MADIGAN ARMY MEDICAL CENTER
CONSENT TO PARTICIPATE IN RESEARCH &
AUTHORIZATION TO USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

PRINCIPAL INVESTIGATOR: **Jeremy Schroeder, DO, 253-968-2077, jeremy.d.schroeder.mil@health.mil**

KEY INFORMATION FOR PROTOCOL: **Photobiomodulation Therapy for Plantar Fasciitis: A Single-Blind Randomized Control Trial**

You are invited to take part in a research study. Your participation is voluntary. This page gives you key information about the study to help you decide whether to participate. Detailed information follows this page. Ask the researchers questions you have. If you have questions later, the contact information for the research investigator is below.

WHAT ARE THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

The purpose of this research is to gather information on the safety and effectiveness of photobiomodulation (PBM) therapy, or low-level laser therapy, to improve function, decrease pain, and resolve plantar fascial thickening in individuals with plantar fasciitis. PBM has been used for treatment of a variety of pain conditions in many different settings, however, it is not known how well it works for treating the pain resulting from plantar fasciitis. If the results of this study show that PBM is more helpful, or results in faster recovery, than the current standard of care for treating pain from plantar fasciitis (i.e., stretching, strengthening, and icing), then future studies may be conducted to compare PBM to more invasive treatments, like injections or surgery.

You are being asked to participate in this research because you are experiencing foot and/or heel pain from plantar fasciitis. If you choose to participate in this study, you will be enrolled for approximately 3 months. During your time in the study, you will be asked to complete questionnaires evaluating your foot function and pain, and complete a pain, activity, and medication diary. You will be randomly assigned to one of two treatment groups, either:

(1) usual care with PBM therapy, or
(2) usual care with sham (placebo/inactive) PBM therapy.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO PARTICIPATE IN THIS STUDY (BENEFITS)?

It is possible that you may benefit from this research by completing the usual care (stretching and icing) at home, and PBM treatment might help your heel/foot pain and improve function; these improvements may happen faster if you are in the PBM treatment group. However, we cannot guarantee that you will directly benefit from your participation in this research study.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE NOT TO PARTICPATE IN THIS STUDY (RISKS AND ALTERNATIVES)?

Possible risks associated with PBM treatment are discomfort from skin/tissue heating, or damage to your eyes if you look directly into the light without appropriate eye protection. If you have a nerve problem or difficulty feeling changes in your skin temperature, you should not participate in this study as you may be at higher risk for burns.

There may be risks associated with this treatment that are currently unforeseeable, however, no serious adverse events have been reported using this treatment.

Safety of PBM treatment in pregnant women has not been established so the risks to pregnant women are unknown. It is not known whether PBM treatment can cause birth defects or other problems in an unborn child. 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.

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.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have at Madigan Army Medical Center if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

The person in charge of this study is Jeremy Schroeder, DO. If you have questions, suggestions or concerns about the study, their contact information is: 253-968-2077, and mailing address: 9040A Jackson Ave., Tacoma, WA 98431.

If you have any questions about your rights as a research subject or if you have concerns or complaints about the research, please contact the Madigan IRB Office at: 253-968-0149, Madigan Army Medical Center, Department of Clinical Investigation, 9040 Jackson Ave, Tacoma, WA 98431-1100.

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

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.

DETAILED CONSENT:

1. 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 DEERS-eligible and you are seeking care for the treatment of your foot pain caused by plantar fasciitis. The purpose of this research study is to learn about photobiomodulation (PBM) therapy to improve function, decrease pain, and resolve plantar fascial thickening in individuals with plantar fasciitis. PBM therapy for plantar fasciitis has not been well-studied; this means that PBM is considered experimental for the treatment of plantar fasciitis.

There will be about 100 people taking part in the study at Madigan over a period of 2 years.

During the study, you will have an initial study visit (today), and two in-person follow-up visits. You will also be asked to return to the clinic three times a week, for three consecutive weeks (for a total of 9 treatment visits), to receive your study treatment. Additionally, you will have one remote follow-up visit at 3-months. After the final remote visit, your involvement in the study will be complete.

At the end of this research study the clinical results, including research results, about you will be shared with you, at your request.

2. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

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

If you are a biological female of child-bearing age and/or capacity, you will be required to complete an hCG urine pregnancy test within 30 days of randomization and study treatment. Results must be negative (i.e., indicating not pregnant) for you to be eligible to continue with study procedures.

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

If you agree to participate in this research, you will be asked to complete the following study procedures after you sign this document:

Day 1, Today (About 60 minutes):

You will complete 3 questionnaires to collect your demographic information, self-report measures of your foot and ankle ability, and overall pain rating. If you have plantar fasciitis on both feet, only one foot will be eligible to receive study treatment. The foot that will receive treatment will be determined by your self-report measures of your foot and ankle ability; the foot with a score indicating higher dysfunction will be treated in this study. A member of the study team will measure your foot and lower leg area to

determine the appropriate PBM treatment dosage. Additionally, the thickness of your plantar fascia will be measured with an ultrasound, which is a safe and non-invasive procedure that uses low-power sound waves to create an image and take measurements of structures in your body. Before you leave the clinic, you will be given instructions about how to complete daily exercises at home and daily pain, activity, and medication diaries.

If you are a biological female of child-bearing age and/or capacity, you will be required to complete an hCG urine pregnancy test before randomization and study treatment. Results must be negative (i.e., indicating not pregnant) for you to be eligible to continue with study procedures. If the results are positive (i.e., indicating pregnant), you will be formally withdrawn from the study, and you will not be eligible to continue with study procedures and treatment.

Randomization: You will be randomly assigned to one of two groups. Randomization is a process like flipping a coin and means you will have a 50% chance of being assigned to either of the two groups.

(1) The Usual Care + PBM Group – If you are assigned to this group, you will receive active treatment with PBM 3 times a week for 3 weeks for a total of 9 treatments.

OR

(2) The Usual Care + Sham (Placebo) PBM Group – If you are assigned to this group, you will receive Sham PBM therapy 3 times a week, for 3 weeks, for a total of 9 treatments. Sham PBM therapy is an inactive harmless treatment that is intended to mimic the active PBM treatment.

This research study is a single blind study, which means that only the study team will know which group you have been randomized to. You will not know which group you are in until after your 6-week follow-up visit.

Days 2-22 BOTH GROUPS (Each treatment session will last about 10 minutes, for a total visit time of about 30 minutes each week, and 90 minutes total for all treatment visits combined):

You will complete your daily exercises and pain diary at home. You will also come to the Podiatry Clinic three times a week for your assigned treatment session. A trained member of the study team will apply the PBM or sham PBM treatment. The device is a plastic handle with a glass massage ball at the end where light comes out. The trained study team member will roll the massage ball on the bottom of your foot and back of your calf. If you feel uncomfortable at any time, the treatment can be stopped. Both you and the trained study team member will wear special eye protection goggles during the entire treatment.

Day 22 BOTH GROUPS (About 60 minutes):
You will return to the Podiatry Clinic to complete a questionnaire to measure your foot and ankle ability and turn in your pain diary. A member of the study team will measure your plantar fascia thickness using ultrasound.

Day 23-43 BOTH GROUPS:
You will continue to complete your daily exercises and ice at home, as well as your daily pain diary.

Day 43 BOTH GROUPS (About 60 minutes):
You will return to the Podiatry Clinic to complete a questionnaire to measure your foot and ankle ability and turn in your pain diary. A member of the study team will measure your plantar fascia thickness using ultrasound. We will confirm your contact information so that we can contact you for follow-up questionnaires. We will also unblind you to the study treatment you received (active PBM or Sham PBM).

Day 43 SHAM PBM GROUP:
If you were assigned to the sham PBM group and would like to receive active PBM treatment, you will be given the option to crossover to the active PBM treatment group after the completion of your 6-week follow-up visit. You will have 2 weeks from the time of unblinding to elect to crossover to receive treatment. If you choose to crossover for active PBM treatment, you will be asked to re-complete all study procedures, including those from the first 6 weeks of the study. However, you will not need to re-complete baseline data procedures. Please note: if you choose to crossover, you will be enrolled in this study for approximately 4.5 months (6 weeks longer than individuals either assigned to the PBM treatment group, or the sham PBM group that do not elect to crossover).

Month 3:
You will receive a questionnaire electronically in your email to complete and send back to the study team. It is important that you complete these questionnaires so that we know how the treatment worked for you after a longer period of time.

If you were assigned to the sham PBM group and you choose to crossover to the PBM treatment group, you will complete the long-term follow-up questionnaire at month 3 after the first day of your PBM treatment.

After you complete the 3-month questionnaires, your study participation will be complete.

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

There may be other options for treating your plantar fasciitis. Alternative treatments and/or procedures that may be available to you include continuing your current course of treatment (prescribed or over-the-counter methods), standard pain management therapies, wearing night splints, wearing shoe inserts, consultation for injections or

surgery, or no medical treatment at all. You should talk with your personal physician (if applicable) about these options.

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

5. <u>IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?</u>

Yes, you may receive $60 to $80 for your participation in this research.

There are four opportunities to receive compensation:

(1) When you complete the 3-week follow-up visit - $20 gift card,
(2) When you turn in the pain diary on Day 43 - $20 gift card,
(3) When you complete the 3-month follow-up questionnaires - $20 gift card, and
(4) W
(5) hen you turn in the pain diary on day 43 post-elected crossover (only applicable to those initially randomized to the sham PBMT group that elect to crossover to receive treatment with active PBMT) - $20 gift card.

The gift card will be issued to you as a Visa-type card or equivalent. You will only be compensated for research activities that you complete. Should you decide to withdraw from the study, or if you are withdrawn by the PI, you will only receive compensation for the applicable activities you completed prior to being withdrawn from the study.

If you are a federal employee participating in this research activity while on duty (i.e., you are not on leave and you are participating during your regular duty hours), in accordance with the DoDI 3216.02 you will NOT receive compensation for your time.

If you are a federal employee participating in this research while off duty (i.e., you are on leave or you are participating outside of your duty hours), in accordance with the DoDI 3216.02, you will be compensated for your time taking part in this research study as described above.

6. <u>ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?</u>

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

7. <u>PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):</u>

Principal Investigator at MAMC: Jeremy Schroeder, DO
Madigan Army Medical Center
Department of Sport and Exercise Medicine
9040A Jackson Ave., Tacoma, WA 98431
jeremy.d.schroeder.mil@health.mil
253-968-2077

8. **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 de-identified research data.

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

9. **SOURCE OF FUNDING:** Research funding is provided from the Department of Defense (DoD) Defense Health Agency (DHA) through the Uniformed Services University (USU).

10. **LOCATION OF THE RESEARCH:** Madigan Army Medical Center

11. **DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS**: None

12. **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 Madigan Army Medical Center research office, the Institutional Review Board (IRB), and the DoD Higher Level Review, and the Food and Drug Administration (FDA) as part of their duties. These duties include making sure that the 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. Your coded ultrasound images will be stored in Teleray, a secure, access controlled, and encrypted data platform. No identifiable information will be entered into REDCap or Teleray.

Once your coded data is entered in REDCap and Teleray, it will only be accessible by authorized study team members and oversight officials, the local Madigan Human Research Protections Office, the 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. Representatives of MIRROR/USU will not have access to your identifiable information.

The Madigan 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 Madigan 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 Madigan research team will keep this consent form with embedded 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.

13. AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR THIS RESEARCH:

You are being asked for permission to use and disclose your protected health information (PHI) for this research study. Protected health information is defined as individually identifiable health information.

The Health Insurance Portability & Accountability Act of 1996, Public Law 104-191 (also known as HIPAA), establishes privacy standards to protect your health information. This law requires the researchers to obtain your authorization (by signing this document) before they use or disclose your protected health information for research purposes in the study listed above.

WHAT PERSONAL IDENTIFIERS AND/OR PROTECTED HEALTH INFORMATION (PHI) MAY BE USED AND DISCLOSED IN THIS RESEARCH?

The identifiers and/or PHI collected, used, or disclosed are below:

• *Names* • *Address (all geographic subdivisions smaller than a state)* • *Dates (except year) directly related to an individual such as birth date* • *Phone numbers*	• *Any other unique identifying number, characteristic, or code* • *Medical history* • *Surgical history* • *Imaging results*

HOW WILL YOUR PROTECTED HEALTH INFORMATION BE USED OR DISCLOSED IN THIS RESEARCH?

The research team will review your Military Health System (MHS) electronic medical record to collect and document details about your foot pain. This health information includes demographic data (age, rank, race) and medical conditions (foot function and pain).

The following protected health information (PHI) will be collected: name, postal address, dates (date of birth, dates of clinic visits, etc.), telephone number, and other unique identify numbers or characteristics (diagnosis, DoD ID number, rank, etc.).

The use and disclosure of your protected health information is necessary in order to be able to conduct the research described. Records of your participation in this research may only be disclosed in accordance with state and federal law, including the Privacy Act (5 U.S.C. 552a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations (45 CFR 160 & 164).

Note: Protected health information of military service members may be used or disclosed without your authorization to military command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

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

WITH WHOM MAY YOUR PROTECTED HEALTH INFORMATION BE SHARED THROUGH THIS RESEARCH?

- The Madigan Army Medical Center Institutional Review Board
- Madigan Army Medical Center or Department of Defense representatives
- State and Federal Government representatives, when required by law (such as the Food and Drug Administration (FDA))

Those listed above who are covered entities under HIPAA agree to safeguard your protected health information by using and disclosing it only as permitted by you in this Authorization or as directed by state and federal law.

You need to be aware that some parties receiving your protected health information may not have the same obligations to safeguard your protected health information and may re-disclose your protected health information to parties not named above. If your protected health information is re-disclosed, it may no longer be protected by state or federal privacy laws.

You do not have to sign this document. If you decide not to sign this document:

- It will not affect your current treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
- You will not be allowed to participate in the research.

After signing this document, you can change your mind and:

- Notify the principal investigator in writing that you have withdrawn your permission to disclose or use your protected health information (revoke the Authorization).
- Send your written letter to the Principal Investigator, Jeremy Schroeder, DO at 9040A Jackson Ave., Tacoma, WA 98431, to inform them of your decision. Your revocation is not effective until your letter is received.
- Researchers may continue to use and disclose your PHI that was obtained before your revocation became effective to the extent that the researchers have taken action in reliance on your earlier authorization. Researchers may also continue to use or disclose your PHI as necessary to maintain the integrity or reliability of the current research, as, for example, to account for your withdrawal from the study, to conduct misconduct investigations, or to report adverse events.
- If you withdraw the Authorization, you will not be allowed to continue to participate in the research.

During your participation in this research, you will not be able to access your research records. This is done to ensure the research results are reliable. After the completion of the research, you have the right to see or copy your research records related to the research listed above. A Request for Access must be made in writing to the Principal Investigator, Jeremy Schroeder, DO, 9040A Jackson, Ave., Tacoma, WA 98431.

If you have not already received a copy of the brochure entitled "Military Health System Notice of Privacy Practices," you may request one, or it is available on-line at: https://www.health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/HIPAA-Compliance-within-the-MHS/Notice-of-Privacy-Practices

If you have any questions or concerns about your privacy rights, you should contact the Madigan HIPAA Privacy Officer, 9040 Jackson Ave, Tacoma, WA, 98431. Telephone: 253-968-1642.

This Authorization does not have an expiration date.

Your signature at the end of this document acknowledges that you authorize Madigan Army Medical Center and the overall Principal Investigator and other members of the research staff to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

14. USE OF INFORMATION AND SPECIMENS?

The information and that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

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 photobiomodulation (PBM) therapy and/or plantar fasciitis.

You have options with regard to this request. You may choose to allow use of your identifiable data in future research studies 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.

Your de-identified ultrasound images will be maintained within Teleray by the local Madigan research team indefinitely, or as long as it is practical to maintain, and while funding can be allotted for this service. These images may also be used in future research.

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

15. 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. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

You will have the option to choose to opt out of receiving results of incidental findings in this consent form.

16. 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.

17. 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 using the contact information provided in this document. 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 the principal investigator as discussed in the HIPAA Authorization section of this form.

The principal investigator of this research study may terminate your participation in this research study at any time if they determine 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.

18. 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 using the contact information in the section below.

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

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are authorized space-available medical care for your injury at a DoD hospital or an DoD clinic; medical care charges for care at a DoD hospital or a DoD clinic will be waived for your research-related injury. If you obtain care for

research-related injuries outside of a DoD or DoD hospital or clinic, you will not be reimbursed for those medical expenses.

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.

19. WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

20. CONTACT INFORMATION:

Principal Investigator (PI):

The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Jeremy Schroeder, DO
Phone: 253-968-2077
Mailing Address: 9040A Jackson Ave., Tacoma, WA 98431

Madigan Human Research Protection Program (HRPP) Office

The Human Research Protection Program Office staff and/or Human Protections Director (HPD) will be available to answer questions or discuss concerns you may have about this research study.

Madigan HRPP Office: 253-968-0149, Madigan Army Medical Center, Department of Clinical Investigation, 9040 Jackson Ave, Tacoma, WA 98431-1100.

21. FUTURE USE OF INFORMATION:

Please initial the sentences that reflect your choices, and then sign below:

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

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

IRB NUMBER: 222072
IRB APPROVAL DATE: 02/12/2024
IRB EXPIRATION DATE: 08/09/2024