buprofen to Decrease Opioid Use and Post-operative Pain Following Unilateral Inguinal Herniorrhaphy: A Prospective, Placebo-Controlled, Double-Blind, Randomized Controlled Trial

NCT02929589

27 July 2020

Volunteer Name: _____

WILFORD HALL AMBULATORY SURGICAL CENTER
INFORMED CONSENT DOCUMENT

Ibuprofen to Decrease Opioid Use and Post-operative Pain Following Unilateral Inguinal Herniorrhaphy: A Prospective, Placebo-Controlled, Double-Blind, Randomized Controlled Trial
FWH20160095H

INFORMATION ABOUT THIS CONSENT FORM:
You may be eligible to take part in a research study. This form gives you important information about the study. You may be asked to sign in more than one place in this document. Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you may have for them. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand the procedures of the study and what the study is about, including the risks and possible benefits to you. If you are taking part in another research study, please tell the researchers or study staff.

VOLUNTARY PARTICIPATION:
You do not have to participate in the study if you don't want to participate. You may also leave the study at any time. If significant new findings develop during the course of this study that may relate to your decision to continue to participate in the study, you will be informed. If you choose not to participate in this research study or leave before it is finished, your decision will not affect your eligibility for care or any other benefits to which you are entitled.

PRINCIPAL INVESTIGATOR:
The Principal Investigator (PI) is the researcher directing this study and is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is William Scott, D.O., Maj, Physician, General Surgery, Mike O'Callaghan Military Medical Center.

PURPOSE OF THIS STUDY (Why is this study being done?)**:**
You are being asked to consider participation in this study because you have been identified as needing an open unilateral inguinal herniorrhaphy (hernia repair). The purpose of this research study is to compare the difference in post-operative opioid usage in patients who also take ibuprofen versus those who do not take ibuprofen for pain relief. This study will enroll approximately 185 subjects. Opioids are a class of narcotic drugs approved by the Food and Drug Administration (FDA) used as a pain reliever. Oxycodone is considered an opioid and is a pill taken orally (by mouth). Ibuprofen is an anti-inflammatory pain reliever approved by the FDA and is a pill taken orally. Acetaminophen is a pain reliever approved by the FDA and is a pill taken orally. Oxycodone, acetaminophen and ibuprofen will be the pain relieving medications evaluated for this study. Persons who are already taking opioid medications for pain relief before enrolling in the study are still eligible to participate. You may continue taking your currently prescribed opioid medication, as prescribed by your physician, if you meet the criteria to be included in this study. Other opioid medications allowed in this study (if currently prescribed by your personal physician) include codeine, oxycodone, oxymorphone, hydrocodone, hydromorphone, morphine, methadone, and transdermal fentanyl. You will not be allowed to take other over-the-counter pain medications that are not prescribed to you during this study. This includes acetaminophen, naproxen, or ibuprofen containing medications, or other medications within the non-steroidal anti-inflammatory drug (NSAID) class.

PROCEDURES:

If you decide to take part in this research study, you will be asked to sign this consent form. During your participation in this study, you will be asked to make four visits with William Scott, D.O., Maj, the Principal Investigator (PI) or study staff, and ten additional follow-up phone calls over sixty days to inquire about your pain medication use, to complete questionnaires, and to answer questions.

Screening Procedures– a history will be taken after you sign this consent to participate. This screening is done to find out if you can continue in the study (screening procedures). This screening visit will add approximately 30 minutes to the length of a routine care visit. If you are not allowed to continue in the study, the researcher will discuss the reasons with you. The following procedures will be performed. All are research-driven, unless specifically stated as standard of care:

Screening Visit:

- We will discuss the purpose of this study and the required completion of study-related questionnaires and their potential impact for active duty members.
- Obtain your signed Informed Consent Document and HIPAA Authorization.
- Review your past medical history.
- We will record information from your pre-operative visits, including your name, date of birth, age, phone number, current email address, gender, race, ethnicity, DoD ID, surgical history, family history (first degree relative) of opioid use disorder, medical history, height, weight, blood pressure, temperature, pulse, respiratory rate, allergies, and medications. The medication record will include all current prescription and over the counter medications, including the use, frequency, and dosage. Specifically, the use of acetaminophen alone or in combination with other medications will be recorded. (standard of care)
- We will record your history of tobacco, alcohol, marijuana, and other illicit drug use history, and previous non-prescription use of opioids.
- Ask what your overall pain score is, from 0 to 100, with 100 being the worst pain imaginable.
- Ask what your localized pain score is from 0 to 100, with 100 being the worst pain imaginable, which you believe is related specifically to the hernia that is scheduled for surgical intervention.
- You will be instructed to discontinue use of any over-the-counter pain medications, such as ibuprofen, naproxen, or acetaminophen containing medications that were not prescribed by the investigators during this study.
- You will be instructed to take the study medication preferentially if able, and only use the opioid medication as a "breakthrough medication." The total 24 hour dose of acetaminophen from all prescription and over the counter medications must not exceed 4 grams.
- You will be asked the following (approximately 5 minutes to complete):
  - Beck Depression Inventory-II
  - Opioid Risk Tool (ORT).
  - "How likely do you think it is that you will develop an addiction problem from pain medication you take after surgery?" and chose from 1 of 4 answers: 1: "not at all"; 2: "unlikely"; 3: "somewhat likely"; or 4: "very likely".
- You will have a fasting comprehensive metabolic panel test via 1 venipuncture (5-10 milliliters (mls), 1-2 teaspoons of blood drawn). This test must be completed within 30 days of the surgery, or it will need to be repeated.
- If you are capable of becoming pregnant, you will have a serum pregnancy test (1 venipuncture or 5-10 milliliters, 1-2 teaspoons of blood drawn) or urine pregnancy test (10 drops or less than 1 milliliter of urine). If needed, the

additional 5-10 milliliters for the serum pregnancy test would be gathered via the same venipuncture as the fasting comprehensive metabolic panel.

Study Procedures - as a participant, you will undergo the following study-related procedures:

Randomization:

- You will be randomly assigned (like flipping a coin) into one of the study groups below depending on your past opioid use. Neither you nor your doctor will know which group to which you are assigned.
  - You will be prescribed ibuprofen 800 milligrams by mouth every 8 hours as needed for pain for 5 days, and 1 to 2 tablets of oxycodone/acetaminophen 5 milligrams/325 milligrams (Qty. 30) by mouth every 4 hours as needed for pain for 5 days. Refills will be prescribed if needed through the period of 14 days.
  - You will be prescribed a placebo pill to be taken by mouth every 8 hours as needed for pain and oxycodone/acetaminophen 5 milligrams/325 milligrams (Qty. 30) by mouth every 4 hours as needed for pain for 5 days. Refills will be prescribed if needed through the period of 14 days.

Day of Surgery:

- The standard of care local anesthesia used for this type of surgery is bupivacaine. The surgeon will be reminded via a note in the medical record. (standard of care)
- You will be given standard of care pre-operative instructions regarding the use of your pain medications following your surgery. The preoperative instructions will include standardized verbal and written instructions: "After your surgery, it is expected that you will experience a certain amount of pain for a short period of time. You will be prescribed pain medication that you should take only when you are in pain. If you are no longer experiencing pain, you should stop taking the medication. If you do not require all of the pain medication that was prescribed, you should record the amount of medication that was unused and then properly dispose of the remainder." (standard of care)
- You will receive treatment medications based on your randomization group. These prescriptions will be filled at the Nellis pharmacy.

Pre-Surgery:

- Activities Assessment Scale (AAS)
- You will be asked the following questions:
  - "On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what is your average level of pain at rest in the past 24 hours?"
  - "On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what was your lowest level of pain when at rest in the past 24 hours?
  - "On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what was your highest level of pain when at rest in the past 24 hours?
- You will be given a Medication and Pain Level Diary and will be instructed to complete it every day for 14 days beginning after your surgery. You will be instructed to begin recording your average pain number, highest pain number, and lowest pain beginning 24 hours post-surgical incision. You will also be instructed to record the total milligrams of each medication used in the previous 24 hours. We will issue you a new one at the 14-day visit.

Post-Surgery:

- We will record information from your surgery, for example: the start and end times of surgery and anesthesia,

how long the surgery lasted, how difficult the surgery was, and which opioid medications the anesthesiologist gives at any point during your care.
- Research staff will record the start and end times of your surgery, record the amounts of standard of care pain medications used during your hospital stay, document any standard of care pain assessments that were performed, and document the type of anesthesia you received.
- You will be reminded in the Post Anesthesia Care Unit (PACU) to complete the Medication and Pain Level Diary and bring it to your 14 day follow up visit.

Time of Discharge:
- You will be contacted by a research team member in person or via telephone and asked the following questions:
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what is your average level of pain when at rest in the past 24 hours?
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what was your lowest level of pain when at rest in the past 24 hours?
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what was your highest level of pain when at rest in the past 24 hours?
  - What pain medications are you taking including the strength (in milligrams), and how many total doses have you taken since your surgery? Time of last opioid medication taken?
  - My relief from starting pain is: 0 = none, 1= a little, 2 = some, 3 = a lot, 4 = complete
- You will be reminded to complete your Medication and Pain Level Diary.

Visits 1-5 (Post-Op day 1 through Day 5 Contact (Each visit every 24 hours plus or minus 4 hour visit window):
- You will be contacted by a research team member in person or via telephone and asked the following questions:
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what is your average level of pain when at rest in the past 24 hours?
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what was your lowest level of pain when at rest in the past 24 hours?
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what was your highest level of pain when at rest in the past 24 hours?
  - What pain medications are you taking including the strength (in milligrams), and how many total doses have you taken since your surgery? Time of last opioid medication taken?
  - My relief from starting pain is: 0 = none, 1= a little, 2 = some, 3 = a lot, 4 = complete
- You will be asked to complete the AAS (approximately 5 minutes to complete).
- You will be reminded to complete your Medication and Pain Level Diary.

Visit 6 (Post-Op Day 14 Contact plus or minus 2 day visit window):
- You will be contacted before or after your Post-Operative Follow-up visit and asked the following questions in person or via telephone:
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what is your average level of pain when at rest in the past 24 hours?
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what was your lowest level of pain when at rest in the past 24 hours?
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what was your highest

level of pain when at rest in the past 24 hours?
  - What pain medications are you taking including the strength (in milligrams), and how many total doses have you taken since your surgery? Time of last opioid medication taken?
  - My relief from starting pain is: 0 = none, 1= a little, 2 = some, 3 = a lot, 4 = complete
- You will be asked to complete the AAS (approximately 5 minutes to complete).
- You will return your Medication and Pain Level Diary and be issued new diaries for you to use during the remainder of the study.
- You will be reminded of the two remaining follow-up contacts at 30 days and 60 days.

Visit 7 (Post-Op Day 30 Contact (plus or minus 5 day visit window)):
- You will be contacted by a research team member in person or via telephone and asked the following questions:
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what is your average level of pain when at rest in the past 24 hours?
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what was your lowest level of pain when at rest in the past 24 hours?
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what was your highest level of pain when at rest in the past 24 hours?
  - What pain medications are you taking including the strength (in milligrams), and how many total doses have you taken since your surgery? Time of last opioid medication taken?
  - My relief from starting pain is: 0 = none, 1= a little, 2 = some, 3 = a lot, 4 = complete
- You will be asked to complete the AAS (approximately 5 minutes to complete).
- You will be reminded to complete your Medication and Pain Level Diary and bring it to your next visit.

Visit 8 (Post-Op Day 60 Contact (plus or minus 5 day visit window)):
- You will be contacted by a research team member in person or via telephone and asked the following questions:
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what is your average level of pain when at rest in the past 24 hours?
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what was your lowest level of pain when at rest in the past 24 hours?
  - On a scale of 0-100, with 0 being no pain and 100 being the worst pain imaginable, what was your highest level of pain when at rest in the past 24 hours?
  - What pain medications are you taking including the strength (in milligrams), and how many total doses have you taken since your surgery? Time of last opioid medication taken?
  - My relief from starting pain is: 0 = none, 1= a little, 2 = some, 3 = a lot, 4 = complete
  - Were you diagnosed with post-operative neuralgia (nerve pain) at any point following your surgery
  - Were you diagnosed with an inguinal hernia recurrence at any point following your surgery?
  - Were you diagnosed with a surgical site infection at any point following your surgery
- You will be asked to complete the AAS (approximately 5 minutes to complete).
- The Medication and Pain Level Diary will be collected by the research team.
- You will be informed what group you were randomized into.

RISKS OR DISCOMFORTS:
There are risks to taking part in this research study. One risk is that you may have medication side effects while in the study. Side effects can range from mild to serious. Serious side effects are those that may require hospitalization, are

life threatening or fatal (could cause death). The frequency that people experience a certain side effect can range from many (likely), few (less likely) or only one or two (rarely). Side effects from this study will usually go away soon after you stop taking the study drugs. The side effects related to the blood draw will usually go away soon after the blood draw has been completed. In some cases, side effects can be long lasting or may never go away. Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately, about any side effect that you have while taking part in the study.

The following section will describe the risks related to each drug that is part of this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study. There is a risk of accidental release of confidential information.

The risks and side effects of the standard of care opioid medication given to you during this study will be provided by the pharmacy along with the standard of care prescriptions. Opioid medications such as oxycodone are strong painkillers, and have the potential to be abused and can be habit-forming for some persons. It is important to take only the necessary amount of opioid medication to relieve your pain to reduce the risk of developing addiction.

The risks and side effects associated with the venipuncture (Blood Draw), although not likely, include pain, bleeding, bruising, feeling light-headed, and a slight possibility of infection. The placebo is a capsule filled with lactose. There is a chance, although not likely, that you may have an allergic reaction. The signs and symptoms of an allergic reaction include:

LESS LIKELY and not serious	**RARE and serious**
Hives or skin rash; nausea, stomach cramps, indigestion, vomiting or diarrhea; stuffy or runny nose, sneezing, headaches, asthma.	Anaphylaxis (a potentially life-threatening reaction that impairs breathing and sends the body into shock)

DRUG NAME	**LIKELY *and not serious***	**LESS LIKELY *and not serious***	**RARE and serious**
Ibuprofen	difficulty with bowel, movements; drowsiness, lack of strength; relaxed and calm feeling; sleepiness or unusual drowsiness	upset stomach; heartburn; diarrhea; constipation; bloating; gas; dizziness; headache; nervousness; skin itching or rash; blurred vision; ringing in ears	nausea; stomach pain; itching, weight gain; discolored urine or stool; jaundice (yellowing of skin or eyes); severe headache; neck stiffness; chills; increased sensitivity to light; bruising; numbness; tingling; muscle weakness; fever; sore throat

Rare and serious

- There is a potential for liver injury if more than 4 grams of acetaminophen is consumed in one day.
- There is a risk that completing the Beck Depression Inventory II, Opioid Risk Tool (ORT) and/or the Activities Assessment Scale (AAS) may identify you as at risk for a mental health condition or a substance abuse problem and result in a referral to mental health and command notification. If you are an Active Duty member, and diagnosed with a mental health and/or substance abuse condition, you may require a Medical Examination Board (MEB) referral, be subject to UCMJ action and/or be disqualified from active duty. You may be

reported to command/law enforcement if illicit drug use is affirmed.

- Given the special population of Active Duty members, the identification of any history of substance abuse or any mental health issues, could impact an Active Duty members' military career. At the top of each questionnaire, a sticker clearly states that you are not required to answer any or all questions, without repercussion.
- Subjects participating in this study must disclose all over the counter, herbal, and prescription medications to the investigators and study staff at time of enrollment and screening. There is a risk of adverse medication interactions if you do not comprehensively disclose all additional medication or supplements that you are taking at the time of enrollment.

For more information about risks and side effects, ask one of the researchers or study staff.

As a FEMALE OF CHILDBEARING POTENTIAL wishing to volunteer for this project, you must not be pregnant and agree to take a pregnancy test before you participate in this study. You must also agree to take precautions to prevent pregnancy during the course of this study. The only completely reliable methods of birth control are total abstinence 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 totally effective in preventing pregnancy. Also, you may not breast-feed and participate in this study. If you become pregnant or feel you might be pregnant, contact your provider and the study investigator listed in the voluntary participation section.

Are there risks if you also participate in other research studies? Being in more than one research study at the same time, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researcher.

There may also be unforeseen risks associated with this or any research study.

WITHDRAWAL FROM THE STUDY:
If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care and you will not be penalized or lose any benefits to which you would otherwise be entitled. If you withdraw from the study or you have been withdrawn by the PI, you will continue to receive adequate pain medication for standard of care, as prescribed by your medical provider. However, the pain medication may or may not include the use of ibuprofen.

ARE THERE RISKS RELATED TO WITHDRAWING FROM THE STUDY?
If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researchers may ask you to complete study withdrawal procedures at a final study visit. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

COULD YOUR PARTICIPATION END EARLY:
The researcher may withdraw you from the study prior to the study's end and the study medication may be stopped, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the researchers and study staff.
- The researcher decides that continuing your participation is not in your best interests.

- You become ineligible to participate.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

Should you be withdrawn from the study by the Investigator, the Investigator will refer you to your primary care provider.

If you lose your status as a military health care beneficiary, you can no longer be included in the study. Please let the Principal Investigator and study staff know as soon as you become aware of your situation.

The Principal Investigator of this study may terminate the study and/or your participation in this study for safety reasons.

BENEFITS:
The investigators have designed this study to learn what standard treatments are effective in controlling pain for inguinal hernia repair. There is no guarantee or promise that you will receive any benefit from this study other than knowing that the information may help future patients. The possible benefit of your participation in this study is a decrease in pain.

COSTS: Will taking part in this study cost anything?
The investigators have designed this study so that there is no cost to you to participate in this study other than what it will cost you to travel to the research appointment. The extent of medical care provided on this research protocol is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. Your entitlement to medical and dental care is governed by federal laws and regulations.

PAYMENT (COMPENSATION): You will not receive any compensation (payment) for participating in this study.

ALTERNATIVES TO PARTICIPATION:
Choosing not to participate in this study is your alternative to volunteering for the study. Your other alternative is to receive standard of care treatment for a unilateral inguinal hernia repair, in which Ibuprofen may or may not be prescribed with your other pain medications by your attending physician.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION:
Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. § 552a, the Health Insurance Portability & Accountability Act of 1996, Public Law 104-109 (also known as HIPAA), and their implementing regulations. DD Form 2005, Privacy Act Statement- Military Health Records, contains the Privacy Act Statement for the records.

This is to inform you this study meets the definition of an applicable clinical trial under Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801), which requires responsible parties to register and submit summary results of applicable clinical trials with ClinicalTrials.gov. The law applies to certain clinical trials of drugs (including biological products) and medical devices. As a condition for the publication of research

results generated by the clinical trial, the International Committee of Medical Journal Editors (ICMJE) also requires trial registration through ClinicalTrials.gov.

By signing this consent document, you give your permission for information gained from your participation in this study 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.

Your records may be reviewed by the U.S. Food & Drug Administration (FDA), the Air Force, the DoD, other government agencies that oversee human research, the 59 MDW Institutional Review Board.

Your consent to participate in this study will be annoted in your medical record. A copy of this consent will be stored by the investigator in a locked cabinet in a locked room. All information about you collected on this study will be kept in an electronic database, which will be double password protected and the access will be restricted to people involved in this study. Only the pharmacist and the Research Coordinator will have access to the randomization records and will not reveal the randomization until the end of the study or in the event of a research related adverse event. As soon as possible any link between your identity and the research information will be destroyed. The research information collected about you for this study will not be used for any additional research activity beyond what you have approved by signing this consent.

The study staff advises that you protect your copy of the informed consent document. A breach of confidentiality could occur if you inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate action to assist you.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding potential UCMJ violations or concerns your health and fitness for duty may be required to be reported to appropriate medical or command authorities.

ENTITLEMENT TO CARE:

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers as soon as possible. You may also need to tell your regular doctors.

In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries.

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the Director, 59 MDW Clinical Research Division, (210) 292-7069 or Mike O'Callaghan Military Medical Center Human Subject Research Protections Officer, (702) 653-3298.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

PROTECTED HEALTH INFORMATION (PHI) AND PERSONAL IDENTIFYING INFORMATION (PII) DATA:

All de-identified research data that will be used in the database repository will be kept at the Mike O'Callaghan Military Medical Center, Clinical Investigation Program and will be handled and disposed of in accordance with federal regulations. No unauthorized individual or agency outside of MOFMC will have access to this database without permission of the "Mike O'Callaghan Military Medical Center General Research Data Repository (FWH20180064H)", Manager Col Paul Crawford and the Wilford Hall Ambulatory Surgery Center (WHASC) 59th MDW Institutional Review Board (IRB).

The Investigators are asking for your permission to store your de-identified research data in the database repository for future use in research studies. The specifics of these research studies are unknown at this time, but these studies will frequently be in the area of acupuncture. Your stored de-identified research data will be information such as gender, age, height/weight, medical history, laboratory tests, blood pressure, waist circumference measurements and surgical procedures and post-surgery outcomes. This data is considered non-identifying information and cannot be traced back to you as a donor when added to a database. The Principle Investigator and Database Repository Manager will take every precaution possible to safeguard your information to eliminate the possibility of any breach of confidentiality. This is explained above in the section, "Confidentiality".

The Database Repository Manager, Col Paul Crawford, is responsible for all de-identified research data stored in the repository. All recipient investigators requesting data from the repository must have approval from the Database Repository Manager and must have a research study approved through a DoD Institutional Review Board (IRB) and the 59th MDW IRB. Only de-identified data (no personal identifiers or information) will be released to recipient investigators, so specific information can't be traced back to the donor of the data. Recipient investigators may only receive limited data sets of de-identified information necessary to conduct their research. Generally, you will not be provided with the results of these research studies using your de-identified data from the repository. Any results would be of unclear value and unknown clinical meaning, since your de-identified data will be combined with other de-identified data from numerous patients used for the study. You cannot request that your de-identified research data be withdrawn from the database repository since we will have no way to identify you. This request may be accomplished by calling the Database Repository Manager at Col Paul Crawford or mailing your request to the following address: Col Paul Crawford, MD, c/o Department of Medical Education, 4700 Las Vegas Blvd North, Nellis AFB, NV 89191.

_____NO: I do not authorize the storage of my de-identified research data for future use in research studies.

_____YES: I authorize the storage of my de-identified research data for future use in research studies.

_____

Signature of Study Participant

BLOOD & TISSUE SAMPLES:

All blood specimens collected will be kept at 99MDG will be handled and disposed of in accordance with federal regulations. Laboratories outside of 99MDG, will not have 99MDG permission to use the samples for any additional research. No other blood and tissue samples will be collected.

CONTACT INFORMATION:

Principal Investigator (PI): The principal investigator or a member of Clinical Investigation Department will be available to answer any questions concerning procedures throughout this study. The Principal Investigator is William Scott, D.O., Maj, USAF, MC, Phone: (702) 653-3298.

Institutional Review Board (IRB): The PI is responsible for safeguarding your rights as a research subject. If you have any questions about your rights as a research subject, research-related injuries, or any other concerns that cannot be addressed by the PI, you can contact the Clinical Investigation Program, 4700 Las Vegas Blvd North, Nellis AFB, NV 89191 or (702) 653-3298. In addition, if you have any comments, questions, concerns or complaints, you may also contact the Chairperson of the 59 MDW IRB, at (210) 916-8251. Or mail to: 59th Medical Wing/ST, 1100 Wilford Hall Loop, Bldg 4430, Lackland AFB, TX 78236-9908 Attn: Authorized Institutional Official. Your consent to participate in this study is given on a voluntary basis. All oral and written information and discussions about this study have been in English, a language in which you are fluent. If you agree to participate in this research sign this section. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction.
- Your consent to participate in this study is given on a voluntary basis.

A signed copy of this form has been given to you.

_____ _____

VOLUNTEER'S SIGNATURE **DATE**

_____

VOLUNTEER'S PRINTED NAME

_____ _____ _____

STUDY STAFF SIGNATURE **DATE** **PHONE NUMBER**

_____

PRINTED NAME OF STUDY STAFF

For Protocol Office Use Only:
FWH20160095H, Scott, ICD, PR 2020

59th MDW INSTITUTIONAL REVIEW BOARD

27 Jul 20
Date ICD Approved by IRB

23 Aug 21
Date ICD Expires

Version: 0514