Consent and Authorization Document

Research Study Title: Treatment for sacroiliac joint pain using platelet-rich plasma (PRP) regenerative therapy: a randomized controlled trial in comparison with steroid/anesthetic injection with advanced MR analysis.

Sponsor: This research is being funded by Radiological Society of North America.

STUDY SUMMARY

You are being asked to take part in a research study. Before you consider the research, the most important information is summarized. It is important for you to understand why the research is being done and what it will involve. Following the summary, you will be given more detailed information.

- Participation in this research is voluntary. You do not have to be in the study.
- The purpose of the study is to determine whether platelet-rich plasma injection will reduce sacroiliac joint pain.
- A group will undergo platelet-rich plasma injection, and a second group will undergo steroid/anesthetic injection into the sacroiliac joint for pain treatment.
- The study will involve undergoing either platelet-rich plasma, or steroid/anesthetic injection of the sacroiliac joint. The procedures will be explained in detail later in this consent. Your participation in the study will last about 3 months. You will undergo the procedure then have 2 in-person follow-up study visits with us.
- There are risks with both injections. All the risks will be explained in detail later in the consent.
- There may not be any direct benefit to you for participating in this study. Potential benefits to you or others will be explained later in this consent document.
- If you decide not to take part in the study, you have other options such as continuing with your current treatment plan, or talking with a clinician about different treatments for sacroiliac joint pain.

Please take time to read the following information carefully and discuss it with friends, relatives and health care professionals, if you wish. Ask the research doctor or staff if there is anything that is not clear, or if you would like more information. Take time to decide whether or not to volunteer to take part in this research study.

BACKGROUND AND PURPOSE

The purpose of the study is to assess which of two effective treatments, steroid or platelet-rich plasma injection, performs better for controlling sacroiliac joint pain. Both treatments have been used to treat pain, but at this time we do not have enough evidence to know which treatment is better. You will undergo one of these treatments through an image-guided injection.

In addition to the information we gain from testing your pain and physical status, we will also access information from your medical records relevant to our research on sacroiliac joint pain.

Specifically, we will access information on physical examination findings, medications you are taking, as well as all clinically relevant data.

This research is being conducted by Dr. Miriam Peckham, a Radiologist at the University of Utah.

STUDY PROCEDURES

This section is designed to explain what you will be required to do, undergo, and experience if you decide to take part in this study.

This study is a single-blinded randomized trial which means that two different treatments are available and a computer will select you for one of the treatments by chance. You will not know which treatment group you are in. You have a 50:50 chance of getting either a steroid or platelet-rich plasma injection in your sacroiliac joint.

The research study you have been asked to take part in will last 3 months. You will undergo an image-guided injection of your sacroiliac joint. Before this procedure, we will draw approximately 20-30 cc's of your blood. We will follow up with you in-person in 1 month, and then for a final time at 3 months. If we cannot meet with you in-person, these visits will be conducted virtually. After your procedure, we will also call or email you three times (day 3, day 7, and two months after) to ask you how your pain is. The total study length of time is 3 months.

<u>First visit: Sacroiliac joint injection (~1 hour)</u>

At this visit you will undergo an image-guided injection of your sacroiliac joint.

1. Before the procedure begins we will draw approximately 20-30 cc's of your blood (this is standard of care for PRP, and a research procedure if you are in the steroid/anesthetic group but carries risk).
2. We will have you fill out two surveys: Modified Oswestry Disability Index, and Short Form 12 survey, to assess your physical status. These are research questionnaires, which means that you receive them because you participated in this research study.
3. We will assess your pain and functional status. These are a part of the standard care which means that you will undergo this assessment even if you do not participate in this research study.
4. We will perform an image-guided injection of your sacroiliac joint(s). You will lie down on your stomach on the CT table, and using CT images generated in real-time, we will administer local numbing anesthetic (lidocaine) in your lower back. We will then place a needle through this numb-area of skin into your joint using the images to guide us. Depending on which group you have been randomized to, we will inject either platelet-rich plasma that we have obtained from your blood or a mixture of steroid/anesthetic into your sacroiliac joint(s). These are standard of care procedures which means that you will receive them even if you do not participate in this research study.

5. After the injection we will again assess your pain and functional status. These are a part of the standard care which means that you will undergo this assessment even if you do not participate in this research study.

Day 3 follow-up (~5 min)

1. We will assess your pain by phone or e-mail. These are research assessments, which means that you receive them because you participated in this research study.

Day 7 follow-up (~5 min)

1. We will assess your pain by phone or e-mail. These are research assessments, which means that you receive them because you participated in this research study.

1 month visit: Pain and functional assessment (~1 hour)

1. We will have you fill out two surveys: Modified Oswestry Disability Index, and Short Form 12 survey, to assess your physical status. These are research questionnaires, which means that you receive them because you participated in this research study.
2. We will assess your pain and functional status. These are research assessments, which means that you receive them because you participated in this research study.
    - If we determine that we cannot perform this follow-up visit with you in-person, a study team member will arrange with you to complete it via visual tele-health.

2 month follow-up (~5 min)

1. We will assess your pain by phone or e-mail. These are research assessments, which means that you receive them because you participated in this research study.

3 month visit: Pain and functional assessment (~1 hour)

1. We will have you fill out two surveys: Modified Oswestry Disability Index, and Short Form 12 survey, to assess your physical status. These are research questionnaires, which means that you receive them because you participated in this research study.
2. We will assess your pain and functional status. These are research assessments, which means that you receive them because you participated in this research study.
    - If we determine that we cannot perform this follow-up visit with you in-person, a study team member will arrange with you to complete it via visual tele-health.

A small sub-group of patients will undergo an MRI scan before and 6 months after the procedure. If you are in this small group you will undergo an MRI scan within 1 month before your injection, and then a second MRI scan 6 months after your injection. The scan takes approximately 1 hour to complete.

The MRI Sacroiliac Joint Imaging Procedure (if applicable)

You will have two study visits during which MRI scans of your sacroiliac joints are performed. These scans provide pictures of the sacroiliac joint and allow us to look specifically at your cartilage and joint fluid. The scans do not cause pain, and do not use radiation. The MRI

scanner looks like a large cylinder with a tube in the middle. You will be asked to lie down on your back on a foam-padded table. The table slides inside the "tube" of the scanner. Soft, foam rubber sponges may be placed on both of your sides and under your head for comfort. It is important that you keep your body as still as possible. Because the scanner contains a strong magnet, you will need to remove all metal objects from your body. This includes: watches, rings, necklaces, bracelets, earrings, body piercings, belts, coins, and wallets (with credit cards). Some items of clothing contain metal (like shirt or pants zippers, or shoelace eyelets) and must be removed. These items will be locked in a safe place until the scan is over. Otherwise, you can stay in your street clothes.

You will hear different sounds during the MRI scan. These sounds can be loud, and the sounds change depending on the type of picture that is being taken. Some examples of sounds you may hear are: like a hammer hitting a piece of wood, like an electric saw, loud beeping or clicking, or buzzing noises. These sounds may be repeated several times during the scan, and are part of the normal function of the scanner.

You will be in the scanner for a total of up to 60 minutes.

RISKS

There are certain risks that could occur due to study participation. For example:

Risk of Injection: The injection is for your standard of care treatment, which means that you will receive it even you do not participate in this research.

- Both injections involve risks of pain, bleeding, infection, or injury to surrounding structures.
- Additional risks include the chance that the procedure may not work for you and your pain will not be relieved.
- The CT imaging procedure is a part of your standard care, and you would receive it even if you did not participate in this research study.
- The research team will take precautions to safeguard your confidentiality, but it is possible that a breach of confidentiality could occur.

Risk of MRI (For the subset of patients in the MRI study): Our MRI scans do not use ionizing radiation like x-rays or computed tomography (CT) scans. Instead, magnetic fields and radio waves are used to take pictures and measure brain chemistry. There are no known risks related to MRI scans, other than the risk of injury if metallic objects are brought into the scanning room by mistake. You can be seriously injured during an MRI scan to, if you have any of these:

- Cardiac (heart) pacemakers
- Metal clips on blood vessels, or stents inside of blood vessels
- Artificial heart valves
- Artificial arms, hands, legs, etc.
- Brain stimulation devices
- Implantable drug pumps

- Cochlear (ear) implants
- Ocular (eye) implants, or metal fragments in the eyes
- Exposure to shrapnel or metal fillings
- Other metallic surgical parts or implants
- Orthodontic braces on the teeth
- Body jewelry or piercings that cannot be removed for the scan
- Certain tattoos with metallic ink
- Transdermal (skin) drug delivery patches. Examples include: NicoDerm (nicotine for tobacco dependence), Transderm Scop (scopolamine for motion sickness), and/or OrthoEvra (birth control)

If you have any such items, you cannot have an MRI scan before being cleared by a research physician.

- Serious risks also exist if any ferromagnetic objects (things that stick to magnets) are brought into the scanner area. Ferromagnetic items become dangerous flying objects, and are not allowed near the scanner.
- The FDA has approved the 3 Tesla MRI scanner we use for this study, for performing routine scans in clinical care. The FDA has also decided that MRI scanners with a magnetic field strength of 8 Tesla or less do not pose significant risks to human beings. Although the scans done in this study have no known risks, there could be ill effects that are delayed, that have not yet been recognized by the FDA. The MRI scan does not cause pain. Apart from the scanner noise, you will not know the scan is taking place. Ear protection will be provided.
- Inside the scanner, some people experience claustrophobic anxiety (a fear of being in small spaces), dizziness, headaches, or a metallic taste in the mouth. You may feel cramped inside the scanner. There is a mirror placed inside the scanner so that your can see your face, or look out into the scanner room. The MRI technologist will give you a squeeze ball alarm for emergencies, and there is an intercom inside the MRI scanner so you can talk to the research team during the scan, if you experience discomfort.
- Very rarely, someone having a MRI scan feels tingling in their back, arms or legs. This is due to the magnetic field changing quickly during the scan. If you feel tingling during the scan, you should let us know right away so that the scan settings can be changed. However, the tingling does not mean that the MRI scanner is causing tissue damage, or medical harm.
- Very rarely, some people experience double vision, or see flashing lights during MRI scans. These symptoms are temporary, and will stop when you leave the scanner. Similar to the tingling described above, these visual symptoms do not mean that something is wrong, or that the scanner is causing you harm.
- The sounds made by the scanner can be loud or annoying, but the sounds are not harmful to your hearing. You will be given earplugs or headphones to muffle the noise.

- The researchers will take precautions to avoid all the known risks of MRI scans. You can request to stop the scan at any time, by squeezing the alarm the MRI technologist will give you.

Risks of Answering Study Questions

- There is risk from answering the study questions. *You do not have to answer any questions that you do not want to answer. You* may stop answering questions at any time without affecting your medical care. *All of your answers will remain confidential.*

Risks of blood draw

- There is a rare risk of infection associated with taking blood from a vein. There is a more common risk of bleeding, bruising, fainting or soreness at the site of the blood draw.
- Blood samples obtained from you in this research will only be used for the present study and will not be shared for future research. No whole genome sequencing will be performed.

Risks of Collection of Medical Record Information

- There is a risk of breach of confidentiality regarding collection of medical record information. All research information about you will be handled in a confidential (private) manner consistent with other hospital medical records.

BENEFITS

We cannot promise any benefits to you from being in the study. We do not know how platelet-rich plasma will work as a treatment for individuals with sacroiliac joint pain.

There are possible indirect benefits to this research:

- Results from the study may help doctors understand how platelet-rich plasma functions and if the injection of platelet-rich plasma is helpful for sacroiliac joint pain.
- The MRI scan could improve our understanding of how platelet-rich plasma works and if it helps with cartilage regeneration. This could help support usage of this technique for sacroiliac joint dysfunction. However, this would not directly benefit you.

ALTERNATIVE PROCEDURES

You may choose to not to participate in this study. If you decide not to take part in the study, there are other choices available to you. These include continuing with your current treatment plan, or talking with a clinician about different treatments for sacroiliac joint pain.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, or if you think you may have been injured from being in this study, you can contact Miriam Peckham MD at the University of Utah at 801-581-7553 during business hours. You may also call the University of Utah Medical Center 24 hours per day at 801-581-2121 and ask for on-call Radiologist.

Institutional Review Board: Contact the University of Utah 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, or by U.S. Mail at: 75 South 2000 East, Room 111, Salt Lake City, UT 84112.

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 University of Utah Health Care 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 for any treatment or hospital care 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.

This medical institution and the Radiological Society of North America have not made any provision for monetary compensation in the event of injury resulting from the research. In the event of such injury, treatment will be provided but it is not provided free of charge. Since this is a research study, payment for any injury resulting from your participation in this research study may not be covered by some health insurance plans.

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 Utah Governmental Immunity Act 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 Section 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 decide not to take part, you will still receive all standard care that is available to you. This will not affect the relationship you have with your doctor, nor decrease the standard of care that you receive as a patient at the University of Utah. 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.

UNFORESEEABLE RISKS
There may be risks from taking part in this study that are not known to the researchers right now. They may find out new risks while the study is going on. If this happens, the research staff will tell you the new information, whether it may affect you, and what, if anything, to expect.

RIGHT OF INVESTIGATOR TO WITHDRAW

We expect to continue the study until all participants have been enrolled and all of their information has been collected. However, the study may be stopped at any time by the researchers at this institution or by the Radiological Society of North America. The researcher may also withdraw you from the study without your approval. One reason this may happen is because the researcher feels it is necessary for your health and safety. Another reason is if the entire study is stopped.

COSTS AND COMPENSATION TO PARTICIPANTS

There will be no cost to you to take part in the research study. All study-related equipment and procedures, for example the MRI study if enrolled in the MRI sub-group, and CT guided injection of your sacroiliac joint, will be provided at no cost to you or your insurance company. The costs of your standard medical care will be billed to you or your insurance company in the usual manner, ask your study doctors if you have any questions on research cost.

You will receive compensation for your participation in this study, as follows:

- You will receive $25 for the sacroiliac joint procedure, and $25 for two follow-up visits for a total of $75 which will be paid to you at your final 3-month visit.
- For those enrolled in the MRI sub-group: You will receive an additional $25 per scan (two scans total) for a total of $50+$75=$125 which will be paid at the final 6-month scan.

Payment will be made at the time of the final visit. If you withdraw prior to the final visit you will not receive payment. If you miss a visit between the first and last visits, you will only be paid for total completed visits.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Blood samples obtained from you in this research may help in the development of a commercial product by the University of Utah or its research partners. There are no plans to provide financial compensation to you should this occur.

NEW INFORMATION

During the study, we may learn something about your health that could help you and your doctors make decisions about your healthcare. If this happens, we will tell you about these results. We will contact you by email or phone call, and make arrangements to discuss this with you.

NUMBER OF PARTICIPANTS

We expect to enroll approximately 25 participants at the University of Utah. We also expect to enroll 25 participants at one other local hospital (VA Medical Center).

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 some information about your health for this research study.

This is the information we will use and disclose in our research records:

- Demographic and identifying information like name, address, telephone number, email address;
- Related medical information about you like medical record number, height, weight, history of low back pain, physical examination findings;
- Other information collected about you includes type of medical insurance. Data will be collected on your current medication use and medication use after the procedure;
- All tests and procedures that will be done in the study.

How we will protect and share your information:

- We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

- This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

  The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

- The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the study sponsor Radiologic Society of North America; University of Utah Institutional Review Board, University of Utah, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), and the Government Accountability (GAO).

- If we lose track of you, study staff may collect information from the internet including social network sites in order to find your contact information.

1. Once the study is finished, you may request to have and review a copy of your personal health information collected during this study and placed in your medical record. This right to review and copy your personal health information only extends to information that is placed in your medical record; it does not extend to information that is placed in your research record.

2. If you do not want us to use information about your health, you should not be part of this research. If you choose not to participate, you can still receive health care services at University of Utah Health.

3. If we share your identifying information with groups outside of the University of Utah Health, the groups may not be required to follow the same federal privacy laws that we follow. They may also share your information again with others not described in this form.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

- You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, 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.

This authorization does not have an expiration date.

Because the results from future research will not directly affect your health care, we will not share the results from future studies with you or your doctors.

Please **INITIAL** the appropriate statement to indicate whether or not you give permission for future contact.

YES_____ I give permission to be contacted in the future for research purposes. (Please initial)

NO _____ I do not give permission to be contacted in the future for research purposes. (Please initial)

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

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date