Consent and Authorization Document

STUDY TITLE: Intra-articular platelet-rich plasma in the management of acetabular labral tears: a prospective study

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CO-INVESTIGATOR: Derek Stokes, MD

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BACKGROUND

You are being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask the research doctor or staff if there is anything that is unclear or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

Labral tears are a common cause of hip and groin pain in athletes and the general population. The labrum is an important structure for hip perseveration and function; therefore, it is important to identify and treat labral injuries. Management often consists of a trial of conservative treatment including anti-inflammatory medications, physical therapy, injections with surgery sometimes being indicated.

Platelet-Rich Plasma (PRP) is an injectable preparation of a patient's blood that has received significant attention over the past several years for its potential application for the treatment of pain and functional impairment in various musculoskeletal conditions. One small prior study has shown promising evidence in the treatment of hip pain due to labral tears with a PRP hip injection.

This study aims to evaluate the clinical outcomes of a PRP hip injection in the management of hip pain due to labral tears.

This study is being conducted by Daniel Cushman, MD and Derek Stokes, MD at the University of Utah Orthopedic Center.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

STUDY PROCEDURES

Your involvement in the study will include one office visit for a PRP injection into your hip joint and up to five (5) follow-up events (e.g. surveys) conducted via email, text message, in person and/or by telephone over a period of 1 year as follows:

- Injection procedure treatment visit along with preliminary surveys (in-person)
- One-month follow-up survey (electronic)
- Three-month follow-up survey (electronic)
- Six-month follow-up survey (electronic)
- Twelve-month follow-up (electronic)

Injection Procedure Treatment Visit:

During the injection visit you will (if not already completed):

- Be approached by a member of the research team to discuss the consideration of taking part in the study if they meet the inclusion criteria of this study project
- Review the informed consent document with a member of the study team
- Be asked questions about your health, lifestyle and any current illnesses or medication(s) you are taking
- Be asked to give a summary of all previous treatments that may have been performed to treat your hip pain
- Complete questionnaires on your pain, function, and quality of life levels
- Have your blood drawn by appropriate personnel (approximately 45mL)
- Have your blood processed using PRP preparation method and its complete blood count analyzed using a cell counter
- Have your hip injected with the prepared PRP (8mL) by a board-certified, sports medicine physician

Your procedure outcomes will be assessed using patient questionnaires specific to your physical function. These are all different types of surveys and physical exams used to assess how well the injections work.

Follow-up Visits/Emails/Phone Calls:

You will have one visit as part of standard of care and 4 follow up emails and/or phone calls/texts as part of research. You can come to the clinic for an evaluation at any time if you are experiencing any pain or side effects as part of standard of care.

1 Month: Patient questionnaires sent by mail, email, phone or text. You may receive a phone call to clarify any of your responses.

3 Months: Patient questionnaires sent by mail, email, phone or text. You may receive a phone call to clarify any of your responses.

6 Months: Patient questionnaires sent by mail, email, phone or text. You may receive a phone call to clarify any of your responses.

12 Months: Patient questionnaires sent by mail, email, phone or text. You may receive a phone call to clarify any of your responses.

You may receive additional communications from the study team to assess any adverse events that occur in between the scheduled 1-month follow-up visit and subsequent follow-ups.

RISKS

As with any injection procedure, there are risks involved. These will be similar to standard-of-care injections. First, there is a risk of a bruising, bleeding, or other minor, temporarily painful aspects. Second, although millions of PRP injections have been performed nationwide, zero case reports have been published on post-injection infections. However, there always remains a risk of an infection, which is quite serious. Only local inflammation has been reported as a case report to date, and resolved with time. It is possible to have a temporary worsening of your pain for up to a couple of weeks.

Because we need to collect information from your medical record for this study, there is a risk of loss of confidentiality. We follow strict privacy policies to minimize this risk.

UNFORESEEABLE RISKS

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

BENEFITS

We cannot promise any benefits to you from your being in the study. PRP has been demonstrated to reduce hip pain due to labral tears based on one small prior study. Subjects may have improved function and reduced pain after their injection. This will be a potentially safer and more effective treatment option compared to corticosteroid injection and/or surgery. The results of this study will be helpful in determining whether the treatment can be used successfully for treating this condition in future patients. In addition, it may be helpful in identifying patients who might best benefit from the treatment.

ALTERNATIVE PROCEDURES

You may choose not to participate in this study. If you do not want to take part in the study, there are other choices such as steroid injections, surgery, or other treatments as deemed appropriate by your physician.

CONFIDENTIALITY

We will keep all research records that identify you private to the extent allowed by law. Records about you will be kept in locked in filing cabinets and on computers protected with passwords or encryption. Only those who work with this study or are performing their job duties for the University will be allowed access to your information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, you can contact Dr. Daniel Cushman at 801-587-5458. If you think you may have been injured from being in this study, please call Dr. Daniel Cushman at 801-587-5458. Dr. Daniel Cushman can be reached at this number during the hours of 8:30am and 5:00pm Monday – Friday. An Orthopedic resident is on-call 24 hours a day and can be reached by calling the University Hospital operator at 801-581-2121.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY

If you are injured from being in this study, medical care is available to you at the University of Utah as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

It is up to you to decide whether or not to take part in this study. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate or the decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled. If you don't take part, you can still receive all standard care that is available to you. This will not affect the relationship you have with your doctor or other staff, nor decrease the standard of care that you receive as a patient.

If you want to stop being in this study, please let the research doctor know. That way you can find out what should be done about your routine care outside of the study.

RIGHT OF INVESTIGATOR TO WITHDRAW

The investigator can withdraw you without your approval. Possible reasons for withdrawal include:

- It is not in your best medical interest to continue
- You do not follow instructions/non-compliance
- The study is terminated

COSTS AND COMPENSATION TO PARTICIPANTS

The costs of the injection procedure and visit will be covered by the study. All other visits, imaging (hip x-ray images and hip MRI), and procedures (i.e., diagnostic hip injection) you have are part of your normal care and will be billed to you or your insurance company.

By receiving SMS messages for surveys, you may incur standard SMS messaging costs from your mobile phone provider. You will not be compensated for your text messaging charges. Therefore, these costs will be your responsibility. We encourage you to understand the costs associated with sending and receiving text messages from your mobile phone provider before enrolling in this study.

Participants will be compensated with one $50 Amazon gift card for their participation in the study after the PRP injection is completed.

NEW INFORMATION

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study.

NUMBER OF PARTICIPANTS

We expect to enroll 30 participants at the University of Utah.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this research study. You can choose whether or not you will participate in this research study. However, in order to participate you have to sign this consent and authorization form. This is the information we will use:

- Name
- Address
- Email address
- Telephone number
- Family medical history
- Allergies
- Current and past medications or therapies
- Operative reports, laboratory results, discharge and progress notes
- Any other personal health information that will be obtained from other sources to be used in the research record, including prior medical history, tests or records from other medical facilities
- Information from a physical examination, such as blood pressure reading, heart rate, breathing rate, temperature, and physical exam scores.
- X-ray and MRI imaging and reports
- Answers to questionnaires about pain and function

Others who will have access to your information for this research project are the University's Institutional Review Board (the committee that oversees research studying people) and authorized members of the University of Utah who need the information to perform their duties (for example: to provide treatment, to ensure integrity of the research, and for accounting or billing matters).

You may revoke this authorization at any time. This can be done verbally or in writing**.** You must either give your revocation in person to the Principal Investigator or the Principal Investigator's staff, or mail it to University of Utah 590 Wakara Way, Salt Lake City, UT 84108 ATTN: Dr. Cushman. If you revoke this authorization, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished.

This authorization does not have an expiration date.

CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep. **I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.**

_____

Participant's Name

_____

Participant's Signature Date

STATEMENT OF STAFF OBTAINING AUTHORIZATION AND CONSENT

- ❑ I have carefully explained to the participant the nature and purpose of the above study in language understood by the participant.
- ❑ I provided the participant enough time and an adequate place to read and review this form and discuss the study with study investigators and/or family members. I have answered the participant's questions to their satisfaction.
- ❑ The participant voluntarily agreed to participate in the study and personally signed and dated the consent prior to any study procedures being done.
- ❑ A copy of the signed & dated consent form was given to the participant. The original is kept in the study file.

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Name of Person Obtaining Authorization and Consent

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Signature of Person Obtaining Authorization and Consent Date