DAVID GRANT USAF MEDICAL CENTER
CONSENT TO PARTICIPATE IN RESEARCH &
AUTHORIZATION TO USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

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KEY INFORMATION FOR PROTOCOL: Trigger Point Injections in Reducing Pain Following Total Knee Arthroplasty

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?

By doing this study, we hope to learn other methods of reducing pain following your knee replacement surgery rather than relying on prescription pain killers, i.e. opioids. The method used will be a trigger point injection into the muscle surrounding your knee with a numbing medication called lidocaine. This injection is meant to stop something called a trigger point from forming. A trigger point is more commonly known as a muscle spasm, Charlie horse or a “knot”. Muscle spasms are thought to increase your pain and by completing a trigger point injection, which is a shot into the muscle spasm with a numbing medication, it will prevent this process from occurring and decrease your pain. This study will have two groups, one that gets the shot with the numbing medication and one that gets a shot without the numbing medication. You will be put into a group based on the order that you joined the study. You will get the shots a few minutes after your surgery. You will be asked to complete questionnaires about your pain and/or the amount of pain medication you used on the first day after surgery, and 2 and 6 weeks after surgery. Your participation in this research will last about 6 weeks and your study visits will be conducted during your standard of care follow-up appointments.

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

If you choose to take part in this study, you may experience improvement in your pain following your knee replacement surgery which may help with your knee therapy after surgery and decrease your use of pain killers which may lower your risk of addiction. The main reason for this study, outside of better pain control, is to decrease use of pain killers, or opioids. Opioids come with a risk of addiction even in persons with no history of addiction. Finding other methods to treat pain can lower your risk of opioid use and dependency. However, there is no guarantee that you will benefit from being in this study.

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

If you choose to take part in this study, there is a risk of that you may not be in the group that receives the shot with numbing medication, or you may have a bad reaction to the numbing medication (lidocaine). Risks related to this injection include bleeding, damage to nerves or blood vessels, infection, and pain.

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

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 David Grant Medical Center if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

The person in charge of this study is Dustin Bennett, PA-C. If you have questions, suggestions or concerns about the study, his contact information is: dustin.l.bennett4.mil@health.mil or 707-423-5391.

Madigan Army Medical Center is the Institutional Review Board of record for David Grant Medical Center. 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 Army Medical Center IRB Office at: 253-968-3524, Madigan Army Medical Center, 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 at least 45 years old and scheduled for a total knee replacement. The purpose of this research study is to learn about other ways to control pain besides using pain killers. The duration of each visit is 20 to 45 minutes, depending on your questions. There will be up to 100 people taking part in the study at David Grant Medical Center, over a period of 8 months.

This study is looking at giving shots with numbing medication in different areas of the knee using landmarks (looking at and feeling the knee and the areas around it) to see if it improves pain after knee replacement surgery. Pain level and the amount of pain medication used for pain will be checked at three time points. Trigger point injections have not been well-studied before. This means that trigger point injections are considered experimental for the treatment of pain after knee replacement surgery.

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

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

You will meet with a study investigator to review and sign this consent form. After signing this consent form, you will be enrolled into the study.

You will be assigned to one of two groups based on your order of enrollment in the study. The first person to join the study will be 1, the second 2 and so on. All people assigned an even number will be put into one study group, and people assigned an odd number will be in another study group. Each group will have the same number of people in it. One group will get the shot with the numbing medication (experimental), and the other group will get the shot but no numbing medication (sham). A sham shot looks like the experimental shot, but the needle will not be put into your muscle, and it has no medication in it. You will have an equal (50/50) chance of being in either group.

This research study is a single blind study, which means that you will not know which group you are assigned to, only the researcher will know. To ensure that you are not aware of the group you are in a “blind” will be placed between you and the needle before the investigator gives you the shots. The “blind” will either be a drape or other soft item that will be held by a person not involved in the study while the investigator uses both hands to safely administer the shots. The “blind” is meant to prevent you from seeing exactly what shot you are receiving. This is an important part of the study as it reduces bias answers if you were to see what type of injection technique that you received. In other words, this makes the data collected from your participation in this study more accurate.

On the day of your surgery, a study investigator will give you 8 shots. Depending on the study group you are in it may be in 4 different muscles in your thigh and calf, 2 shots in each muscle. The shots will either contain a small amount (less than a ¼ teaspoon) of lidocaine, a numbing medication, to relax those muscles to decrease tightness and pain (experimental), or no medication (sham). Each shot may take 5-10 seconds to give. This will be done a few minutes after your surgery while the numbing medicine the anesthesiologist (provider who provides pain mediation and puts you to sleep during the surgery) gives you is still working. The study investigator will also review your medical record to collect demographic information (age, sex, beneficiary status, height/weight measure), medical (if you have diabetes) and medication history, tobacco use, and information about the surgery (numbing medication used during surgery, knee that was operated on, complications), and the date you were sent home.

The day after your surgery, typically the day you are discharged, a study investigator will give you a pain questionnaire to complete.

You will return to David Grant Medical Center at 2 weeks and 6 weeks after your surgery. You will have the standard knee replacement surgery follow-up with a clinic provider and be given two questionnaires to complete for the study, one will be about your pain and the other about the amount of pain medication you used. The investigator will count the number of pain medication (pills) you have left in your bottle. You will receive a phone call from a study investigator 1-2 days before both follow-up visits to remind you to bring your pain medication bottle with you to the visit. After completing the 6-week visit, your participation in the study will be over.

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

There are other options for treating pain after knee replacement surgery such as prescription and over-the-counter pain medication, cold packs, raising your leg by putting it on a pillow, massage, exercise, and physical therapy which are standard practice. Choosing not to take part in this research study is also an option.

The medication involved in this research study may also be available through your personal physician without taking part in this study.

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

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

5. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

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

6. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study): Dustin L. Bennett, PA-C

7. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data): David Grant Medical Center. As

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

8. **SOURCE OF FUNDING:** Funding is not needed for this study.

9. **LOCATION OF THE RESEARCH:** David Grant Medical Center, Travis AFB, CA

10. **DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS**: Completing a research study is a graduation requirement for the Doctorate program through Baylor University. There are no financial interests to completing this study. If you have any questions or concerns about your privacy rights, you should contact the DGMC HIPAA Privacy Officer, 101 Bodin Circle, Travis AFB, CA, 94535. Telephone: 707-423-7916.

11. **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 David Grant Medical Center, the 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: coding data, removing personal information from the data, requiring a CAC card to access the computer, using password protection on files, locking drawers and offices.

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.

Only those study team members approved by the IRB 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.

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

As a Federal facility, David Grant Medical Center is allowed under California Law to ask you for HIPAA Authorization and research participation Informed Consent in the same document – this one. 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*
- *Date of Birth*
- *Discharge Date*
- *Age (over 89 years, will be grouped as age 90 or older)*
- *Phone numbers*
- *E-mail addresses*
- *Medical history*
- *Surgical history*
- *Medication list*
- *Pain score (pain questionnaire response)*
- *Opioid use (pain killer use questionnaire response)*

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

Your name and date of birth will be used to access and review your electronic medical record and verify your identity when making reminder calls. Your medical, surgical, and medication history, age, and discharge date will be used to conduct the study. Your

email address and phone number will be used to schedule and coordinate follow-up study visits (weeks 2 and 6). Your answers to the pain and opioid use questionnaires will be used to monitor your pain levels and the amount of medication you used for your pain. All the above information will be de-identified (not linked with any information that can identify you) in the study results.

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 David Grant Medical Center Human Research Protections Program
- 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 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 Dustin Bennett, PA-C, at 60 MDG, Orthopedic Department, 101 Bodin Circle, Travis AFB, CA, 94535 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.

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 Dustin L. Bennett, PA-C, at 60 MDG, Orthopedic Department, 101 Bodin Circle, Travis AFB, CA, 94535.

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 DGMC HIPAA Privacy Officer, 101 Bodin Circle, Travis AFB, CA, 94535. Telephone: 707-423-7916.

This Authorization does not have an expiration date.

Your signature at the end of this document acknowledges that you authorize David Grant Medical Center, Madigan Army Medical Center, and the study team members to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

13. 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.

14. 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.

15. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must inform the investigators that you wish to withdraw from the study. If you decide to no longer participate in this research study, the data that was collected for this study will still be used.

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 he determines 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.

16. 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.

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: Dustin Bennett, PA-C
Phone: 707-423-5391
Mailing Address: 60 MDG, Orthopedics Department, 101 Bodin Circle, Travis AFB, CA 94535

David Grant Human Research Protection Program (HRPP) Office
The Human Research Protection Program Office staff and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study. Please contact the 60 MDG HRPP Office at: 707-423-7268, Clinical Investigation Facility/SGSE, 101 Bodin Circle, Travis AFB, CA 94535 or usaf.travis.60-mdg.mbx.60mdg-cifprotocoloffice@health.mil .

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

CALIFORNIA HEALTH & SAFETY CODE §24172

Experimental Research Subject's Bill of Rights

California law, under Health & Safety Code '24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This list includes the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of the signed and dated written consent form.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.