A Randomized, Single Blinded Study of the Augmentation of Anterior Cruciate Ligament Reconstruction using Stump-Derived Mesenchymal Stem Cells Versus Standard of Care Anterior Cruciate Ligament Reconstruction

**RESEARCH SUBJECT INFORMATION AND CONSENT FORM**

**TITLE OF PROJECT:** A Randomized, Single Blinded Study of the Augmentation of Anterior Cruciate Ligament Reconstruction using Stump-Derived Mesenchymal Stem Cells Versus Standard of Care Anterior Cruciate Ligament Reconstruction

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**FUNDING MECHANISM:** State of Florida Grant

**INVESTIGATOR CONTACT INFORMATION:**

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**INTRODUCTION:**

In order 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 to make an informed decision. This process is known as "informed consent."

This written consent form provides detailed information about the research study. This consent form may contain words that you do not understand. Please ask the study doctor 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 of your questions are answered to your satisfaction.

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

**PURPOSE OF THE RESEARCH STUDY:**

You are being asked to participate in research being conducted by the Andrews Research & Education Foundation (AREF). The purpose of this study is to see if a novel technique that utilizes your own stem cells to augment your anterior cruciate ligament (ACL) graft will result in improved clinical outcomes and healing.

**SELECTION OF SUBJECTS:**

The study involves 50 participants undergoing ACL reconstruction. If you are between the ages of 14 and 50 years old and are scheduled to have ACL reconstruction you may participate in this study. If you require ACL and posterior cruciate ligament (PCL) combined surgery, have with a history of an autoimmune disease, diabetes, a blood/clotting disorder, or a history of previous surgery on the injured knee, then you cannot participate in this study.

**RESEARCH PROCEDURES:**

If you meet the above criteria, you will have the study explained in detail and you will have to give your written consent to be in the study. After giving consent, twenty-five randomized participants will receive standard of care (SOC) ACL reconstruction surgery. The other twenty-five randomized participants will receive ACL reconstruction surgery augmented with their own ACL stump tissue harvested with the GraftNet device and the tissue applied to the ACL autograft. You

will not know which group you have been randomized to during the research project. This technique has been practiced using cadaver specimens.

**RISKS AND DISCOMFORTS:**

Standard sterile precautions for surgical procedures will be utilized for the ACL reconstruction, but with any surgery there is risk of infection, bleeding, and swelling. Pain post operatively should be equivalent to levels experienced by individuals undergoing ACL reconstruction without bioaugmentation. Also since this project includes stem cells, there is a small risk of tumor formation.

There is a small risk of the disclosure of your protected health information, which will be minimized where possible including removing all identifiable information from data collection sheets and storing study information in secure locations as described in more detail below.

**ALTERNATIVES:**

You do not have to participate in this study and can choose to have the standard-of-care ACL reconstruction surgery performed without the bioaugmentation procedure.

**BENEFITS:**

If you are randomized to the intervention group, you may directly benefit by improved healing of your ACL repair as a result of agreeing to participate in the study. All participants will also benefit indirectly due to the increased follow-up monitoring. Future patients may benefit from the information obtained in this study (aspirational benefit).

**CONFIDENTIALITY:**

All patient protected health information and other confidential information is protected by state and federal law, unless you allow it to be disclosed. During the course of this study, your information will be identified by a letter-number combination. Any new information that might develop during the course of the project will be provided to you if that information might affect your willingness to participate in the project. Pictures of you will be taken only if you sign below where it states: “I am willing to have photographs taken of the inside of my knee for use in presentations or publications.”

All information and data collected during this research will be recorded on the appropriate forms and stored in a locked room in the AREF research facility. In addition, all subject data forms, including summary information and spreadsheets, will be scanned and stored in a secure password protected folder on a laptop that only the study investigators will have access to, and will be permanently deleted following publication of any and all manuscripts written as a result of this research. Records related to this study will be retained in a secure location for as long as required by applicable law, but no less than

a period of 3 years after the completion of the study. At this time, all records will be properly destroyed.

**HIPAA and PROTECTED HEALTH INFORMATION:**

We know that information about you and your health is private. 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 can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make, about this research study will not have an effect on 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. This section describes your rights and explains how your health information will be used and disclosed for this study.

During this study, the researchers will need to use personal health information about you. Your personal health information is health information about you that could be used to identify you because it includes information, such as your name, address, telephone number, photograph, date of birth, social security number, new and existing medical records, or the types, dates, and results of various tests and procedures. This may include information in your medical record and information created or collected during the study. By signing this consent, you are agreeing to allow the research personnel to use your personal health information to carry out this study.

By signing this document, you also allow the research staff to disclose your personal health information to outside entities who may be directly involved in completing the study project. 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 Baptist Hospital 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 personal health information may no longer be protected by the Privacy Rule once it is disclosed, your personal health information will be kept as confidential as possible under the law; however, absolute confidentiality cannot be guaranteed.

If you cancel this authorization, the researchers will no longer use or disclose your personal health information under the authorization for this study, unless it is needed to preserve the scientific

integrity of the study. Information obtained before you cancel this authorization may still be used by the researchers.

**COST AND COMPENSATION:**

All procedures are part of standard-of-care. You will be responsible for any costs not covered by your insurance policy for the standard-of-care procedures. This includes the costs associated with the surgery and follow-up imaging. There will be no additional costs to you for the research-specific procedures (follow-up patient reported outcome measures (PROMs) and functional assessments). In the unlikely event of an emergency, the 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 does not have programs for compensating subjects for injury or complications related to human subjects' research. Any treatment will be at your expense.

**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. 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 or not 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 researcher, you may contact them at (850) 916-8590.

If you have questions about your rights as a research subject 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:

I agree to participate as a subject in this study and for my protected health information to be released as described in this consent.

I understand that my participation is completely voluntary, and that I may withdraw at any time without prejudice by sending a written request to the researcher 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) 916-8796 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 Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion Date

**PHOTOGRAPH CONSENT:**
Please indicate your preference below with regard to photographs to be taken of you during your participation:

_____ I am willing to have photographs taken of the inside of my knee for use in presentations and/or publications.

_____ _____
Signature of Participant Date



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