A Prospective, Single-blind, Randomized, Multi-Center Study Comparing Platelet Rich Plasma and Corticosteroid for Patients with Glenohumeral Osteoarthritis in the Military and Civilian Population

NCT05160441

Informed Consent Form v1.9

Approved Date: 02 MAY 2024

WALTER REED NATIONAL MILITARY MEDICAL CENTER
CONSENT TO PARTICIPATE IN RESEARCH

Title: A Prospective, Single-blind, Randomized, Multi-Center Study Comparing Platelet Rich Plasma and Corticosteroid for Patients with Glenohumeral Osteoarthritis in the Military and Civilian Population

Principal Investigator: Dr. Sean E. Slaven

Other Study Sites: Naval Medical Center San Diego (NMCSD) and Brooke Army Medical Center (BAMC)

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your participation in this study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

You are being asked to consent to participate in a voluntary research study. The purpose of this study is to determine if platelet rich plasma (PRP) is effective at treating refractory glenohumeral osteoarthritis (OA), which is osteoarthritis in the shoulder joint that has not improved with previous treatment. PRP therapy involves the injection of a concentration of one's own platelets (created by using a centrifuge to spin down a sample of his/her own blood) with the goal of speeding up the healing process of injured tendons, ligaments, muscles, and joints.

Participants that volunteer for this study will be asked to complete 7-10 study visits, lasting approximately 45 minutes each, over a period of approximately 12 months. Participants will be randomized to one of three study groups:

1) PRP injection alone,
2) Corticosteroid injection (CSI) alone, *or*
3) CSI injection first with the option for PRP injection later.

Participants will be blinded to their study treatment, which means they won't know which injection they received, until they exit the study or crossover to a new study treatment (available for those assigned to group 3 only). All participants will complete follow-up activities (either in person at the hospital or via telephone, email or mail, as applicable) including questionnaires at 3-weeks, 6-weeks, 3-months, 6-months, and 12-months post-injection. Participants will be asked not to use any non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., aspirin, ibuprofen, naproxen, celecoxib/Celebrex®, etc.) or acetylsalicylic acids (ASAs) (e.g., Asacol®, Pentasa®, Salofalk®, Mezavant®, etc.) for the 5 days before they receive their study injection and for 2 weeks after their injection. Participants are allowed to take acetaminophen (e.g., Tylenol®) as needed.

Your participation in this study is completely voluntary. If you do not decide to participate in the study, you and your doctor will decide on the treatment you get, as opposed to having the study decide on the treatment you receive.

Possible risks/discomforts:

- Possible risks and discomforts associated with blood draw include pain, bleeding, bruising, swelling, hematoma (collection of blood under the skin), blood clot, infection, lightheadedness, and fainting.
- Possible risks of corticosteroid injections include pain, bleeding, infection, damage to surrounding nerve and vascular structures, a temporary increase in blood sugar, whitening or lightening of the skin around the injection site, hypersensitivity/allergic reaction at the injection site (e.g., warmth, redness, itchiness, swelling), blood clot, temporary flare of pain and inflammation in the joint, dizziness, flushing, as well as the lack of a desired treatment effect and the need for further medical care to treat osteoarthritis in the shoulder joint.
- Possible risks of platelet rich plasma injections include donor site/administration site pain, bleeding, infection, damage to surrounding nerve and vascular structures, hypersensitivity or allergic reaction at the injection site (e.g., warmth, redness, itchiness, swelling), temporary flare of pain and inflammation in the joint, dizziness, flushing, blood clot, whitening of lightening of the skin around the injection site, as well as the lack of a desired treatment effect and the need for further medical care to treat osteoarthritis in the shoulder joint.
- The desired treatment effect includes reducing pain and allowing for patients to maintain or increase their activity level. Further medical care for the treatment of shoulder joint osteoarthritis could include activity modifications, anti-inflammatory medications, physical therapy, additional injections, or the need for surgery.
- Additionally, any time information is collected for a study, there is a small risk of breach of confidentiality.

Possible benefits: We cannot guarantee that you will directly benefit from participating in this research study. However, you could experience reduced pain, increased function, improved quality of life, faster return to sports, and/or faster return to work/duty.

Your decision will not affect your future care at Walter Reed National Military Medical Center (WRNMMC). If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are a Department of Defense (DoD) healthcare beneficiary between the ages of 18 and 70 (inclusive) and have symptoms of shoulder pain caused by mild to moderate shoulder osteoarthritis (OA). The purpose of this research study is to help determine the best treatment for your condition. The treatment options being tested in this research study are corticosteroid and platelet rich plasma (PRP). Platelet rich plasma uses your own blood to help heal your shoulder. The goals of these treatments are to get you back to your normal higher level of function so that you are able to perform your required work duties, return to

full duty, and complete your service-specific physical fitness tasks. If you choose to participate, you will be in this study for 12 months. If you are randomized to group 3 (CSI injection, with the option to receive PRP later) and you choose to crossover to receive the PRP injection, your study participation will be extended by 6-12 weeks. Please see Section 4, "What will happen if you decide to be in this research?" for additional information on the time commitments involved.

This study is called a multi-site study because participants from several military treatment facilities (MTFs) across the country will be in the study. Participating MTFs include Naval Medical Center San Diego (NMCSD), Brooke Army Medical Center (BAMC), and Walter Reed National Military Medical Center (WRNMMC).

There will be about 600 people taking part in this study overall with about 250 of those participants to be enrolled here at Walter Reed National Military Medical Center (WRNMMC). Enrollment for the study will occur over a period of 1 year.

This study is looking at using platelet-rich plasma (PRP) for the treatment of glenohumeral (i.e., shoulder) osteoarthritis (OA). PRP therapy involves the injection of a concentration of your own platelets (created by using a centrifuge, which is a machine, to spin down a sample of your own blood) with the goal of accelerating the healing of injured tendons, ligaments, muscles, and joints.

Although early clinical evidence has shown positive results and minimal adverse events, PRP has not been well studied for the treatment of shoulder OA. This means that PRP injections are considered experimental for the treatment of shoulder OA.

Currently, physical therapy, anti-inflammatory drugs, corticosteroid injections, and shoulder surgery are the standard treatment options for prolonged relief from glenohumeral osteoarthritis. If your shoulder OA symptoms remain persistent after you receive study treatment, surgical intervention may still be an option for you.

You will be asked to avoid oral steroids, additional steroid injections, and viscosupplementation (hyaluronic acid (HA) injections), into the shoulder during the first 6 months of your time in the study.

At the end of this research study the clinical results, including research results about you will only be shared with you if they are relevant to your clinical care, and only at the discretion of your treating medical provider. The summary of results published will not individually identify you; all data will be presented as anonymous data.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to provide some information so that the Investigator can confirm that you qualify for the study. This is called the "Screening Process." This information may have already been collected as a part of your regular medical care.

The researchers will also ask both you and your provider questions to ensure you qualify. These include questions regarding your age, current orthopaedic condition, medical history, and medical care eligibility.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

If you agree to participate in this research study, the following research activities will take place outside standard of care:

Contact Information

As soon as possible following consent, you will be asked to complete a questionnaire collecting your contact information. The local study team will use the information you provide on this form to contact you regarding study-related procedures and appointments. This questionnaire will take approximately five (5) minutes to complete.

Baseline Data Collection:

As part of the screening and baseline research activities, the following activities will occur before you receive your study injection:

- A study team member will determine if one or both of your shoulders qualify for this study. If both shoulders are eligible, then you will be given the option to have either one or both of your shoulders enrolled in the study. If you choose to enroll both shoulders to receive study treatment, you will be asked to complete all study data collection measures for each of your shoulders.
- You will complete a series of questionnaires about your demographic characteristics, your military history and duty status, your relevant medical history, your current level of physical function, and your current shoulder pain and symptoms.
- A study provider will perform a standard physical examination and assess the current range of motion in your shoulders.
- A member of the research team will conduct a medical record review of clinical notes and results related to shoulder pain/symptoms and related treatments.
- If you are a biological female of child-bearing age and/or capacity, you will be asked to self-report your pregnancy status prior to receiving your study injection. If you do not know your pregnancy status, you will be asked to complete a urine hCG pregnancy test prior to receiving a study injection. If you are pregnant via self-report or as indicated by a positive urine hCG pregnancy test, you will be formally withdrawn from the study.

The baseline study activities will require you to be at the hospital for approximately 45 minutes.

Randomization:

Once the study team confirms that you are eligible for this research study, you will be randomly assigned to one of three groups. Randomization is a process like flipping a coin and means you will have a chance of being assigned to any of the groups. If both of your shoulders are enrolled in the study, you will only be randomized to one group for treatment of both of your shoulders.

The three study groups are:
(1) Platelet Rich Plasma (PRP) injection alone,
(2) Corticosteroid injection (CSI) alone, and
(3) CSI injection first with the option for PRP injection later.

You will have a one in three (33.3%) chance of being placed in the research study group that receives the PRP injection only.

You have a one in three (33.3%) chance of being placed in the standard of care group that receives the Corticosteroid injection only.

You have a one in three (33.3%) chance of being placed in the group that receives the Corticosteroid injection at first, but is eligible for PRP at a later time, if appropriate.

This research study is a single blind study, which means that you will not know which research study injection (i.e., PRP or CSI) you are receiving. After 12 months of being in the study, you will be unblinded and will have the opportunity to receive a different study treatment if you did not receive the PRP injection or the Corticosteroid injection and you are not satisfied with your results.

If you are randomly assigned to the 3rd group (PRP-eligible CSI), you will receive a corticosteroid injection. If you report no improvement in pain level at the 6-week follow-up visit (as compared to baseline), at the end of your visit you will be unblinded to the treatment you received and will be offered the option to stay in the study and receive a PRP injection. You will have 6 weeks from the time you are unblinded to elect to receive the PRP injection option.

Study Treatments:
After the study team confirms that you are eligible to participate in this research study and you are randomized to a study arm, you will be able to schedule your study injection. The injection procedure will be completed by a trained orthopaedic provider under ultrasound guidance and will take approximately 45 minutes.

Regardless of the study group you are assigned to, you will have 60cc (approximately 4 tablespoons) of blood drawn for each shoulder enrolled in the study on the day of your study injection.

You will be asked not to use any non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., aspirin, ibuprofen, naproxen, celecoxib/Celebrex®, etc.) or acetylsalicylic acids (ASAs) (e.g., Asacol®, Pentasa®, Salofalk®, Mezavant®, etc.) for the 5 days before you receive your study injection and for 2 weeks after your injection. You will be allowed to take acetaminophen (e.g., Tylenol®) as needed.

Follow-Up Visits:
Regardless of the study group you are assigned to, you will complete follow up research activities at 3-weeks, 6-weeks, 3-months, 6-months, and 12-months after your study injection. The 3-week follow-up activities can be conducted in person at WRNMMC, over the phone, via email, or via mail (based on your preference) and should take approximately 30 minutes to complete. The 6-week, 3-month, 6-month, and 12-month follow-up activities will be conducted in person at WRNMMC and will take approximately 40 minutes to complete.

At all research follow up time points, you will complete a series of questionnaires asking about your current military/work status, your current level of function, and your current shoulder pain and symptoms. In addition, a study provider will assess the current range of motion in your study shoulder at 6-weeks, 3-months, 6-months, and 12-months after your injection.

If you were randomly assigned to group 3 (CSI with PRP option), and you elect to receive the PRP injection, you will be asked to complete baseline data collection procedures prior to receiving the

PRP injection. The follow-up data collection procedures described above will occur at 3-weeks, 6-weeks, 3-months, 6-months, and 12-months post-elected PRP injection.

Your study participation will end after you complete the 12-month (1 year) follow-up activities.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there are risks associated with study treatments.

- Corticosteroid injections: Possible risks of corticosteroid injections include pain, bleeding, infection, damage to surrounding nerve and vascular structures, a temporary increase in blood sugar, whitening or lightening of the skin around the injection site, hypersensitivity/allergic reaction at the injection site (e.g., warmth, redness, itchiness, swelling), blood clot, temporary flare of pain and inflammation in the joint, dizziness, flushing, as well as the lack of a desired treatment effect and the need for further medical care to treat osteoarthritis in the shoulder joint. To minimize risks, injection procedures will be completed by trained orthopaedic provider using standard universal precautions and guided by ultrasound.

- PRP injections: Possible risks of platelet rich plasma injections include donor/administration site pain, bleeding, infection, damage to surrounding nerve and vascular structures, hypersensitivity or allergic reaction at the injection (e.g., warmth, redness, itchiness, swelling), temporary flare of pain and inflammation in the joint, dizziness, flushing, blood clot, whitening of lightening of the skin around the injection site, as well as the lack of a desired treatment effect and the need for further medical care to treat osteoarthritis in the shoulder joint. To minimize risks, injection procedures will be completed by trained orthopaedic provider using standard universal precautions and guided by non-invasive ultrasound.

- Blood draws: Potential risks and discomforts associated with blood draw include pain, bleeding, bruising, swelling, hematoma (pool of blood under the skin), blood clot, infection, lightheadedness, and fainting. These risks are mitigated by using trained professionals who follow industry standards for minimizing these risks.

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

If you become pregnant or feel you might be pregnant, contact your personal physician and the principal investigator of this study listed in the Contact Information section at the end of this document.

There may also be other risks of taking part in this study that we do not yet know about.

All available precautions will be taken to minimize these risks.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

The possible benefits to you as a participant in this research study are reduced pain, increased function optimization, improved quality of life, faster return to sports, and/or faster return to work/duty. However, there is no guarantee that you will benefit from being in this research. Additionally, others may benefit in the future from the information learned during this study. The possible benefits to others are improving future rehabilitation care for musculoskeletal injuries in the military population for positive impact on force readiness.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

There may be other options for treating your condition. Alternative treatments and/or procedures that may be available to you include: physical therapy, anti-inflammatory medications, and shoulder surgery.

One of the medications (corticosteroid injection) involved in this research study may also be available through your personal physician without taking part in this study.

You should talk with your personal physician about these options.

Choosing not to take part in this research study is also an option.

There may be also other research studies involving experimental treatments that could be helpful to your condition.

If you do not join this study, your medical care will not be affected.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Principal Investigator at WRNMMC: Sean E. Slaven, MD
Walter Reed National Military Medical Center
Department of Orthopaedics
8901 Wisconsin Avenue
America Building (Bldg. 19), 2nd Floor, Rm. 2157
Bethesda, MD 20889
Sean.E.Slaven.mil@health.mil
301-295-8522

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at the Uniformed Services

University (USU), is overseeing this research study. As such, authorized staff from MIRROR and the USU will have access to your coded research data.

The Department of Defense (DoD) Defense Health Agency (DHA) is providing funding for this study. As a sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

12. SOURCE OF FUNDING:

Research funding is provided from the Department of Defense (DoD) Defense Health Agency (DHA) through the Uniformed Services University (USU).

13. LOCATION OF THE RESEARCH:

Walter Reed National Military Medical Center (WRNMMC) Dept. of Orthopaedics

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

The study team does not have any conflict of interests related to financial sponsors.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The research team will keep your research records. These records may be looked at by authorized research staff, staff from the local research office, the WRNMMC Department of Research Programs (DRP) and Institutional Review Board (IRB), the Department of Defense (DoD) Higher Level Review, and the Food and Drug Administration (FDA) as part of their duties. These duties include making sure that research participants are protected.

Authorized research team members and those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Every effort will be taken to protect your identity as a participant in this study. Procedures to protect the confidentiality of the data in this study include but are not limited to:

Your research data will be identified only by a unique coded study number and not by your name, social security number, DoD ID, or other protected identifier. The unique coded study number cannot be linked to your name except at the clinic where you complete visits.

All paper research records will be stored in a locked cabinet inside of a locked room accessible only by authorized staff. Your coded study data will be entered into Research Electronic Data Capture (REDCap), a secure, access controlled, and password protected electronic data capture and

management system housed on a DoD server and maintained by the Uniformed Services University (USU) in Bethesda, MD. Once your coded data is entered in REDCap, it will only be accessible by authorized study team members and oversight officials, the local research office, the WRNMMC DRP & IRB, authorized staff from USU, and authorized staff from Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR), which is based out of the Department of Physical Medicine & Rehabilitation at USU, and is serving as the data coordinating center for this study. MIRROR/USU will not have access to your identifiable information.
The Walter Reed National Military Medical Center (WRNMMC) research team will maintain a separate confidential electronic enrollment log which matches the unique coded study numbers with participants' names, date of consent, date of birth, and DoD ID number. This enrollment log will be stored separately from all other electronic research data in a secure, password-protected database on a DoD computer and network that requires CAC access.

The Walter Reed National Military Medical Center (WRNMMC) research team will also maintain an intake form that collects your preferred contact information. This paper intake form will be kept in a locked cabinet inside of a locked room and stored separately from your coded research records. The WRNMMC research team will keep this consent form and your signed HIPAA authorization for six (6) years following study closure. They will keep your coded paper research forms for five (5) years following study closure. The master code list which connects your identity with your unique study code will be destroyed at study closure.

By signing this document, you give your permission for information gained from your participation in this research study to be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data. So, your name will not appear in any published paper or presentation related to this study.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

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 results. You can search this Web site at any time.

16. LONG TERM USE OF DATA

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. This future research may be in the same area as the original study or it may be for a different kind of study or distributed to another investigator for future research studies. The specifics of these future research studies are unknown at this time, but these studies will likely be in the area of shoulder injuries and/or shoulder osteoarthritis.

You have options with regard to this request. You may choose to allow use of your identifiable data in future research studies now, or you may decline use of your identifiable data in future research studies. You will be provided these choices at the end of this consent form.

If you consent to participate in this research study, your de-identified data, meaning that all of your personal identifiers have been removed, collected as part of this research may be kept for future research studies or given to others for future approved research studies. If you would not like your de-identified data collected as part of this research to be kept for possible future research, you should not consent to participate in this research study.

Your de-identified research data will be securely sent to Musculoskeletal Injury Rehabilitation Research for Operational Readiness (MIRROR) and stored at the Uniformed Services University (USU) alongside other de-identified research data. This de-identified research data will be kept indefinitely, or as long as it is practical to maintain, and may be used in future research studies.

Any future research using your retained data will require a research protocol for the proposed study reviewed and approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants), an Exempt Determination Official (EDO), or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

17. USE OF INFORMATION AND SPECIMENS

During this research study, you will be asked to provide a blood sample (biological specimen) on the day of your study injection. Your specimens will only be identified by your unique study ID number and not by your name or other similar identifier. Your specimen will not be stored beyond your clinical appointment for your study injection. At the end of the clinical appointment for your study injection, all leftover blood will be safely discarded per standard clinic protocols.

18. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. As long as you remain a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

19. VOLUNTARY PARTICIPATION:

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any

time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

20. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled.

Should you choose to withdraw, you must contact the Principal Investigator in writing via mail or email:

Sean E. Slaven, MD
Walter Reed National Military Medical Center
Department of Orthopaedics
8901 Wisconsin Avenue
America Building (Bldg. 19), 2nd Floor, Rm. 2157
Bethesda, MD 20889
Sean.E.Slaven.mil@health.mil
301-295-8522

If you decide to no longer participate in this research study, the researcher may keep and analyze all data that was collected during your participation in this study. However, no additional data will be collected after the time of your withdrawal.

If you are receiving treatment as part of this research study, you will no longer be eligible for such research-related treatment. Contact your personal physician to discuss medical treatment for your condition.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to or email the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, if you no longer meet eligibility criteria, if you are no longer eligible to receive medical care at a military hospital, if the military mission requires it, or if the study is cancelled.

21. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator immediately at 301-295-8522.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active-duty military, dependent of active-duty military, retiree), you are authorized

space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries.
You are not waiving any legal rights.

22. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff at Walter Reed National Military Medical Center (WRNMMC) will be available to answer any questions throughout this study:

Sean E. Slaven, MD
Walter Reed National Military Medical Center
Department of Orthopaedics
8901 Wisconsin Avenue
America Building (Bldg. 19), 2nd Floor, Rm. 2157
Bethesda, MD 20889
Sean.E.Slaven.mil@health.mil
301-295-8522

Human Research Protection Program (HRPP) Office
The Walter Reed National Military Medical Center Human Research Protection Program Office Point of Contact (POC) and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

WRNMMC HPA/HRPP POC Phone: 301-295-8239

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the WRNMMC IRB Office at:

Walter Reed National Military Medical Center
Department of Research Programs, Building 17B, 3rd Floor, Suite C
4650 Taylor Road
Bethesda, MD 20889
(301) 295-8239

If at any time you believe you have suffered an injury or illness as a result of participating in this research study, you should contact the Human Protections Administrator (HPA), Department of Research Programs (DRP) at Walter Reed National Military Medical Center (WRNMMC) at (301) 295-8239 or (301) 319-7736.

23. <u>FUTURE USE OF INFORMATION:</u>

With regard to future research studies using stored data that has a link to your personal identity, please initial next to the statements below that reflect your choices:

____ I *do not* authorize the storage of identifiable data collected as part of this study for use in future research studies

____ I authorize the storage of identifiable data collected as part of this study for use in future research studies

____ I *do not* wish to be notified by investigators in the event of incidental findings, as discussed in section 18 above, of potential impact to my family members or myself.

____ I wish to be notified by investigators in the event of incidental findings, as discussed in section 18 above, of potential impact to my family members or myself. I agree that the principal investigator may use any appropriate identifier to locate me in the future.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT

(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date