US Army Research Institute of Environmental Medicine

CONSENT TO PARTICIPATE IN RESEARCH

Title of Protocol: The effects of non-steroidal anti-inflammatory drugs on circulating markers of bone metabolism following plyometric exercise in humans

Principal Investigator: Jeffery S. Staab

Introduction: You are being asked to participate in this research study because you are a young, healthy Soldier or civilian capable of performing strenuous exercise. Your participation in this research is voluntary and you do not have to take part in this research. It is your choice.

The table below summarizes some **key** points to think about. After reading this summary, if you think you might be interested in participating, read the rest of the consent form for more details about the study.

RESEARCH SUMMARY	
Informed Consent	It is important that you understand this research study so that you can make an informed decision. This process is called informed consent. • Please ask questions about anything you do not understand. • Feel free to talk with your family, friends, or others before you decide. • After your questions have been answered, you will be asked if you want to participate. If you agree, you will sign this consent form. • You will be given a copy of this form to keep.
Voluntary Participation	You do not have to take part in this research. It is your choice. You can also choose to stop participating at any time during the study.
Purpose	The purpose of this study is to determine if taking non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Motrin or Advil), celecoxib (Celebrex), or flurbiprofen (Ansaid) affects how your bones and muscles respond and recover from a strenuous bout of exercise.
Duration	You will be in this study for about 5 to 10 weeks.
Procedures	While you are in the study, you will: • On 4 occasions, perform 10 sets of 10 jump squat exercise on a leg press machine, with periodic testing of your maximal strength • Have **32 blood samples** collected from your arm, either by a needle stick or an intravenous (IV) catheter • Have **8 biopsies** taken from your leg muscle before and after the 4 exercise sessions • Eat a study provided breakfast on the 4 jump squat days and not eat again for another approximately 7 hours • Collect all your urine for **6-7** hours on exercise test days in a study provided container

	• Have scans of your body and your bones
Restrictions	• **No** nutritional supplements, alcohol, and nicotine for 5 consecutive days during each of the 4 study weeks • **No** NSAIDs other than those provided to you by the study team for the duration of the study and 4 days after the study • **No** excessive or novel outside exercise during the study weeks • **No** Blood donation within 8 weeks of the study • **No** discontinuation of hormonal contraception
Drugs/Devices	The drug(s) and their maximal daily dosage used in this study are: Ibuprofen (e.g., Motrin, Advil); 800 mg per day Celecoxib (e.g., Celebrex): 200 mg per day Flurbiprofen (e.g., Ansaid): 100 mg per day These NSAIDs are dispensed under the guidance of USARIEM's Office of Medical Support and Oversight (OMSO)
Risks	The **main** risks from being in this study are: • Soreness and/or injury associated with the jump squat exercise • Pain, bruising, discomfort, and/or infection from collecting blood samples and muscle biopsies • Stomach discomfort from taking NSAIDs • Extremely rare risk of developing rhabdomyolysis – a condition of excessive muscle breakdown induced by extreme exercise
Benefits	There are no direct benefits to you for your participation in this research study. However, you participation may benefit future Soldiers by reducing their possibility of injury during training.
Payment	You will be compensated for your participation in this study.
Covid-19 Risk Mitigation	If you agree to participate, you will be asked to follow all COVID-19 risk mitigation procedures in place at USARIEM during the time of data collection. You must be fully vaccinated for COVID-19. You may be asked to wear facemasks and use hand sanitizer or wash your hands during data collection activities (in accord with prevailing recommendations at the time of data collection) and may be asked to wear gloves (i.e., nitrile gloves) during data collection.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to determine if taking commonly used non-steroidal anti-inflammatory drugs (NSAIDs) affects how your bone and muscles respond to a bout of strenuous exercise. Experimental evidence in animal studies suggest bones and muscles may

not adapt to physical training if they were to exercise after taking a NSAID. Research has also demonstrated that Army basic trainees are 5 times more likely to develop a stress fracture if they are prescribed an NSAID during training. Stress fractures are one of the most common injuries in military training, affecting up to 5 percent of men and up to 20 percent of women in these environments. Reducing stress fractures, and thereby reducing lost duty time, is a key objective of the military operational medicine program. Determining the link between NSAIDs and injury development in humans is one primary focus of this study.

WHAT WILL HAPPEN DURING THIS RESEARCH?

If you agree to participate in this research, you will be asked to do the following:

You will first need to be cleared by USARIEMs Office of Medical Support and Oversight (OMSO), to determine your eligibility to participate in the study. This will consist of 1-2 visits in which the medics and doctors will have you provide blood samples, as well as complete a physical. If you are cleared by OMSO to participate, you will complete one week of baseline testing and familiarization, followed by 4 testing weeks in which you will perform strenuous jump squat (plyometric) exercise on one day, followed by a brief day for checking recovery. On the first day of each study week you will take a pill that is either one of the NSAIDs or a placebo (an inactive sugar pill) that has no effect. You will be assigned an order of testing using a random number generator to determine which study drug you get on which week. You will not know what study drug you are taking, nor will the investigators until after the study is over. During each test week, we will measure your strength, soreness, and collect urine and blood samples as well as small samples of muscle tissue. We will provide you a light breakfast on the exercise test day of each week.

A study timeline for the baseline week and the four testing weeks is in Figure 1. All study times are approximate.

<u>BASELINE and FAMILIARIZATION</u>

During the baseline and familiarization week, you will fill out a background questionnaire about your demographics, exercise and injury history as well as a nutritional survey. You will report to a USARIEM laboratory 2 times, in comfortable exercise attire, during that week to complete these baseline tests:

Body Composition and Bone Scans
Your body composition (percent fat, percent lean body weight) and bone density will be measured with a device called a 'Dual-Energy X-ray Absorptiometer (DEXA)' after an overnight fast. You will lie still on your back, on a padded table, while an X-ray scanner moves across your body. This test does not cause any pain and will take about 10 minutes. We will also measure the density and structure of your forearm and shin bones with a device called a 'High Resolution peripheral Quantitative Computed Tomography (HRpQCT).' The scan does not cause any pain or discomfort and is done using a machine with a circular tube that you place your arm or leg into. You hold your arm or leg still for up to 20 minutes while the machine scans your arm or leg in a similar fashion to an x-ray and provides us with a 3 dimensional image of your bones. We will also measure your height and weight.

If you are a female, your urine will be tested before the scans to see if you are pregnant, and your result will be recorded and communicated to you by a female member of the research team. If you are pregnant, you cannot have the scan or participate further in the study.

Vertical Jump
You will be asked to perform 3 jumps after warming up to determine your maximal jump height. Using a device designed to measure vertical jump height, you will first determine your maximal reach height while standing still. After setting the device you will jump from a standing position and reach to the highest degree possible, which will be recorded. You will practice this at least once during the familiarization week and once for record. You will also complete this test three times during each of the four testing weeks. This test should take less the 10 minutes to complete.

Maximal Strength
On the leg press machine, called the plyopress, you will push with your legs against an immovable platform for 5-10 seconds, while a device measures how much force you generate (your muscle (MVC) strength). You will practice this several times before doing it for score. After a brief rest period, we will then measure the maximal amount of weight you can press in the leg machine by having you perform single repetition leg presses while progressively adding in more weight until you cannot perform the exercise anymore, or estimated by the number of repetitions you can press 600 lbs. We will give you 3-5 minutes rest breaks between presses. You will be given the opportunity to practice these tests before testing.

Figure 1. Sample Schedule for Baseline Week.

BASELINE WEEK	Mon	Tue	Wed	Thur	Fri
Approximate time required for baseline/familiarization testing = 2-3 hr/day		Inprocessing			
		Questionnaires			
		DEXA			
		HRpQCT			
		Vert Jump Practice		Vertical Jump	
		Strength Practice		Strength	
		Plyometric Practice		Plyometric Practice	
	*Days may be Mon/Wed or Tue/Thur, or Wed/Fri. Schedule is for example purposes only				

Note: HRpQCT schedule may be adjusted or removed if the machine is not available.

TESTING WEEKS

You will perform 4 exercise test days during this study while wearing comfortable exercise clothing. You will take an NSAID (either ibuprofen, celecoxib, flurbiprofen) or a placebo ("sugar pill") in each test week. Each test week will involve one exercise testing day (Day 1) and one brief follow up day (Day 2, Table 2). You will start the period of restricted activity, supplements, and nicotine the three days prior to Day 1 and continue through Day 2. We will also ask you to limit your physical training to light activities during this time (no running). After the end of Day 2 you will be released from restrictions (other than no outside NSAIDs) but you will need to check in with USARIEM's OMSO so they can assess the healing of the muscle biopsy site. Study staff will ask you daily as to your degree of soreness during the study. Day 1s (exercise day) will be separated by approximately one week or more to allow for recovery. If you are female and not taking hormonal contraceptive, your study weeks will be matched to your menstrual cycle phase.

Table 2. Sample Testing Week Schedule

Iterations	Day 1 - EXERCISE					Day 2 - RECOVERY				
Clock	Dose	Urine	Blood	Exercise	Ratings	Dose	Urine	Blood	Exercise	Ratings
0600		Spot	AM	BIOPSY	Soreness					
	Dose 1									
0700				Vert Jump						
				MVC Strength						
0800										
			Pre/Post	Plyometric Exer						
0900		6.5 hr collection	+15, +30							
1000			+60							
1100			+120							
1200				BIOPSY	Soreness				BIOPSY Check	Soreness
			+240	Vert Jump					Vert Jump	
1300				MVC Strength					MVC Strength	
1400										

Dietary Monitoring, Activity Monitoring & Controlled Diet
You will fill out food records and log your daily activities for 3 days prior to each study week to ensure adequate dietary control as well as adherence to a light exercise/activity program.

You will need to fast overnight (about 8 hours) before Day 1 of each of the study iterations. Upon taking your NSAID (or placebo), we will provide you a light breakfast. This breakfast will be identical for each testing week. You will not be allowed to eat for the remainder of Day 1 until testing is complete (at approximately 1300), at which time you will be released to have lunch on your own.

You will perform the following tests/procedures during each of the 4 testing weeks:

Urine Collection
On Day 1 of each study week, we will ask you to provide a small urine sample at 0600 h and then to collect all your urine for the following 6-7 hours. We will provide the collection container for collection. If you are a female, we will also screen you for pregnancy using the spot urine sample. A female staff member will record and communicate the results to you; you are not allowed to participate further if you are pregnant.

Blood Draws
On the morning of Day 1 of each testing week, a trained technician, using an germ-free technique, will place a flexible plastic needle called an IV catheter in your arm or hand. Sterile

saline (salt water) will slowly be infused while the catheter is in place to keep the IV open for us to draw blood. This IV catheter will remain in place for the next 6.5 h. We may use a venipuncture technique (a straight needle method, similar to giving blood sample during a medical exam) if the technician is unable to successfully place the catheter. You may refuse repeated attempts for blood draw.

We will collect blood samples using the catheter to determine information about your nutrition, metabolism, muscle response, bone metabolism, hydration, and your recovery. This will be collected at several time points during your exercise day. See Table 2 for approximate collection times. There are 32 total planned collection time points across all study weeks. We plan to collect about 16.2 fluid ounces or about 2.0 cups over the duration of the entire study.

Muscle Biopsy
Before and after each exercise session, we will take a small muscle biopsy from your leg muscles. There will be a total of 8 biopsies and we will alternate which leg we take it from each time. That is, you will have a biopsy taken from one leg before you exercise and one taken a few hours after you exercise from the other leg (See Table 2).

The muscle biopsy will be done while you are awake. After cleaning the skin with a medical cleaning solution and using a local anesthetic (e.g., lidocaine or similar injection which will numb the skin), a trained investigator will make a small cut (1 centimeter) in the skin and introduce a needle under the skin to remove a small piece of muscle tissue (about the size of an un-popped popcorn kernel). More than one needle insertion may be needed to obtain a large enough specimen.

During the biopsy, there is usually minor discomfort. You will feel some pressure (similar to a "Charlie horse") or tugging. This should not be painful. The anesthetic may burn or sting when injected before the area becomes numb. After the anesthetic wears off, the area may be sore for about a week. The cut will be covered with a sterile dressing and an elastic bandage for 24 hours for proper healing. You will receive instruction for wound care. We will examine the site approximately 24 hours after the biopsy and USARIEM's OMSO will examine it at approximately 48 hours after to ensure proper healing.

Soreness Rating
You will fill out a survey for evaluating your pain/soreness three times during each testing week - twice on Day 1, after muscle biopsies and once on the recovery day after biopsy check.

NSAID Dosing
At approximately 0630 of Day 1 of each testing week, you will be provided a coded NSAID capsule and ingest under supervision of USARIEM OMSO. The NSAID dose will be either ibuprofen (800 mg), celecoxib (200 mg), flurbiprofen (100 mg), or an inactive sugar pill. These NSAID doses are within the recommended single dose amounts for each drug. You will not know, nor will the study staff know what NSAID (or in active sugar pill) you are taking until after the study is completed. We ask you do not discuss the appearance of the pills with any other participants or study team members; however, you will fill out a quick survey at the end of Day 1 to record what pill you think you consumed.

Vertical Jump & Muscle Strength
We will test you for vertical jump and muscle strength three times at each study week as described previously, twice on Day 1 and once on the recovery day after biopsy check.

Jump Squats (Plyometric Jumping on the Plyopress)
On Day 1 of each testing week, you will perform 10 sets of 10 jumps on the plyopress set to a weight equal to 40 percent of your maximum press. Figure 2 shows how the jumps are performed. You will start the exercise with your knee slightly bend and your feet shoulder width apart. Upon a verbal command, you will slightly bend your knees, and then forcefully jump from the force platform. While performing the exercise, make sure your knees do not bend over the toes and maintaining a tempo of approximately 1 second to 1 second for ascending and descending phases of the jumps. We may use a metronome to aid you for proper pacing. You will get a 2-minute rest break between sets.

If you have trouble maintaining proper jumping form or are unable to complete all 10 jumps in a set, the staff will instruct you to terminate immediately the rest of the set. The set will still count towards the 10 sets if you do not perform all 10 jumps. The weight will be lowered about 20 percent for all subsequent sets. If you still cannot maintain proper form, the weight will be further lowered about 20 percent each time until all the remaining sets are completed.

We will ask you to wear a heart rate monitor (chest strap device) and will periodically ask you to rate how hard you feel you are working during the test. You will be allowed as much water as you want during this test. You will practice the jump squats at baseline and familiarization week.

Figure 2. Plyopress Plyometric Exercise.

HOW LONG WILL I BE IN THE STUDY?

You can expect to be in this study a minimum of 5 weeks and as many as 10 weeks or more depending on scheduling. It is possible unplanned circumstances such as equipment availability, staffing scheduling, weather events, participant injury or illness may delay your completion of the study.

WHAT PRECAUTIONS DO I NEED TO TAKE?

We will ask you to limit your exercise to light activity in the three days prior to Day 1 and through the end of Day 2. You will be asked to refrain from alcohol consumption, nutritional supplements, smoking or ingesting other forms of nicotine starting 3 days prior to Day 1 and continuing through Day 2 of each week. You will not be allowed to consume anti-inflammatory or pain-relieving medication during the course of the study or 4 days after the study, other than what is provided to you or if medically advised to do so. Since we are collecting repeated blood samples, we ask that do you not donate blood within 8 weeks of the study. If you are a female on hormonal birth control, we ask that you continue it throughout the course of the study.

HOW MANY PEOPLE WILL BE IN THE STUDY?

12 people are expected to complete this study.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Source of Risk	Risk(s)	How We Will Minimize
Jump Squat Exercise (Plyopress)	Cardiovascular risk Muscle soreness, Musculoskeletal injury, Skin blisters and chafing, Rhabdomyolysis	• Monitored by cardiopulmonary resuscitation (CPR) certified study staff • Familiarization training • Wear comfortable shoes and socks • Foam padding available for comfort • Testing done at room temperature and drinking water will be available • Study staff will instruct you to look out for dark or bloody urine • Study staff will query you daily as to your degree of soreness
Muscle Biopsy	Feeling faint or passing out, panic attack, bleeding, swelling, infection, nerve damage, bleeding, bruising, pain, mild scarring at incision site	• Procedure performed by trained study team members • Use of sterile procedures • We will numb the incision site with local anesthetic, such as lidocaine or similar numbing medication approved by OMSO • You will receive biopsy care instructions and a qualified researcher will watch for any sign of infection, bleeding or bruising.
Lidocaine (or similar anesthetic) Injection	Slight pain at the site of injection; Rare: allergic reaction; Unlikely, but possible: dizziness, confusion, shakiness, visual changes, nausea, and unusually slow heartbeat	• Screen for allergies • Medication, such as an “Epi-Pen” used to counteract allergic reaction will be available.
Vertical Jump	Musculoskeletal injury, joint discomfort or pain	• Use trained technicians • Warm up jumps • Make sure jump area is free of obstructions
Maximal Strength	Cardiovascular risk Muscle soreness, Musculoskeletal injury,	• Familiarization training • Foam padding will be available for comfort • Proper warm up and rest between attempts • Monitors by CPR certified staff

Venous Catheter/Venipuncture	Pain, soreness, bruising, infection at insertion site, scarring at insertion site, feel dizzy or faint	• Use trained technicians • Germ-free technique • Look for sign of infection • Immediately covering and applying pressure to the insertion site after removal of catheter • lie down or recline, put your head between your knees if feel dizzy
NSAID Dosing	Stomach discomfort, nausea, heartburn, headaches, and ringing in ears allergic reaction, kidney and liver problems increased risk of cardiac problems	• We will exclude those with known adverse or allergic reaction to NSAIDs or know stomach problems • Medication to counteract allergic reaction will be available
Bone and Body Composition Scans	X-ray exposure	• Total dose less than a set of chest X-rays • Quality check before use • Females will have pregnancy test prior to scans
Heart rate monitoring	Skin irritation/chafing	• Study staff will monitor your skin for irritation • Medical staff is available to treat you in the event of skin irritation

WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS RESEARCH?

There are no direct benefits from participating in this research study. Your participation may benefit future Soldiers by reducing their risk of possible injury during training.

WHAT IF UNEXPECTED INFORMATION IS LEARNED ABOUT MY HEALTH?

There is potential for unexpected health information to be found from your medical clearance and screening for this study, and from DEXA and HRpQCT scans conducted during study that may provide information leading to a medical concern. If this happens, the PI would provide this information to you and advise you as to how to seek additional medical care.

WILL RESEARCH RESULTS BE SHARED WITH ME?

If you are interested, we will share with you results that are readily available at the time if they do not potentially affect your performance, such as DEXA and strength/power scores. Other results, such as your jump performance scores, will not be shared until study completion. Many of the clinically relevant results will not be shared with you because biological samples will not be analyzed until after you finish the study.

WHAT ARE MY OTHER OPTIONS IF I DO NOT PARTICIPATE IN THIS STUDY?

The only alternative is not to participate in the study.

WILL I HAVE TO PAY FOR ANYTHING IF I TAKE PART IN THIS RESEARCH?

There are no anticipated costs for this study. We will not reimburse you for expenses paid (travel, etc.) related to participation in the study.

WILL I BE PAID TO TAKE PART IN THIS RESEARCH?

You will be paid $35 for each successful blood draw completed during this study. There are 32 blood draws for the total study period, so you can earn up to $1120 if you complete the study. No compensation will be offered for the blood draw performed by OMSO as part of the medical clearance. If you do not complete the study, you will be paid for the number of blood draws that you have successfully completed. Payment will be processed within two weeks of study completion/end and you will receive payment within approximately ten weeks of study completion/end.

Your social security number (SSN) and bank account information will be needed to process your direct deposit payment, as required by law. This information will be carefully protected. Total payments of $600 or more within one calendar year will be reported by the Defense Finance and Accounting Service to the Internal Revenue Service (IRS). This may require you to claim the compensation that you receive for participation in this study as taxable income.

WHAT HAPPENS IF I AM INJURED AS A RESULT OF TAKING PART IN THIS RESEARCH?

If at any time you believe you have suffered an injury or illness as a result of participating in this research, please contact Jeffery S. Staab, Jeffery.s.staab.civ@mail.mil, 508-206-2393.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are entitled to medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary.

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are entitled to care for your injury at DoD hospitals or clinics, but care for your injury may be limited to a given time period, and your insurance may be billed. It cannot be determined in advance which DoD hospital or clinic will provide care. If you obtain care for research-related injuries outside of a DoD hospital or clinic, you or your insurance will be responsible for medical expenses.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: Transportation to and from hospitals or clinics will not be provided. No reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights. If you believe you have sustained a research-related injury, please contact the Principal Investigator (PI). If you have any questions, please contact the PI.

HOW WILL YOU PROTECT MY PRIVACY AND THE CONFIDENTIALITY OF RECORDS ABOUT ME?

The principal investigator will keep records of your participation in the research. To protect your privacy, any of your research-related records including blood samples will be labeled or “coded” with an assigned research participant number that will not include your name or social security

number. The principal investigator or study coordinator will keep the link between your participant number and your research records in a locked office and in a password-protected study computer. The principal investigator and study coordinator are the only people who will be able to match your research participant number with any of your personal identifying information. Financial information, such as social security number and bank account that required for direct deposit of compensation for research, will be kept in a separate locked file cabinet from the research records. Only the principal investigator and project coordinator will have access to this cabinet. These records will be destroyed upon project completion and compensation is complete.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity to others. If photographs of you will be used for educational purposes, your identity will be protected or disguised by blurring or darkening your face, or we will have written permission to use your photograph by having you complete an "Audio and Visual release form"

Authorized representatives of the following groups may need to review your research and/or medical records as part of their responsibilities to protect research participants:

- U.S. Army Medical Research & Development Command Institutional Review Board responsible for review and oversight of human research
- DoD and other Federal offices charged with regulatory oversight of human research
- USARIEM Office of Research Quality and Compliance

Once information that personally identifies you is removed from your data or specimens, then your de-identified data or specimens may be used for future research studies or given to other researchers for future research studies without your permission to do so.

Complete confidentiality cannot be promised for military personnel, because information bearing on your health may be reported to appropriate medical or command authorities.

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.

WHAT IF I DECIDE NOT TO PARTICIPATE IN THIS RESEARCH?

It is your choice whether you want to participate in this research. You can choose not to be in the study now without any penalty or loss of benefits to which you are entitled.

If you decide to participate, you can stop taking part in this research at any time without any penalty or loss of benefits to which you are entitled. Deciding not to participate now or withdrawing at a later time does not harm, or in any way affect, your future relationships with the U.S. Army Research Institute of Environmental Medicine.

If you decide to withdraw, you may do so by notifying the PI or research staff verbally or in writing. If you decide to withdraw, we will continue to use your data and specimens collected to date. If you do not complete the entire study, you will be compensated for the number of blood draws you did complete.

WHAT COULD END MY PARTICIPATION IN THE RESEARCH?

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. The investigator will make the decision and let you know if it is not possible for you to continue. Your taking part in the study may be stopped without your consent if it is determined by the investigator that remaining in the study might be dangerous or harmful to you or if unforeseen circumstances warrant postponement or cancellation of the study. We may have to end your participation if you take NSAIDs other than the study-provided ones during the course of the study or if you fail to follow study-related restrictions.

WHAT IF ANY NEW INFORMATION IS FOUND OUT?

During the course of the research, the investigators will tell you of any new findings that might cause you to change your mind about continuing in the study. If you receive any new information, the investigators will obtain your consent to continue participating in this study.

WHO SHOULD I CALL IF I HAVE QUESTIONS OR CONCERNS ABOUT THIS RESEARCH?

If you have questions about the research at any time, you should contact Jeffery S. Staab, Jeffery.s.staab.civ@mail.mil, 508-206-2393.

If you have questions regarding your rights as a research participant, you may contact the HQ USAMRDC IRB Office at 301-619-6240 or by email to usarmy.detrick.medcom-usamrmc.other.irb-office@mail.mil, or the USARIEM Human Protections Director at 508-206-2371 or by email to at usarmy.natick.medcom-usariem.mbx.usariem-rqc-protocol@mail.mil .

By signing below, I agree that I have been provided time to read the information describing the research study in this 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.

SIGNATURE OF RESEARCH PARTICIPANT

Printed Name of Participant

Signature of Participant | Date

CONSENT DISCUSSION CONDUCTED BY:

Printed Name	Date Received