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

PRINCIPAL INVESTIGATOR: **Dr. Scott P. Grogan, DO**
scott.p.grogan.mil@health.mil, 253-651-4190

KEY INFORMATION FOR PROTOCOL: Investigating Orthobiologics After Platelet-Rich Plasma and Photobiomodulation Treatment of Knee Osteoarthritis

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 study is to compare:
(1) Physical therapy (PT; physical examination/education/rehabilitation),
(2) Platelet-rich plasma (PRP; plasma and platelets concentrated from your own blood sample) injection, and
(3) Photobiomodulation therapy (PBMT; low-level laser therapy),
for the treatment of knee osteoarthritis (OA), and to assess the effects of PBMT on PRP injections for the treatment of knee OA.

By doing this study, we hope to learn more about orthobiologics (biological substances within your body that may treat orthopaedic conditions to reduce pain and inflammation) and how they are affected by these various treatment approaches. If you choose to take part in this study, procedures will include completing questionnaires and activity logs, x-ray imaging (if applicable), two blood draws and knee joint aspirations, and treatment from one of four study groups that you will be randomly assigned to. Your participation in this research will last about 6 weeks.

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

You may experience improvements in your knee osteoarthritis symptoms and/or function by completing the standard of care physical therapy. If you are randomized to the PRP or PBMT group you may receive a therapeutic benefit. However, there is no guarantee that you will benefit from being in this research.

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

Potential risks associated with the study include:
- Blood draw/joint aspiration: discomfort, bruising swelling, or infection
- PRP injection: donor site pain, bleeding, infection, or blood clot

- PBMT: discomfort, headaches, redness, or eye damage (if protection is not worn)

The alternative is to not participate in this study and receive the care you typically would from your medical provider.

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 photobiomodulation therapy (PBMT) 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 Dr. Scott P. Grogan. If you have questions, suggestions or concerns about the study, the contact information is: 253-651-4190, and mailing address: 9040 Jackson Avenue, 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, Department of Clinical Investigation, 9040 Jackson Avenue, 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 a DEERs eligible adult, between the ages of 18-64 (inclusive), and you are seeking care for knee osteoarthritis. The purpose of this research study is to learn about the effects of: (1) PT only, (2) PT + PRP, (3) PT + PBMT, and (4) PT + PRP + PBMT for the treatment of knee OA. The duration of participation per visit will vary depending on which treatment group you are randomized to; however, the average visit can be expected to last approximately one hour. Diagnostic x-ray imaging, blood draws, and joint aspirations may add an additional hour to the visit duration.

There will be up to 200 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), treatment visits, a 3-week follow-up visit, and a 6-week follow-up visit. During the first 3 weeks of this study, you will be asked to return to the clinic for your assigned treatment visits. The schedule of these treatments will vary between groups. The 6-week follow-up visit will be your final visit and your involvement in the study will be complete.

At the end of this research study the clinical results, including research results about you will not be shared with you.

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.

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:

Baseline Data Collection Visit:

Formal Screening:

As part of formal screening procedures, your final eligibility status will be confirmed by diagnostic X-ray imaging, which must indicate that you have minimal to severe knee osteoarthritis. X-ray is a medical imaging technique that uses a type of electromagnetic radiation to create detailed images of structures in the body. If X-ray imaging has been completed within one month prior to your study enrollment, the previous images may be used. If diagnostic images are required, X-ray imaging will be ordered by an authorized medical provider, and you will be asked to complete the imaging procedures prior to study randomization and treatment.

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

If you are determined to be ineligible by formal screening criteria, you will be formally withdrawn from the study, and you will not be eligible to continue with study procedures and treatment.

Demographics & Baseline Data:
You will be asked complete three (3) questionnaires to collect your contact information, demographics, and self-report measures of your medical history, knee function, and pain.

Blood Draw & Knee Joint Aspiration:
Finally, you will be asked to provide a baseline blood sample and a synovial fluid sample. The amount of blood that will be collected is approximately 2 ¼ teaspoons (11 mL). The blood sample will be collected by a needle inserted in your arm near the bend in your elbow, or the back of your hand, if needed.

The synovial fluid sample will be collected by an Orthopaedic Surgeon, Physician, or Physician Assistant. This sample will be collected by using a needle and syringe to withdraw the fluid sample from your knee joint. The amount of fluid that will be withdrawn from your knee is approximately ⅓ of a teaspoon (1.5 mL). These samples will be used to assess orthobiologics related to your knee osteoarthritis.

Before you leave the clinic, you will be given instructions to complete a daily activity log. The baseline visit will take up to one (1) hour. The X-ray imaging procedures may take one (1) additional hour.

Randomization:
After you complete all baseline study procedures, you will be randomly assigned to one of four groups:
(1) PT only,
(2) PT + PRP,
(3) PT + PBMT, or
(4) PT + PRP + PBMT.

Randomization is a process like flipping a coin and means you will have a 25% chance of being assigned to one of the four groups.

Study Treatment:

PT:
All participants will complete a standard PT program addressing individual strength, mobility, and flexibility deficits. The PT treatment you will receive in this study will be

standard of care; that is, the PT treatment will not be standardized across study participants and/or dictated by study-specific criteria. Your time and amount of treatment visits will be dependent on your individual care plan.

PRP:

If you are randomized to a study group that will receive a PRP injection you will undergo an additional blood draw. The PRP (plasma and platelets concentrated from your own blood sample) will be prepared by a study provider by drawing about 4 Tablespoons (59.1 mL) of blood and spinning the blood sample in a centrifuge. The injection area will be sterilely prepared and anesthetized, so that it is numb. You will receive the PRP injection in the affected knee under ultrasound guidance by a qualified study provider. The PRP injection procedure is expected to take approximately one hour, and you will be provided with post-procedural instructions to take home.

A small portion, less than ¼ of a teaspoon (1 mL), of the whole blood and PRP collected for individuals receiving PRP will be analyzed for complete blood count and then will be promptly discarded.

PBMT:

If you are randomized to the study group that will receive PBMT, these treatments will occur three times each week, for 3 weeks. You will start PBMT on the same day as your PRP injection (described above). You will be instructed to rest for 5-10 minutes after your injection, and a study team member will ensure you are comfortable enough to proceed with treatment. A trained member of the study team will apply the PBMT to your knee. The PBMT device is a hand piece with a rolling glass massage ball that emits light. If you feel uncomfortable at any time, the treatment can be stopped. Both you and the trained study team member that will be administering the PBMT will wear special eye protection (goggles) during the entire treatment. You will be instructed to NOT use any perfumes or plant-based extracts in the treatment area(s), as this can increase your skins photosensitivity. Each treatment session will last approximately 5-20 minutes.

(1) PT Only Group:

If you are randomized to the PT only group, you will complete the SOC PT visits as stated above. Your time and amount of treatment visits will be dependent on your individual care plan.

(2) PT + PRP Group:

If you are randomized to the PT + PRP group, you will complete the SOC PT visits as stated above. Your time and amount of treatment visits will be dependent on your individual care plan. You will return to the clinic once for the administration of the PRP injection (approximately one hour).

(3) PT + PBMT Group:
If you are randomized to the PT + PRP group, you will complete the SOC PT visits as stated above. Your time and amount of treatment visits will be dependent on your individual care plan. You will return to the clinic 3 times each week, for 3 weeks, to receive your PBMT study treatment (each visit will last approximately 5-20 minutes).

(4) PT + PRP + PBMT Group:
If you are randomized to the PT + PRP group, you will complete the SOC PT visits as stated above. Your time and amount of treatment visits will be dependent on your individual care plan. You will return to the clinic once for the administration of the PRP injection (approximately one hour). You will start your PBMT on the same day after receiving your study PRP injection (with 5-10 minutes of rest in between the PRP and PBMT). Then you will return to the clinic to complete all remaining (8) PBMT visits (each visit will last approximately 5-20 minutes)

Follow-Up Data Collection:
Regardless of what group you are assigned to, you will be provided with a daily activity/pain/medication log to document your daily activity, function, pain, and medication intake during the course of the study.

Once a week, a study team member will follow-up with you to collect your log and assess for any adverse events. This visit may be completed remotely or in-person.

You will be asked to complete a brief (5-10 minute) follow-up questionnaire at week 3. This visit may be completed in-person or remotely.

For your final study visit, you will be asked to return to the clinic to complete a follow-up questionnaire and turn in your daily activity/pain/medication log. You will also be asked to provide a 6-week blood sample (11 mL) and a synovial fluid sample (1.5 mL) following the same procedures from baseline sample collection. Your participation in this study will end after you complete the 6-week follow-up visit procedures.

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

If you choose to take part in this study, there is risk associated with:

Diagnostic Imaging:
There is no known minimal level of radiation exposure that is recognized as being totally free of the risk of causing genetic defects (cellular abnormalities) or cancer. However, the risk associated with the amount of radiation exposure received from this study is considered to be extremely low when compared to the everyday risks.

Blood Draw/Joint Aspirations:
Discomfort, bruising, hematoma, redness, swelling, light-headedness, fainting, nerve damage and, rarely, infection.

PT:
The PT treatment you will receive in the study procedures is standard of care. Possible risks associated with physical therapy treatment include: worsening of pre-existing conditions, continued and/or increased pain that may limit activities, no improvement in mobility or strength, soreness, or failing during and/or injury from physical therapy exercises and/or performance-based tests.

PRP:
Donor/administration site pain, bleeding, infection, damage to surrounding neurovascular structures, hypersensitive or allergic reaction, blood clot, skin discoloration, inefficacy and need for further procedures.

PBMT:
Possible risks include discomfort from skin/tissue heating, and a rare risk of damage to your eyes if you look directly into the light without appropriate eye protection.

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

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

There may be other options for knee OA. Alternative treatments and/or procedures that may be available to you include: standard of care physical therapy, dry needling, medication, corticosteroid or PRP injections, arthroscopic surgery (a procedure using fiber-optic video camera to allow surgeons to see inside of your joint to diagnose and treat joint conditions), and/or arthroplasty (joint replacement). 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.

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

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

Yes, you may receive up to $150 for your participation in this research. There are three opportunities to receive compensation:

(1) When you complete the baseline blood draw - $50,
(2) When you turn in the completed daily activity log at the 3-week follow-up visit - $50, and
(3) When you complete the 6-week follow-up blood draw - $50.

You will receive compensation in-person (or electronically, if needed), immediately following completion of the study activities mentioned above. You will receive payment in the form of a gift card or Visa-type card equivalent. You will only be paid for applicable research activities that you complete; you will not receive compensation for research activities that you do not complete. In accordance with DoDI 3216.02, all research participants (including federal employees both on and off duty) participating in DoD-conducted or supported research are eligible to be compensated up to $50 for each blood draw.

DHA-AI 3200.01 indicates active-duty service members may be compensated for the completion of a daily health diary for research purposes, *when completed off-duty*. In accordance with DHA-AI 3200.01 the following definitions of 'on-duty' and 'off-duty' will apply to active duty-service member study participants:

- An individual is *on-duty* when they are expected or required to perform the duties of their assigned job or position.
- An individual is *off-duty* if the individual is not scheduled to perform any work that may arise during the period.

It will be your responsibility to provide accurate information regarding your duty/leave status.

7. **ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?**
   No, there are no costs to you for taking part in this research study.

8. **PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):** Dr. Scott P. Grogan, DO

9. **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.

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

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

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

13. 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 staff from the Madigan Human Research Protection Office, the Madigan Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

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 ID and not by your name, DoD ID, or other protected identifier. Only the research staff will have access to the file which links your identifiable personal and health information with the study ID number. This file will be password-protected and stored on a server which requires CAC access and is only accessible by the research staff and will never be printed.

- 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 x-ray 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, Madigan IRB, 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.

- Your biospecimen samples will be securely stored it in a freezer at Madigan Department of Clinical Investigation (DCI). Madigan DCI will not keep your name or any other identifiable information with your sample directly. Your biospecimen

samples will be identified only by a unique coded sample ID (different from your study ID). The sample key that links your study ID with your biospecimen sample ID will not contain any identifying information and will be maintained by the study team under direct guidance by the Principal Investigator.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

If applicable, 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.

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.

The local study team will keep this signed consent form which includes your HIPAA authorization for six (6) years following study closure and your coded research forms will be kept for five (5) years following study closure. The master code list which connects your identity with your unique study code will be permanently deleted by the local study team at study closure, unless you opt to allow the study team to keep your identifying information, as described in sections 14 and 21 below. The PI will ensure adherence to the records destruction schedule.

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.

Information gained from your participation in this research study may 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

14. 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* • *E-mail addresses* • *Any other unique identifying number, characteristic, or code*	• *Medical history* • *Surgical history* • *Laboratory results* • *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 knee OA. This health information includes demographic data (age, rank, race), imaging results and lab results to confirm eligibility, relevant medical history.

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 Dr. Scott P. Grogan at Madigan Army Medical Center, 9040 Jackson Avenue, Tacoma, WA 98431, to inform him 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.

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 Avenue, 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 Madigan research study team members to use

and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

15. USE OF INFORMATION AND SPECIMENS?

The investigators have requested to save selected data collected from your participation in this research study for possible use in future research. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. This future research may be in the same area as the original study or it may be for a different kind of study.

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 x-ray 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.

Future Use of De-Identifed Biological Specimens:

If you consent to participate in this research study, your de-identified (meaning that all of your personal identifiers have been removed) biospecimens, 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 biospecimens 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 samples will be stored using a unique sample ID.

While this study is ongoing and the master list exists, your specimen will be coded; this is considered identifying information and can be traced back to you as the donor. When the master list is destroyed at study closure, your specimen will then become de-identified and will no longer be able to be traced back to you as the donor.

Future Use of Identifiable Biological Specimens:

The investigators in this study are also asking for your permission to store your **identifiable** samples for future use in other research studies. The specifics of these future research studies are unknown at this time, but these studies will frequently be in the area of knee osteoarthritis. You will be provided choices at the end of this consent form to either allow or deny the use of your identifiable biospecimens in future research studies.

Your identifiable samples would also be stored with the following information: unique sample ID. However, when the master list is destroyed at study closure, your identifiable information from the study master list would be retained; this includes your name, DOD ID, date of birth, and phone and email contact information. Your biospecimen will remain coded indefinitely; this is considered identifying information and can be traced back to you as the donor.

Your samples could be stored indefinitely, or until none is left to use.

Your samples will be handled in accordance with this study's protocol and applicable regulations at the following laboratory: Madigan Army Medical Center Department of Clinical Investigation, 9040 Jackson Avenue, Tacoma, WA 98431-1100. The study PI, Dr. Scott P. Grogan, will maintain responsibility for the storage of specimen. Investigators requesting portions of your samples for future research must have the approval of the PI and must have a research protocol for their newly proposed research study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants). It is possible these other researchers will request approval from an IRB to contact you in the future.

Some future research studies may include genetic testing of your samples stored at the bank. Since storage (banking) of biologic specimens for future genetic testing is still undergoing development, the benefits and risks of genetic testing are not fully known right now. Using new technology, genetic information gained from your banked samples can be used to see if there is a risk for having some kinds of disease. This genetic information is unique to you and may indicate changes in your future health status or life expectancy. It may also indicate changes for your children or other relatives. These discoveries could be stressful and cause psychological difficulties or family problems. It is also possible that during future research, people of your ethnic background may be found to be at more risk for certain diseases. This could stigmatize your ethnic or cultural group.

Release of personally identifiable genetic information may pose a possible risk of discrimination or increased difficulty in obtaining certain types of insurance for you and your family members. The Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110-233), also known as “GINA,” is a federal law that prohibits discrimination in health insurance coverage and employment based on genetic information. However, GINA does not apply to employers with fewer than 15 employees. GINA's protections in employment do not apply to the US military. It also doesn’t apply to TRICARE health insurance, the Indian Health Service, the Veterans Health Administration, or the Federal Employees Health Benefits Program. Lastly, the law does not cover long term care insurance, life insurance or disability insurance.

Potential risk would occur if the confidentiality of your data is breached. Because of the consequences of a breach of confidentiality, every effort will be made by the bank to protect your privacy. The storage procedures to protect the confidentiality of your data include: removing direct identifiers from specimen samples, coding your specimen with a unique sample ID during the course of this study, ensuring de-identification of specimen at study closure (if applicable), and ensuring the destruction of specimen at the conclusion of analyses or until the samples have been used up (whichever comes first).

Generally, you will not be provided with the results of the future studies using your samples from this bank. This is typically the case because the research results at that early point will not have a clear meaning for or direct clinical benefit to you.

You may request that your specimen be withdrawn from storage at any time while the specimens are still coded. Once your specimens have been de-identified, it will be impossible for the researchers to locate your specific specimen. if you decide you no longer want to take part, you will need to notify the study PI.

Your biospecimens (even if identifiers are removed) may be used for commercial profit. You will not share in this commercial profit.

16. 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 not have the option to choose to opt out of receiving results of incidental findings in this study.

17. 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.

18. 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 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, or if you no longer meet eligibility criteria.

19. 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.

20. 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.

21. 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.

Dr. Scott P. Grogan
Madigan Army Medical Center
9040 Jackson Avenue, Tacoma WA 98431-1100
scott.p.grogan.mil@health.mil
253-651-4190

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 Avenue, Tacoma, WA 98431-1100.

22. FUTURE USE OF INFORMATION:

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

_____ I **DO NOT** authorize the storage of my ***identifiable*** biological specimens for future use in research studies.

_____ I **DO** authorize the storage of my ***identifiable*** biological specimens for future use in research studies.

With regard to future research studies done on my biological specimens kept at the storage bank:

_____ I **DO NOT** wish to be notified by investigators in the event of research findings of potential impact to my family members or myself.

_____ I **DO** wish to be notified by investigators in the event of research findings of potential impact to my family members or myself. I agree that the investigators conducting this study may use my stored personal identifiers 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