorization at any time by writing to the Investigator at the Contact Information provided above. If you cancel this authorization, the Researchers will no longer use or disclose your PHI under this authorization for this study, unless it is needed to preserve the scientific integrity of the study. Information obtained before you cancel the authorization may still be used by the Researchers. If you do not cancel this authorization, it will automatically expire at the conclusion of the research study.

CONFLICT OF INTEREST:

There are no conflicts of interest to disclose for the investigator and this study.

VOLUNTARY PARTICIPATION/WITHDRAWAL:

Taking part in this study is **voluntary.** Your medical treatment, costs of treatment and eligibility for benefits will not be affected if you decide not to sign this Consent Form or participate in the study. If you agree to participate, in the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether to continue your participation.

QUESTIONS:

It is your right, as a research participant, to ask questions at any time regarding the procedures involved and any aspects of this study including the potential benefits or risks. For any questions you may have for the Investigators, you may contact them at (850) 916-8748. For any questions you may have for the Research Team, you may contact them at (850)916-8570.

If you have questions about your rights as a research participant or if you have questions, concerns, or complaints about the research, you may contact the Baptist Hospital Institutional Review Board* at (850) 469-2227. The IRB will not be able to answer some types of questions, such as questions about appointment times.
*The IRB is a group of individuals who independently review research

STATEMENT OF CONSENT TO PARTICIPATE IN THIS RESEARCH STUDY:

By signing this consent form, I agree to and acknowledge the following statements:

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I agree to participate as a participant with the understanding that my participation is completely voluntary, and that I may withdraw at any time without prejudice by sending a written request to the Investigator at the Sports Medicine Research Lab, Andrews Research and Education Foundation, 1020 Gulf Breeze Pkwy, Gulf Breeze, FL 32561.

I have read and understand the above information and have been given the opportunity to discuss it and ask questions.

I understand that this authorization does not have an expiration date.

I have received a copy of this authorization form for my records.

I have been informed that I may contact the Investigators by phone at (850) 916-8748 in order to answer any questions that I may have at any time during my participation.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Conducting Informed Consent

_____ _____
Signature of Person Conducting Informed Consent Date

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