Addendum: Cover Page

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Title: A Randomized Placebo-Controlled Trial of Platelet Rich Plasma (PRP) for Facet Mediated Lumbar Low Back Pain

WOMACK ARMY MEDICAL CENTER
CONSENT TO PARTICIPATE IN RESEARCH

Title: A Randomized Placebo-Controlled Trial of Platelet Rich Plasma (PRP) for Facet Mediated Lumbar Low Back Pain

Principal Investigator: Dr. Min Ho Chang

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

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions that you have. You may want to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research 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 any consequence.

1. KEY INFORMATION:

You are being asked to consent to participate in a voluntary research study. The purpose of this study is to see if platelet-rich plasma (PRP) is effective at reducing pain and improving function for patients with chronic facet mediated (joints in the lower back) low back pain. PRP therapy involves the injection of a concentration of your own platelets (created by using a centrifuge to spin down a sample of your own blood) with the goal of speeding up the healing of injured tendons, ligaments, muscles, and joints.

Participants who volunteer for this study will be asked to participate for approximately 7-10 months. Participants will be randomized to one of two study groups: 1) PRP injection or 2) Saline (placebo) injection. A placebo is an inactive, harmless substance that does not contain the active therapy (i.e., PRP) being tested in this research study. Both study groups will return to the clinic for follow up visits. These visits include a physical examination and questionnaires at 1 month, 3 months, and 6 months post-injection. At the end of the 3-month follow up visit, you may choose to receive a different study treatment if you are not satisfied with your results. If you received the saline injection at the beginning of the study, and then choose the PRP injection at the 3-month follow up visit, we will also ask you to return to the clinic at 3- and 6-months after your PRP injection. This means that your total time in the study will be about 3 months longer than if you do not choose to receive PRP therapy.

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

Possible risks/discomforts include: bleeding, swelling, irritation, bruising, pain and infection at the injection site, increased pain, headache, dizziness, hematoma, and nausea. Possible but very rare side effects include: nerve or joint/capsule damage, severe allergic reaction, seizure, confusion, tremors, arrhythmias. There is also a chance that you experience no pain relief. Any time information is collected for a study there is a chance of breach of confidentiality.

Your decision will not affect your future care at Womack Army Medical Center (WAMC). 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.

NOTE: If you are providing consent as a legally authorized representative (LAR), "you" or "your" refers to the research participant.

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 Department of Defense (DoD) healthcare beneficiary between the ages of 18 and 75 (inclusive) and have chronic facet mediated low back pain. The purpose of this research study is to learn about treatment options for this type of back pain. The treatment option being tested in this research study uses your own blood (in the form of platelet rich plasma) to help heal your back. If you choose to participate, you will be a part of this research study for approximately 7-10 months. The duration of participation per visit varies based on the activities scheduled. 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 Madigan Army Medical Center (MAMC), Brooke Army Medical Center (BAMC), and Womack Army Medical Center (WAMC). Overall, up to 150 patients will be enrolled in this study nationwide over a period of 2 years. Up to 100 of those participants will be enrolled here at WAMC.

During the study, you will have about six or seven (6-7) visits with the research team. After consenting to participate in this research study, you will provide your contact information and complete a demographics questionnaire. You will then return to the WAMC Pain Clinic to complete formal screening procedures, to receive the study treatment, and for follow ups at 1 month, 3 months, and 6 months after your study treatment. If you initially received the placebo injection, at 3 months after the study treatment, you may be offered to try the PRP treatment method. If you decide to try this method, you will come back 3 months and 6 months after the PRP treatment.

This study is looking at using platelet-rich plasma (PRP) for the treatment of facet mediated low back pain. 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 low back pain. This means that PRP injections are considered experimental for the treatment of facet mediated low back pain.

Currently, corticosteroid injections, radiofrequency ablation, and spinal surgery are the standard treatment options for continued relief from chronic facet mediated low back pain. If your low back pain continues after you receive study treatment, both corticosteroid injections and radiofrequency ablation may still be an option for you.

At the end of this research study the clinical results, including research results about you will not be directly shared with you. However, a summary of results will be available to the public on http://www.ClinicalTrials.gov.

3. 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 you qualify for the study. This is called the "Screening Process." These tests may have already been done, or this information already collected, as a part of your regular medical care. The researchers will ask both you and your physician questions to ensure you qualify. These include questions regarding your age, current condition, medical history, medical care eligibility, and plans to relocate/separate/retire.

The screening tests required for this study are a standard diagnostic lumbar medial branch block (MBB) and hCG urine test for pregnancy (for female participants only). The MBB is to ensure you have facet mediated pain.

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 Questionnaires & Screening Activities:

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

- You will complete a series of questionnaires about your demographic characteristics, your military history and active-duty status, your relevant medical history, your current level of function, and your current pain and symptoms.
- If you are a biological female of child-bearing age, you will be required to go to the lab for an hCG urine test for pregnancy.
- A member of the research team will conduct a medical record review of clinical notes and results related to your back pain/symptoms.
- You will undergo a standard diagnostic lumbar MBB and complete a pain diary for eight (8) hours following the procedure. This procedure is commonly used in categorizing back pain and involves injecting an anesthetic into the nerves connected to specific joints in your spine. This procedure will help confirm that your type of low back pain is the kind that we are treating in this study and that you are a good candidate for the study injection. If your type of

low back pain is different than the type of pain the study is exploring, you will not proceed with the study treatment.

Overall, the screening and baseline activities will require you to be at the hospital for approximately two and a half (2.5) hours. You are required to complete all screening and baseline activities within 60 days after consent.

Randomization:
Once the study team confirms that you are eligible for this research study (via the diagnostic lumbar MBB and, if applicable, hCG urine test for pregnancy), you will be randomly assigned to one of two (2) groups. Randomization is a process like flipping a coin and means you will have a 50/50 chance of being assigned to either of the groups. Both groups will have the same number of study visits and will complete the same questionnaires, but will receive different study treatments. The two study groups are: 1) PRP injection or 2) Saline injection.

You will have a one in two (50%) chance of being placed in the placebo control group that receives a saline injection. This saline injection is an inactive, harmless substance that looks like the research study medication, but contains no medication.

You have a one in two (50%) chance of being placed in the research study group that receives PRP injection.

This research study is a double (assessor) blind study, which means that you will not know whether you are receiving the research study medication (i.e., PRP injection) or a placebo (i.e., saline injection). At the end of your 3-month follow up visit, you and will be un-blinded to the injection type you received. The provider who conducts your clinical follow up visits will also not know what injection type you received until after your 3-month follow up visit.

Study Treatments:
After the study team confirms that you are eligible to participate in this research study and you are randomized to a study group, you will be able to schedule the clinic appointment for your study injection(s). Your study injection must take place within 30 days of being randomized to a study group. The injection procedure will be completed by a trained physician. This appointment will take approximately 1 hour.

If you are a biological female of child-bearing age, you will be required to take another hCG urine test for pregnancy at the lab before your study injection. If this test indicates you are pregnant, you will be withdrawn from the study and will resume normal care with your medical provider.

If your symptoms only occur on one side of your back, you will receive injections only on that side. If your symptoms occur on both sides of your back, you will receive injections on both sides. Regardless of the study group you are assigned to, you will have 30ml (for injections on one side) or 60ml (for injections on two sides) of blood drawn on the day of your study injection.

PRP Injection Group:
If you are assigned to the PRP treatment group, the PRP mixture will be prepared by using a centrifuge to spin down your blood sample creating a concentrate. This PRP concentrate created from your own blood will be injected into your affected joint(s) with the goal of relieving pain and helping your back heal.

Saline (Placebo) Injection Group:
If you are assigned to the saline (placebo) injection study group, your blood sample will be safely discarded and you will receive saline injection(s) into your affected joint(s).

Other Treatments and Medications (both groups):
No matter what study injection you receive (PRP or placebo/saline), you will be asked to avoid other treatments that are considered invasive while participating in this study.

You will also be asked to not take NSAIDs for treating typical pain symptoms for at least the first 3 months following the study intervention/injection. NSAIDs include: aspirin (e.g., Bayer), ibuprofen (e.g., Advil, Motrin), naproxen (e.g., Aleve), Celecoxib (e.g., Celebrex), etc. PRP works by promoting an inflammatory reaction that kick starts potential repairing and healing processes. You are asked to avoid NSAIDs because they could potentially interfere with that inflammatory reaction and therefore reduce the potential efficacy of the PRP/study injection.

You can, however, take other medications to treat pain such as acetaminophen (e.g., Tylenol) and tramadol.

You will also be offered other rehabilitative and/or complementary techniques such as physical therapy, aquatics, yoga, biofeedback, pain psychology support.

Follow Up Visits:
During the follow up visits at WAMC, the following things will happen:

- A study physician will perform a standard physical examination which is like a normal doctor's visit.
- You will complete a series of questionnaires asking about your current military status, your current level of function, and your current pain and symptoms.
- You will be asked about your satisfaction with the study treatment you received.
- You will be asked if you have experienced any complications or if you've had any additional treatments for your back pain.
- A member of the research team will conduct a medical record review of clinical notes and results related to your back pain/symptoms.

The follow up visits at WAMC will each take approximately 1 hour to complete.

PRP Injection Group:
If you are assigned to the PRP injection group, you will be asked to return to the WAMC Pain Clinic for study follow up visits at 1 month, 3 months, and 6 months after your study (PRP) injection(s). Your participation will end after your 6 month follow up visit.

If you don't experience a positive result from the PRP injection(s), you will still have other treatment options (e.g., corticosteroid injections, radiofrequency ablation, spinal surgery, etc.) available to you as standard of care through your personal physician once your study participation ends.

Saline (Placebo) Injection Group:
If you are assigned to the saline (placebo) injection group, you will be asked to return to the WAMC Pain Clinic for study follow up visits at 1 month, 3 months, and 6 months after your study (saline/placebo) injection.

At the end of your 3 month follow up visit, you may be offered the option to extend your study participation and receive PRP injection(s). If you decide to try the PRP treatment method, you will be asked to return to the WAMC Pain Clinic for study follow up visits at 3 months and 6 months after your PRP injection. This means that your total time in the study will be about 3 months longer than if you choose not to receive PRP injection(s). If you choose to receive PRP injection(s), your study participation will end after your 6 months post-PRP injection follow up visit.

If you are not interested in receiving PRP injection(s) you will also have other treatment options (e.g., corticosteroid injections, radiofrequency ablation, spinal surgery, etc.) available to you as standard of care through your personal physician. If you chose to forego PRP injections and to resume treatment/follow-up care with your personal physician, you will still be asked to return to the WAMC Pain Clinic to complete study questionnaires at your originally scheduled 6 months post-study (saline/placebo) injection. In this case, your study participation will end after your 6 months post-study (saline/placebo) injection.

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 the study activities:

- Low back injections (including the MBB, the PRP injection, and the saline injection): There are rare minor side effects associated with low back injections (including the use of local anesthetics and fluoroscopy with contrast) which include: bleeding, pain, irritation, bruising, nausea, dizziness, headache, confusion, tremors, arrhythmias, and infection. Even rarer are potential side effects of nerve or joint/capsule damage, severe allergic reaction, and seizure. Other extremely rare risks include a very small chance of radiation exposure resulting in injuries to the tissue/skin, burns and the possibility of inducing cancer in the future. Additionally, there is a chance you experience no pain relief. To minimize risks, trained physicians will complete the injection procedures using standard universal precautions.

- Blood draws: There are rare minor side effects associated with blood draws that include: pain or discomfort, bruising, infection, redness, and swelling. Even rarer are potential side effects of hematoma and nerve damage.

If you are a FEMALE ABLE TO BECOME PREGNANT and you want to take part in this study, you should know that the local anesthetics and fluoroscopy with contrast used in this study might be harmful to (1) an unborn child if you are pregnant; or (2) an infant if you are breast-

feeding. You will take a pregnancy test before you can participate in this study. You should not get pregnant or breastfeed while in this study. The only completely reliable methods of birth control are not having sex or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not completely effective in preventing pregnancy.

If you become pregnant or feel you might be pregnant during your time participating in this study, 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.

There are currently no known additional risks specific to PRP injections, however because this treatment is not yet offered as a standard procedure in the military health system, there may be 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 research participant in this research study are: reduced pain and improved function. However, there is no guarantee that you will directly benefit from being in this research study.

The diagnostic MBB performed as part of the screening process could help your medical team better diagnose your pain problem and develop an appropriate treatment plan.

Additionally, others may benefit in the future from the information learned during this research study. We may better understand the benefits of using point of care generated PRP as a minimally invasive treatment option for treating facet mediated low back pain.

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

There may be other options for treating your chronic low back pain. Alternative treatments and/or procedures that may be available to you include: corticosteroid injections, radiofrequency ablation, and spinal surgery. 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 other research studies involving experimental treatments that could be helpful to your condition.

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

8. **IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?**
Yes, for your participation, you will receive a $50 USD gift card following the blood draw on the day of your study treatment/injection. If you initially received the placebo saline injection, but later opt for the PRP procedure after un-blinding, you are eligible to receive an additional $50 USD gift card following the blood draw on the day of your second study treatment/injection.

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 WAMC: Min Ho Chang, MD
Interdisciplinary Pain Management Center (IPMC)
Womack Army Medical Center
2817 Reilly Road
Fort Liberty, NC 28307
(910) 907-9189

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) provided 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:**
Womack Army Medical Center (WAMC) – Fort Liberty, NC

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 WAMC Human Research Protections Program Office (HRPPO), the Naval Medical Center Portsmouth (NMCP) Institutional Review Board (IRB), and the Department of Defense (DoD) Higher Level Review as part of their duties. These duties include making sure that the research participants are protected.

Authorized research team members 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.

Procedures to protect the confidentiality of the data in this study include but are not limited to:

Every effort will be taken to protect your identity as a participant in this study. You and 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 WAMC HRPPO, the NMCP 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.

The WAMC 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 their 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 WAMC research team will also maintain an intake form that collects your preferred contact information. This intake form will be kept in a locked cabinet inside of a locked room and stored separately from your coded research records.

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. Your research records may be disclosed outside of the hospital, but in this case, you will be identified only by a unique code number.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA).

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. The data that will be stored and that may be used in future research will be de-identified, meaning that all of your personal identifiers will be removed. This future research may be in the same area as the original study or it may be for a different kind of study.

Any future research using your retained de-identified data will require a research protocol for the proposed study reviewed by 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.

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.

The local study team will keep this consent form and your signed HIPAA authorization for six (6) years following study closure. They will keep your coded 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 as soon as all data collection is completed and analyzed, and no later than 1 year following study closure.

If you consent to participate in this research study, your de-identified data 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.

17. USE OF INFORMATION AND SPECIMENS

During this research study, you could be asked to provide the following types of samples (biological specimens): blood. Your specimens will only be identified by your unique study ID number and not by your name or other similar identifier. Your specimens 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.

Although research that uses your samples may lead to the development of new inventions, products, or discoveries (some that might be patented and licensed), there are no plans to pay you for them.

HIPAA AUTHORIZATION

I. Purpose

An Authorization is your signed permission to use or disclose your health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or disclose your health information with a valid Authorization. The MHS is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force. A valid Authorization must include the core elements and required statements as contained in this document.

Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information.

II. Authorization

The following describes the purposes of the requested use and disclosure of your health information: The purpose of this research study is to investigate Platelet-Rich Plasma (PRP) as a minimally invasive treatment option for facet mediated low back pain.

A. What health information will be used or disclosed?

The local research team will review your Military Health System (MHS) electronic medical record to collect details about your low back pain including opioid medication use, previous diagnostic medial branch blocks (MBBs) and urine hCG test results (for females only). We will also collect information about your overall health status, level of function, and additional medical/treatment history related to your low back pain/symptoms.
The following protected health information (PHI) will be collected: name, address, months and dates of diagnostic tests, related clinic visits, and lab tests, results of diagnostic tests, clinical evaluations, and lab tests, telephone numbers, e-mail addresses, date of birth, DoD ID number, Rank, and/or medical record number.

B. Who will be authorized to use or disclose (release) your health information?

Authorized members of the local research team will have access to your health information recorded in the MHS electronic medical record in order to confirm that you qualify to participate in this study, to administer research treatments and/or procedures, to monitor your progress and ensure your safety, and to collect and analyze relevant research data.

C. Who may receive your health information

Only researchers involved in this specific study will have access to your health information.

However, your health information may be made available to federal health oversight groups such as the Naval Medical Center Portsmouth (NMCP) Institutional Review Board (IRB), the local DoD research office, the DoD Higher Level Review, and the Food and Drug Administration (FDA) as part of their duties. These duties include making sure that human research participants are protected.

D. What if you decide not to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you will not receive research-related treatment.

The MHS will not condition (withhold or refuse) treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this Authorization.

E. Is your health information requested for future research studies?
No, your health information *is not* requested for future research studies.

F. Can you access your health information during the study?
You may have access to your health information at any time, unless your identifiers are permanently removed from the data.

G. Can you revoke this authorization?

- You may change your mind and take back your Authorization at any time. However, if you revoke this Authorization, any person listed above may still use or disclose any already obtained health information as necessary to maintain the integrity or reliability of this research.
- If you revoke this Authorization, you may no longer be allowed to participate in this research study.
- If you want to revoke your Authorization, you must write to:
  Min Ho Chang, MD
  Interdisciplinary Pain Management Center (IPMC)
  Womack Army Medical Center
  2817 Reilly Road
  Fort Liberty, NC 28307
  (910) 907-9189
  min.h.chang.mil@health.mil

H. Does this Authorization expire?
Yes, it expires 1 year following study closure.

III. What else may you want to consider?

- No publication or public presentation about the research described above will reveal your identity without another signed Authorization from you
- If all the information that does or can identify you is removed from your health information, the remaining de-identified information will no longer be subject to this Authorization and may be used or disclosed for other purposes
- In the event your health information is disclosed to an organization that is not covered by HIPAA, the privacy of your health information cannot be guaranteed.

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

You do not have an option to decline receiving information about an incidental finding.

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. If you leave the study early, we may retain and analyze all coded/de-identified data collected up to the time you withdraw if the data is necessary to maintain the integrity of the study. However, no additional data will be collected.

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

Min Ho Chang, MD
Interdisciplinary Pain Management Center (IPMC)
Womack Army Medical Center
2817 Reilly Road
Fort Liberty, NC 28307

(910) 907-9189
min.h.chang.mil@health.mil

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 (910) 907-9189.

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.

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 a 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.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: 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 WAMC will be available to answer any questions throughout this study:

Min Ho Chang, MD
Interdisciplinary Pain Management Center (IPMC)
Womack Army Medical Center
2817 Reilly Road
Fort Liberty, NC 28307
(910) 907-9189
min.h.chang.mil@health.mil

Womack Army Medical Center Human Research Protection Program (HRPP) Office
The Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Caryn Duchesneau, CIP
Human Research Protection Program Office
Womack Army Medical Center
2817 Reilly Road
Fort Liberty, North Carolina, 28310
Phone: 910-907-6277
Email: caryn.l.duchesneau.civ@health.mil

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 IRB Office at:

Naval Medical Center Portsmouth
620 John Paul Jones Circle
ATTN: CID
Portsmouth, VA 23708
(757) 953-5939

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.

23. SIGNATURES

SIGNATURE OF PARTICIPANT

Your signature below indicates that:

- You authorize the Military Health System to use and disclose your health information for the research purposes stated above;
- You have read (or someone has read to you) the information in this consent including the HIPAA Authorization;
- You agree that you 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 you. You have been provided with the opportunity to ask questions
- You 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 (DDMONYYYY)

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 (DDMONYYYY)