4-drug Nerve Block versus Plain Local Anesthetic for Knee and Hip Arthroplasty Analgesia in Veterans

Consent Version 9.0

Consent Date: January 11, 2018

NCT02891798

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM

Subject Name: _____Last 4 SSN:_____ Date: _____

Title of Study: 4-drug Nerve Block versus Plain Local Anesthetic for Knee and Hip Arthroplasty Analgesia in Veterans

Principal Investigator: Brian A. Williams, MD, MBA VAMC: Pittsburgh (646)

LAY TITLE: *Study of two different types of pain relief nerve blocks for patients having a knee or hip replacement*

STUDY CONTACT INFORMATION:
If you have a general question about this research study, or if you have any concerns or complaints related to this research study, you may call Dr. Brian Williams at 412-360-1602 or any of the investigators listed below.

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call Dr. Williams at 412-360-1602 during the day and after-hours or on weekends call 1-866-785-9015 and tell the operator that you are a research subject from Nerve Block study and need to speak with Dr. Williams. Then give the operator a phone number where you can be reached. The operator will get in touch with Dr. Williams or another person listed below who will call you back. In the case of a medical emergency contact your local emergency medical service or go to your local emergency room.

PRINCIPAL INVESTIGATOR:
Brian A. Williams, MD, MBA
VA Pittsburgh Healthcare System (VAPHS)
University Drive C
Pittsburgh, PA 15240
412-360- 1602

CO-INVESTIGATORS:

Catalin S. Ezaru, MD
Marsha RitterJones, MD
VAPHS
University Drive C
Pittsburgh, PA 15240
412-360-6770

Visala Muluk, MD
VAPHS
University Drive C
Pittsburgh, PA 15240
412-360-3957

James Ibinson, MD, PhD
VAPHS
University Drive C
Pittsburgh, PA 15240
412-360-6152

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Principal Investigator: Brian A. Williams, MD, MBA VAMC: Pittsburgh (646)

STUDY SPONSOR:
Department of Defense
Department of the Army – US Army Medical Research and Materiel Command
Additional information regarding the study sponsor can be provided upon request.

PURPOSE OF THE RESEARCH STUDY:
During orthopedic surgery, nerve blocks are used to decrease post-operative pain. The purpose of this research study is to compare two different dosing plans for nerve blocks to try to control pain following the surgery, and will specifically look at your self-reported and physical therapy progress after your surgery. The study will evaluate the effectiveness of bupivacaine (a Novocain®-like drug) versus bupivacaine plus CBD (clonidine-buprenorphine-dexamethasone). All of the drugs utilized in this research study are all FDA approved, however, not all are FDA approved for this indication, and the combination of bupivacaine plus CBD is not FDA-approved. Bupivacaine plus CBD, however, has been used routinely here for such nerve blocks since 2011, after the hospital approved this drug combination. You are being asked to participate in this research study because you are scheduled to undergo a total knee or hip replacement at the VA Pittsburgh Healthcare System (VAPHS).

You will be randomly assigned to one of the two treatment arms (bupivacaine or bupivacaine +CBD). This is a double blind study, so neither you nor your anesthesiologist or surgeon will know what study treatment group you are assigned to.

VAPHS plans to consent approximately 250 patients, in order to enroll 200 patients into this study (100 patients undergoing hip replacement, and 100 patients undergoing knee replacement).

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 Website will include a summary of the results. You can search this Web site at any time.

DESCRIPTION OF THE RESEARCH STUDY:
You will be in this research study for up to approximately 6 weeks after your surgery. Your participation in this study could be as long as 3-4 months. This will depend on how long after you sign consent that

your surgery is scheduled. However, your last study visit will be approximately 6 weeks after your surgery.

Your participation in this research study should not require you to spend any more time in the hospital than would occur with your routine medical care after having knee or hip replacement surgery. We will attempt to coordinate your research visits with your other standard of care appointments at VAPHS, but if we cannot do so, then additional visits to VAPHS will be required to accomplish these.

Whether or not you participate in the research study, you will be asked to return to VAPHS for routine medical and orthopedic care. Your participation in this research study will require that you spend more time at VAPHS than would occur with your routine medical care, to complete any questionnaires requested from you, and undergo any of the described testing, unless (as described above) we need to schedule separate visits. The total additional time required for your participation in this study (not including the hospital stay itself, and not including transportation to/from VAPHS) is approximately 4-5 hours (over the course of a typical 2-5 day hospital stay).

While taking part in this study, the following tests and procedures will be completed:

Prior to surgery (Screening/baseline visit):

- Demographics, including your age and weight
- You will be asked about whether you smoke or not and if so, how much
- You will undergo a pre-surgery evaluation at the IMPACT clinic at VAPHS. You would have this evaluation done whether or not you were participating in this study.
- You will undergo the following physical therapy tests (all physical therapy tests done prior to surgery are being done only because you are taking part in this research study):
    - Climbing stairs (timed)
    - Straight leg raise
    - Range of motion test
    - Standing balance test
    - Walking speed
    - Sensation test

- Repeated Chair Stand test: For this test you will be asked to stand up from a chair five times. It will take approximately one minute to complete this test.
- Functional Independence Measure (FIM). For this test you will be asked to complete 18 specific tasks related to transfers, walking and stair climbing. It will take approximately 15 minutes to complete these tests.

You will be asked to complete several study questionnaires. These questionnaires will take approximately 20 minutes to complete and will ask about current pain you may have and your ability to complete various daily tasks.

If you experience a significant health status change after your baseline visit, but before your surgery, the study team will re-evaluate your current health status and determine if it will affect your initial baseline data. If they determine that it will affect your baseline data, you will be asked to come in for a repeat baseline visit (all previously-listed procedures will be conducted). Repeating this baseline visit is for data purposes only, and not for any safety concerns. If there are safety concerns, your orthopedic team will alert you if your surgery needs to be cancelled or reconsidered. If you are unable to come in for this repeat visit, you will not be removed from the study; rather, you will be able to move forward in the study as originally planned.

Day of Surgery:
Prior to receiving anesthesia, you will be asked to complete 3 study questionnaires. You will have regional anesthesia (which, as opposed to general anesthesia, is the anesthetic of choice for your surgery at VAPHS). Another word to describe "regional anesthesia" is "nerve block". For this study, you will be randomly assigned (like a flip of a coin) to receive one of two different nerve blocks. These nerve blocks all help with pain relief after surgery for a limited period of time (hours), and are also used to avoid the need for general anesthesia (breathing tube and breathing machine) during surgery. Please understand that patients are routinely "asleep" for their surgery, including with nerve blocks; the nerve blocks simply allow for the avoiding of the breathing tube and breathing machine. Regardless of which of the 2 groups you are assigned to, we will take precautions to use a detailed standardized treatment plan to prevent and treat both pain and sickness to the stomach (nausea and vomiting). We will assure that you will be as comfortable as is safely possible throughout your hospital stay after your surgery. Once your regional anesthesia sets in (the nerve blocks described as well as a spinal anesthetic), you will have your scheduled

knee or hip replacement surgery. The spinal anesthetic and nerve blocks are the recommended anesthesia plan whether or not you participate in the study.

After your surgery, there will be orders for prescribed pain medications. These pain relievers, taken by mouth, include both prescription medication (for example sustained-release morphine and immediate-release oxycodone) and over-the-counter medication (for example acetaminophen, dextromethorphan, and salsalate). These are the same pain pills that you would receive whether or not you participate in the study. If the pain after your surgery is more severe than can be managed with pain pills by mouth, we will have injectable pain medications available, which again are the same as those used for all patients regardless of participating in the study.

Later that day after your surgery, you will also be asked to complete two questionnaires about your recovery from anesthesia, these will take approximately 10 minutes to complete.

Hospital Stay:
Questionnaires:
After your surgery, you will be in the hospital for approximately two to five days for recovery and start of physical therapy. Throughout your hospital stay, you will be asked to complete several study questionnaires. These questionnaires will address your general health, pain, anesthesia recovery and knee or hip function. Each day, these questionnaires will take approximately 30 minutes to complete. These questionnaires are not part of your standard of care, and are for research purposes only.

Physical Therapy Testing:
All of the physical therapy testing done after your surgery is the same as what you would normally be doing if you were not taking part in this research study, with the exception of the walking speed test, standing balance test, stair climb test, single leg balance test and the repeated chair stand test. The following physical therapy tests will be conducted during your hospital stay at VAPHS:

- Straight leg raise (every day while in the hospital)
- Standing balance test (every day while in the hospital)
- FIM (every day while in the hospital)
- Range of motion test (every day while in the hospital)

- Walking speed (every day while in the hospital)
- Repeated chair stand test (Post-op Day 2 and on only)

After your approximate 2-5-day hospital stay, you will be discharged from VAPHS as per the routine procedure.

Follow-Up Visit 1:
Approximately two weeks after your surgery, you will be scheduled to have your standard of care post-op follow up orthopedic visit. At this visit, a member of the study team will also meet with you to administer two study questionnaires and ask you about any adverse events or medications you have been taking. The study team visit with you will add approximately 30 minutes to your already scheduled orthopedic visit. If a study team member is unavailable to meet with you on this day, this visit may be completed as a phone call between you and the study team member. The study team member will administer the questionnaires over the phone.

Follow-Up Visit 2:
Approximately six weeks after your surgery, you will come back to the hospital for your orthopedic follow-up visit. The study team will meet with you as well during this visit; this will extend your normal visit by approximately 1-2 hours. This will be your final study visit. You would be scheduled for this follow-up visit even if you were not taking part in this research study. During this visit, you will meet with your orthopedic care team to see how well you are doing after your surgery. You will also complete study questionnaires and the following physical therapy tests (range of motion, straight leg raise, FIM, standing balance test, single leg balance test, walking speed, stair climbing test and the repeated chair stand test). The walking speed, standing balance test, stair climb test, single leg balance test and repeated chair stand tests are only being done because you taking part in this research study, all other procedures and assessments done at your Follow-Up visit 2 are considered standard of care.

Once you complete Follow-Up Visit 2 you will complete this research study.

RISKS AND BENEFITS:
When the drugs listed below are given intravenously at comparable doses the side effects listed below may occur. Please note that for this research study, these drugs will not be given intravenously. So

although it is possible for these intravenous side effects to occur when given instead as nerve blocks (as in this study), it is very rare.

Risks of Bupivacaine:

- Excitation and/or depression
- Restlessness
- Anxiety
- Dizziness
- Ringing/buzzing in the ears
- Blurred vision
- Tremors
- Nausea
- Vomiting
- Chills
- Constriction of the pupils
- Heart block (Slowing of the electrical activity of the heart)
- Low blood pressure
- Slow heart action
- Abnormal rapid heart rhythms
- Cardiac arrest
- Allergic reaction

Risks of Buprenorphine:

Less Frequent (occurs in 5-10% of patients (5-10 patients out of 100)):

- Nausea
- Dizziness/vertigo

Rare (occurs in 1-5% of patients (1-5 patients out of 100)):

- Sweating
- Low blood pressure
- Vomiting
- Constriction of the pupils
- Headache
- Hypoventilation

Very Rare (occurs is less than1% of patients (less than1 out of 100 patients)):

Very Rare (continued):

- Visual abnormalities
- Injection site reactions
- Urinary retention
- Dreaming
- Flushing/warmth
- Chills/cold
- Ringing or buzzing in the ears
- Pinkeye
- Heart block (Slowing of the electrical activity of the heart)
- Psychosis
- Feeling of discomfort/uneasiness
- Hallucinations
- Coma
- Depersonalization

- Confusion
- Blurred vision
- Euphoria
- Weakness/fatigue
- Dry mouth
- Nervousness
- Depression
- Slurred speech
- ”Pins and Needles” feeling
- High blood pressure
- Abnormally rapid heart rate
- Abnormally slow heart action
- Constipation
- Difficult or labored breathing
- Bluish discoloration of skin
- Indigestion
- Gas
- Apnea (temporary cessation of breathing)
- Rash
- Reduced vision
- Tremors
- Paleness
- Loss of appetite
- Dysphoria/agitation
- Diarrhea
- Red patches on the skin
- Convulsions/lack of muscle coordination
- Allergic reactions
- Itchy skin
- Double vision

Risks of Clonidine:
Common:

- Low blood pressure (45%)

Less Frequent (occurs in 10-15% of patients (10-15 out of 100 patients)):

- Dry mouth
- Nausea
- Drowsiness
- Dizziness
- Confusion
- Vomiting

Rare (occurs in less than 10% of patients (less than 10 out of 100 patients)):

- Nausea
- Sweating

- Chest pain
- Hallucination
- Ringing/buzzing in the ears
- Constipation
- Abnormally rapid heart rate
- Hypoventilation

Risks of Dexamethasone:

- Sodium retention
- Fluid retention
- Congestive heart failure
- Decrease in potassium levels
- High blood pressure
- Muscle weakness
- Loss of muscle mass
- Osteoporosis (may cause vertebral fractures)
- Tendon rupture
- Peptic ulcer
- Perforation of the small and large bowel
- Pancreatitis (inflammation of the pancreas)
- Abdominal distension
- Convulsions
- Increased intracranial pressure
- Vertigo
- Headache
- Psychic disturbances
- Menstrual irregularities
- Development of cushingoid state (symptoms include weight gain and facial puffiness)
- Abnormal grown of hair on face and body
- Cataracts
- Glaucoma
- Increased eye pressure
- Bulging of the eye
- Blood vessel obstruction caused by a clot
- Weight gain
- Increased appetite
- Nausea
- Feeling of discomfort/uneasiness
- hiccups
- Ulcers in the esophagus
- Slow would healing
- Thin fragile skin
- Skin discoloration
- Increased sweating
- Burning or tingling
- Allergic reaction

Surgery:

With respect to your knee or hip replacement surgery, we do not expect any risks above and beyond those related to routine care of surgery. Prior to your surgery, you will be asked to sign a general surgery consent form, which all patients would sign prior to having knee or hip surgery, regardless of taking part in this research study.

"Nerve Blocks"/Anesthesia
From the anesthesia perspective, the "two-needle" nerve block technique is our standard of care for patients that do not participate in the study. Spinal anesthesia is also a standard of care for our patients undergoing joint replacement surgery (knee or hip). Prior to your surgery, you will be asked to sign a general anesthesia consent form (which is part of the same surgery consent form described above), which all patients would sign prior to having knee or hip surgery regardless of taking part in this research study. There are no differences in risks from the two nerve block procedures in the two treatment groups. The drug treatment differences between the two groups do not necessarily change the risks but are indeed likely to change the outcomes when comparing one-drug treatment to the 4-drug treatment. We are not exactly sure how the outcomes will differ, which is why the study is being done. For example, the 4-drug treatment may lead to longer-duration pain relief, but does this longer-duration pain relief lead to better physical therapy, or not as effective physical therapy? Does the longer-duration pain relief and possible changes in physical therapy progress lead to a shorter hospital stay or a longer hospital stay? So the differences in outcomes are expected between the two treatment groups, but this is not the same as stating "the risks will be higher (or lower)" with one treatment or the other.

Risks of Allergic Reaction:
Patients may have a history of allergy to Novocain®; our nerve blocks do not use Novocain® itself, and the risk of allergy from the nerve block drugs that we use for patients is exceedingly rare.

Physical Therapy Testing:
With respect to the described physical therapy testing, The risks associated with the physical tests may include temporary muscle soreness (common: 10 to 25 out of 100 people), a short-term increase of your knee or hip pain and inflammation (rare: less than 1 out of 100 people), or tripping and falling during testing (rare: less than 1 out of 100 people). During testing, risks of tripping and falling will be minimized by our team providing direct stand-by supervision with trained testers. Signs and symptoms of inflammation will be monitored before and after each testing visit. If this inflammation occurs, you will

be referred to your physician for evaluation. Because you will participate in physical tests, there is a rare risk (less than 1 out of 100 people) that you may experience chest pain, dizziness, shortness of breath, heart attack, or stroke. To minimize this risk, we will follow the recommendations from the American College of Sports Medicine and American Heart Association (ACSM/AHA) guidelines for physical testing. As with any experimental procedure, there may be adverse events or side effects that are currently unknown, and some of these unknown risks could be permanent, severe, or life-threatening.

Questionnaires:
Completing the described questionnaires on paper should not constitute a significant risk.

Standard of Care Risks:
You may also experience some side effects related to the procedures/medications/treatments you receive that are not part of the research, but are considered standard of care for your condition. A description of these side effects should have been provided to you by your physician. If you have not received information regarding these side effects, please contact your physician. Orthopedic procedure details are commonly discussed with the surgeon in the clinic before surgery, and anesthesia-specific details are routinely discussed with the anesthesiologist physician the morning of surgery. As a study participant, you are openly invited to discuss anesthesia-specific details with the anesthesiologist before the morning of surgery.

Unknown Risks:
As with any experimental procedure, there may be adverse events or side effects that are currently unknown, and such unknown risks could be permanent, severe, and/or life-threatening.

Confidentiality Risks:
Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you.

The information that we collect about you will be put onto paper forms. The forms will include study ID#, date of birth and date of study events. This information will also be placed into the secure electronic

database system (REDCap). None of your identifiable information will be sent off-site. Completely de-identified information will be sent to the University of Pittsburgh for routine safety analysis, known as a Data Safety Monitoring Review Board. This protocol will also be reviewed by the University of Pittsburgh IRB; however the University of Pittsburgh IRB will not receive any identifiable information. The University of Pittsburgh Research Conduct and Compliance Officer (RCCO) will routinely monitor this study on site at VAPHS. The RCCO monitor will have access to your entire research chart and will have access to PHI, however, they will not be able to take any identifiable information off site. All of the paper forms with your initials and date of birth on it will be stored only at VAPHS in a locked cabinet, and will be accessed only by authorized members of the study team. The Independent Research Monitor may have access to your records as part of their duty to review/evaluate any safety issues, risks or concerns of the research study.

In order to receive your study compensation, you will receive a ClinCard Mastercard, (additional information regarding the ClinCard is located in the COST and PAYMENTS section of this form) your name, date of birth, address and social security number will be sent to Greenphire.

In addition, Federal agencies, including but not limited to, the Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), VA's Office of Research Oversight (ORO), Department of Defense (DoD) and the VA Office of the Inspector General (OIG) may have access to your research records. The Food and Drug Administration (FDA) may also choose to inspect research records, which may include your individual medical records, if this research is FDA-regulated. Research records, just like hospital medical records, may be released or disclosed pursuant to applicable federal and state law as well as to federal and state agencies that are responsible for oversight of medical research. Additionally, any medical information may be shared with your healthcare provider(s) with your consent, and possibly without your consent if permissible under federal laws and regulations. Finally, you consent to the publication of the study results so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed.

You will not directly benefit from participating in this study. You may however, receive indirect benefit given that you are contributing to medical science or helping to advance future understanding of specific pain management techniques to allow a more prompt return to normal activities of daily living and a better outcome from physical therapy.

Subject Name: _____Last 4 SSN:_____ Date: _____

Title of Study: 4-drug Nerve Block versus Plain Local Anesthetic for Knee and Hip Arthroplasty Analgesia in Veterans

Principal Investigator: Brian A. Williams, MD, MBA VAMC: Pittsburgh (646)

ALTERNATIVES TO PARTICIPATION:
There may be other studies that you qualify for. Talk to your provider about such options.

If you decide not to participate in this research study, you will undergo knee or hip replacement surgery and be offered the routine choices of anesthetic currently offered to our patients undergoing the same procedure. The same nerve block techniques are used, which may or may not include a spinal anesthetic depending on the clinical situation and other health status factors. Nerve blocks are routine at VAPHS.

NEW FINDINGS:
You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate.

INVESTIGATOR INITIATED WITHDRAWAL:
The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury. You may also be withdrawn at the discretion of the investigator(s) due to surgical complications or other concerns that may impact your safety.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW:
Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

Your doctor may also beinvolved as an investigator in this research study. As both your doctor and a research investigator, he is interested both in your medical care and the conduct of this research study. You are under no obligation to participate in this or any other research study offered by your doctor. Before you agree to participate in this research study, or at any time during your participation in this study, you may discuss your care with another doctor who is not associated with this research study.

MEDICAL TREATMENT:

Subject Name: _____Last 4 SSN:_____ Date: _____

Title of Study: 4-drug Nerve Block versus Plain Local Anesthetic for Knee and Hip Arthroplasty Analgesia in Veterans

Principal Investigator: Brian A. Williams, MD, MBA_____VAMC: Pittsburgh (646)

In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA medical facilities.

However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION:
If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable federal law. If you believe that you are injured as a result of participation in this study, please contact the Principal Investigator. If compensation is available, the Principal Investigator will provide you with an explanation as to what that compensation consists of, or where you can obtain further information regarding it.

COST AND PAYMENTS: You or your insurance will not be charged for any costs related to the research. However if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in federal regulations as a "category 7" veteran, you may be required to make co-payments for the care and services that are not required as part of this research study.

You will receive compensation for your time and travel for participating in this study. You will receive $20.00 for completing the pre-surgery questionnaires and physical therapy tests, $20.00 total for the tests completed while you are in the hospital and then $60.00 when you complete the study tests at Follow-Up Visit 2 after your surgery. (Possible total of $100.00 if you complete all study visits.)
In order to provide you with your reimbursement, you will receive a Greenphire ClinCard. The Greenphire ClinCard is a MasterCard Debit Card and can be used anywhere MasterCard is accepted. In order to receive your compensation via the ClinCard, we will need to send Greenphire your name, date of birth, address and social security number.

This debit card will be activated and the funds will be loaded onto the card by the study team. Please talk to the study team if you have any additional questions regarding the reimbursement ClinCard.

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Title of Study: 4-drug Nerve Block versus Plain Local Anesthetic for Knee and Hip Arthroplasty Analgesia in Veterans

Principal Investigator: Brian A. Williams, MD, MBA VAMC: Pittsburgh (646)

RECORD RETENTION:
Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule.

RESEARCH SUBJECTS' RIGHTS:
You have read or have had read to you all of the above, and any applicable consent addenda. Dr. Williams or his authorized representative has explained the study and any optional study components to you and answered all of your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.

A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions related to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you (or the person representing you) have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You understand that these Research Subjects' Rights also apply to any optional study components to which you have agreed to participate. You will receive a copy of this signed consent form.

If you have any questions about your rights as a participant in this study, or wish to speak more about the study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at (412) 360-2394

As long as the study is renewed as required by the IRB, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

By signing this form, you agree to participate in this research study.

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Principal Investigator: Brian A. Williams, MD, MBA_____VAMC: Pittsburgh (646)

_____	_____	_____
Subject's Signature	Date	Time
_____	_____	_____
Investigator/Person Obtaining Consent*	Researcher (Print)	Date

**If person other than the Investigator is obtaining consent, he/she must be approved by the IRB to administer informed consent.*

Version Date: January 11, 2018
Version #: 9.0

Department of Veterans Affairs

Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

VA Facility (Name and Address):
VA Pittsburgh Healthcare System (VAPHS), University Drive C, Pittsburgh, PA 15240

VA Principal Investigator (PI):	**PI Contact Information:**
Brian Williams, MD	412-360-1602

Study Title:
4-drug Nerve Block versus Plain Local Anesthetic for Knee and Hip Arthroplasty Analgesia in Veterans

Purpose of Study:

The purpose of this research study is to evaluate patient outcomes after two different forms of regional anesthesia and pain relief after having a full knee or hip replacement. The study will compare two different ways to try to control pain following the surgery, and will specifically look at your self-reported and physical therapy progress after your surgery. The study will evaluate the effectiveness of bupivacaine versus bupivacaine plus CBD (clonidine-buprenorphine-dexamethasone).

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization.

Your individually identifiable health information used for this VA study includes the information marked below:

☒ Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings

☒ Specific information concerning:

☒ alcohol abuse ☒ drug abuse ☐ sickle cell anemia ☐ HIV

☒ Demographic Information such as name, age, race

☐ Billing or Financial Records

☐ Photographs, Digital Images, Video, or Audio Recordings

☒ Questionnaire, Survey, and/or Subject Diary

☐ Other as described:

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH: (Instruction: When banking or further analysis is an **optional** research activity, complete page 5 and leave this section blank. If banking is a required research activity to store "Data" and/or "Specimen" for future use or if "Not Applicable" is selected, remove page 5 in its entirety.)

☒ Not Applicable - No Data or Specimen Banking for Other Research

An important part of this research is to save your

☐ Data

☐ Specimen

in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

☒ Non-VA Institutional Review Board (IRB) at University of Pittsburgh
who will monitor the study

☒ Study Sponsor/Funding Source: Department of Defense - USAMRMC
VA or non-VA person or entity who takes responsibility for; initiates, or funds this study

☐ Academic Affiliate (institution/name/employee/department):
A relationship with VA in the performance of this study

☒ Compliance and Safety Monitors: VA RCO, Michael Mangione, MD (VAPHS) - Independent Research Monitor, Pitt RCCO
Advises the Sponsor or PI regarding the continuing safety of this study

☒ Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO):
FDA, OHRP, GAO, VA OIG, DOD

☒ A Non-Profit Corporation (name and specific purpose):
Veterans Research Foundation of Pittsburgh - participant payments

☒ Other (e.g. name of contractor and specific purpose):
University of Pittsburgh - DSMB (De-identified data only), VAPHS Statcore - Data analysis, RedCAP - electronic data capture online system, Greenphire - Patient Compensation

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial)**:**	**Subject SSN** (last 4 only)**:**	**Date of Birth:**

Note: *Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VA/VHA job duties.*

Access to your Individually Identifiable Health Information created or obtained in the course of this research: While this study is being conducted, you

☐ will have access to your research related health records

☒ will not have access to your research related health records

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

REVOCATION: If you sign this authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:

Brian Williams, MD
VA Pittsburgh Healthcare System
University Drive C
Pittsburgh, PA 15240

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:

☒ Expire at the end of this research study

☐ Data use and collection will expire at the end of this research study. Any study information that has been placed into a repository to be used for future research will not expire.

☐ Expire on the following date or event:

☐ Not expire

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial)**:**	**Subject SSN** (last 4 only)**:**	**Date of Birth:**

TO BE FILLED OUT BY THE SUBJECT

Research Subject Signature. This permission (authorization) has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.

I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this form. I will be given a signed copy of this form for my records.

Signature of Research Subject _____ Date _____

Signature of Legal Representative (if applicable) _____ Date _____

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State Law)

Name of Legal Representative (please print) _____