

**FORM D – INFORMED CONSENT DOCUMENT**

<b>Volunteer Name:</b>	
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99<sup>th</sup> Medical Group**INFORMED CONSENT DOCUMENT**

<b>Title of Protocol:</b>	Acupuncture for vasectomy pre-procedural anxiety and pain control in the primary care setting: A randomized comparative effectiveness trial.
<b>FWH #:</b>	FWH20190062H

**KEY INFORMATION ABOUT STUDY PARTICIPATION:** You are being asked to take part in a research study. Research studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make a decision. The purpose of this study is to compare ear and body acupuncture versus clinic pre-vasectomy medications to determine which has better outcomes at improving pre-procedural anxiety and procedural pain relief and medication usage in adult male patients following vasectomy. Your participation in this study would consist of one screening visit to review your eligibility for the study. Once you are deemed eligible to participate, you will be randomized (like flipping a coin) into either the intervention or control group. The intervention group will receive body acupuncture plus standard of care post-procedure ibuprofen for pain control. Participants who tolerate the auricular needles will be offered replacement with ear acupuncture needles for continued pain management. The control group will receive the clinic standardized pre-procedure medications that includes diazepam, oxycodone/acetaminophen plus standard of care post-procedure ibuprofen for pain control. Both groups will have study visits pre and post procedure (4 contacts total the day of your vasectomy), and one visit 2 weeks after your vasectomy which can be completed either via Survey Monkey or Google forms or in person. During the visits, both groups will be asked to complete a few questionnaires regarding pain and anxiety, satisfaction, and post-procedure medications taken.

Risks and side effects related to your participation in this study include:

**ACUPUNCTURE (Group 1):****LIKELY: Likely and not serious:**

- Pain
- Bleeding

**LESS LIKELY: Less Likely and not serious:**

- Infection
- Muscle cramp
- Muscle spasm

**RARE AND NOT SERIOUS:**

- Needle Shock (extremely rare response which causes your blood vessels to dilate and your blood pressure to suddenly drop. Usually people quickly recover without lasting effects when the needles are removed and you are placed in a supine position with your legs slightly raised so that your blood begins to flow back to the brain and heart)

\*Those people exhibiting symptoms of needle shock will immediately have the needles removed and the procedure completed as usual.

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**DIAZEPAM, OXYCODONE/ACETAMINOPHEN (Group 2-pre-procedure):**

**LIKELY: Likely and not serious:**

- Lightheadedness
- Dizziness
- Sedation
- Dysphoria (state of unease)
- Nausea/vomiting

**IBUPROFEN (Group 1 & 2-post-procedure):**

**LIKELY: Likely and not serious:**

- Indigestion
- Nausea
- Abdominal pain

**RARE AND SERIOUS:**

- Gastrointestinal bleeding/ulcer

There is also a risk of accidental breach of confidentiality.

The possible benefit of your participating in this study is that you may experience an improvement in pain and physical function in both the treatment and control groups. However, there is no guarantee or promise that you will receive any personal benefit from this study. We hope the information learned from this study may help future patients. You can still receive standard of care treatment for your vasectomy pain without participating in this study. The only reason these interventions are considered "research" for this study is because we are randomizing participants to groups. You can choose to receive both options as part of standard of care in the family medicine residency.

**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 your name in more than one place in this document, as needed. Please take time to review this information carefully. You should talk to the researchers and ask any questions you may have about the study. You may also wish to talk to 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 purpose and procedures of the study, including risks and possible benefits to you. If you are taking part in another research study, please tell the researchers or study staff.

**VOLUNTARY PARTICIPATION:** Your participation in this study is completely voluntary. If you choose not to participate in this research study or leave before the study is completed, your decision will not affect your eligibility for care or any other benefits to which you are entitled as a DoD beneficiary. 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.

**PRINCIPAL INVESTIGATOR:**

The Principal Investigator (PI) is the researcher directing this study and is responsible for protecting your rights, safety and

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welfare as a participant in the research. The PI for this study is:

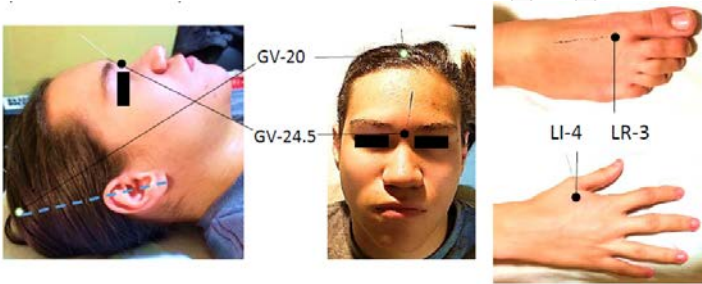
PI Name and Degrees:	Rank:	Branch:	Department and Base:
Matthew Snyder, DO	LtCol	USAF	Family Medicine Residency, 99MDG

You are being asked to consider participation in a research study acupuncture in male adult patients following vasectomy. The purpose of this study is to compare ear and body acupuncture versus clinic pre-vasectomy medications to determine which has better outcomes at improving pre-procedural anxiety and procedural pain relief and medication usage in adult male patients following their vasectomy procedure.

The type of acupuncture being used in this study is routinely done as part of another standard of care procedure in our Family Medicine and Acupuncture Clinics both in conjunction with a standard of care and by itself. However, for this study, the acupuncture is deemed a research-related intervention.

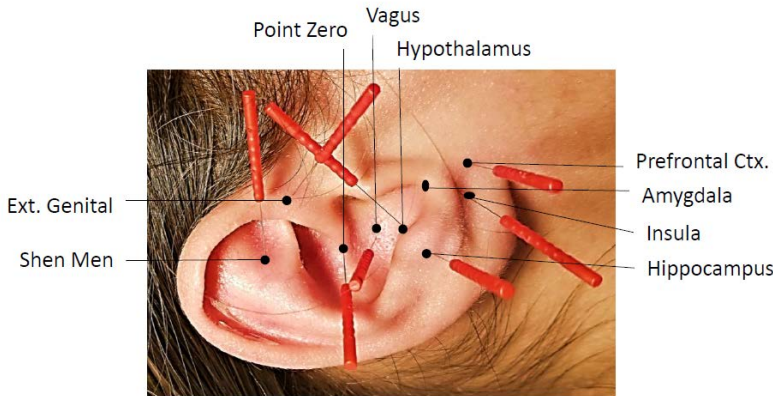
Acupuncture is a method where doctors place small needles into certain points in your body to stimulate a reduction in pain. Acupuncture is a form of alternative medicine in which certain points on the body, when stimulated, are believed to correspond with specific areas of the body. The purpose of acupuncture is to balance the flow of the body's energy, which is supposed to release chemicals to targeted areas of the body to achieve results (for example, these points are used to reduce pain associated with vasectomy).

Body acupuncture points:

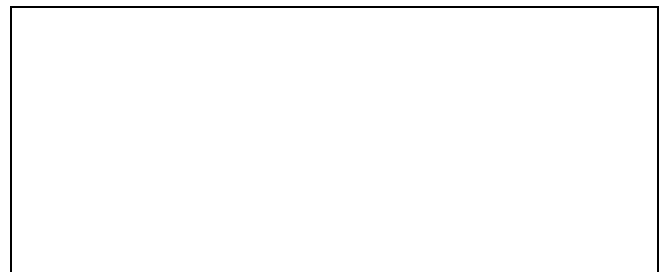


Print Sign

Ear Acupuncture Point:



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This study will enroll approximately 85 subjects overall.

**PROCEDURES:** If you decide to take part in this research study, you will be asked to sign this consent form.

**Screening** – Some exams, tests, and/or procedures may be done after you sign this consent to participate. This screening is done to find out if you can continue in the study (screening procedures). We may be able to use the results of some exams, tests, and/or procedures you completed before enrolling in this study to avoid any additional screening tests. You will be told which results we will obtain and which procedures will not have to be repeated. Any procedure described below as “standard care” would be done even if you do not take part in this research study. All of the research-related procedures for the screening visit will add approximately 20 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. All procedures are research-related unless otherwise stated as standard of care:

**Screening/Pre-Procedure Visit:**

- Obtain your signed Informed Consent Document and HIPAA Authorization.
- Review your past medical history.
- We will record your date of birth, age, gender, race, ethnicity, DoD ID number, over-the-counter and prescription medication use, current email address (to be used for scheduling), height, weight, history of prior injury to the genital region.

**Study Procedures:** As a participant, you will undergo the following procedures.

**Assignment to Research-Related Study Groups:** When it is determined that you are eligible for the study, you will be assigned by chance (like flipping a coin) to 1 of 2 study groups:

- **Group 1:** Acupuncture involving the Koffman protocol (body acupuncture). Subjects who tolerate the body acupuncture needles will be offered replacement with auricular (ear) ASP acupuncture needles for continued post-procedure pain management.
- **Group 2:** The clinic standardized pre-procedure medications alone prior to the procedure.

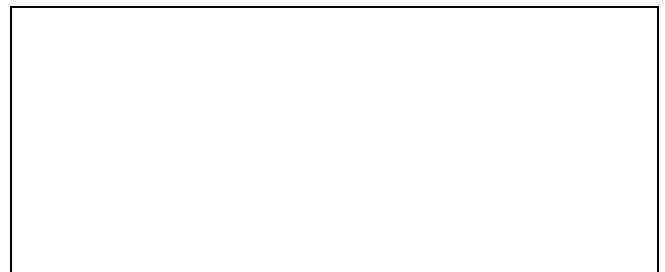
**Pre-procedure (before study intervention):**

- We will provide you the clinic standardized pre-procedural vasectomy counseling and exam. (standard of care)
- You will complete the Hospital Anxiety Scale.
- You will complete the Defense and Veterans Pain Rating Scale (DVPRS).
- You will be given a study diary to document the number of times you used post-procedure medications, as well as, reminded to complete the DVPRS every day for the 2 weeks following the procedure. You will be informed that you have the option to either return it in paper format or input it into Survey Monkey or google forms at the last visit.

**Study Intervention:**

- You will receive treatment according to the group that you were randomized into.

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**Post-procedure (after study intervention but BEFORE the vasectomy):**

- You will complete the Hospital Anxiety Scale.

**Post-procedure (after the vasectomy is completed):**

- You will complete the Defense and Veterans Pain Rating Scale (DVPRS).
- **For the acupuncture group only:** If you tolerate the body acupuncture needles, you will be offered replacement with ASP acupuncture needles for continued post-procedure pain management. If you have the auricular (ear) ASP acupuncture needles placed, you will be instructed to have no heavy meals, no excessive hot or cold foods, no heavy exercise or intercourse, and no alcohol for 24 hours. The needles will fall out on their own within about one week.

**2 Week Follow up Visit (2 weeks from Post-Op Check Visit):**

- You will complete a questionnaire via paper, Survey Monkey, or Google Forms (whichever is most convenient for the patient) that includes patient satisfaction, the study diary, and the date they returned to normal duties.

**RISKS OR DISCOMFORTS:** There are risks to taking part in this research study. One risk is that you may have side effects while on the study. Some side effects are more likely than others to occur. You may experience a certain side effect many times, a few times, or only once or twice, if at all. Everyone taking part in this study will be watched carefully for any side effects. However, the study doctors do not 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 research drug, intervention or procedure 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 this study.

**ACUPUNCTURE (Group 1):****LIKELY: Likely and not serious:**

- Pain
- Bleeding

**LESS LIKELY: Less Likely and not serious:**

- Infection
- Muscle cramp
- Muscle spasm

**RARE AND NOT SERIOUS:**

- Needle Shock (extremely rare response which causes the subjects blood vessels to dilate and their blood pressure to suddenly drop. Usually subjects quickly recover without lasting effects when the needles are removed and the patient is placed in a supine position with their legs slightly raised so that they blood begins to flow back to the brain and heart)

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**DIAZEPAM, OXYCODONE/ACETAMINOPHEN (Group 2-pre-procedure):**

**LIKELY: Likely and not serious:**

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- Dizziness
- Sedation
- Dysphoria (state of unease)
- Nausea/vomiting

**IBUPROFEN (Group 1 & 2-post-procedure):**

**LIKELY: Likely and not serious:**

- Indigestion
- Nausea
- Abdominal pain

**RARE AND SERIOUS:**

- Gastrointestinal bleeding/ulcer

**Rare and Serious:**

- There may be a risk of an accidental breach of confidentiality

**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 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.

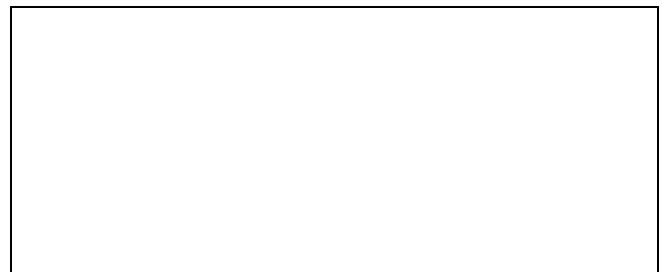
**BENEFITS:** The possible benefit of your participating in this study is that you may experience an improvement in pain and physical function in both the treatment and control groups. However, there is no guarantee or promise that you will receive any personal benefit from this study. We hope the information learned from this study may help future patients.

**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 appointments, beyond any scheduled standard of care appointments. 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.

**POTENTIALLY BENEFICIAL ALTERNATIVES TO STUDY PROCEDURES OR INTERVENTIONS:** You can still receive standard of care treatment for your vasectomy pain without participating in this study. The only reason these interventions are considered “research” for this study is because we are randomizing participants to groups. You can choose to receive both

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Acupuncture for vasectomy pre-procedural anxiety and pain control in the primary care setting: A randomized comparative effectiveness trial.

options as part of standard of care in the family medicine residency. You also have the option not to participate in the study.

**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.

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 the generalizable knowledge of the medical science community. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the Air Force, the DoD, other government agencies that oversee human research and the 59 MDW Institutional Review Board.

A copy of this consent will be stored by the investigator in a locked cabinet in a locked room, as part of your research record. Information collected on this study about you that represents standard care and results of tests run by accredited laboratories will be placed in your medical record. Your medical record will be annotated to reflect you are participating in a research study for each visit because this study involves an intervention that is for research purposes only. All information about you collected on this study will be kept in an electronic database, which will be double password-protected, firewall-protected and access-restricted to people involved in this study. As soon as possible, any link between your identity and the research information will be destroyed which means research information about you will be permanently de-identified. Personal identifying information will be destroyed no later than at the closure of the study. 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 in contacting the 59 MDW Privacy Office for assistance.

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

**ENTITLEMENT TO CARE:** If you believe that you have been harmed, notify the researchers as soon as possible. You may also need to tell your regular doctors. If you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may also contact the Mike O'Callaghan Military Medical Center Human Subject Research Protections Point of Contact, (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.

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**PROTECTED HEALTH INFORMATION (PHI) AND PERSONAL IDENTIFYING INFORMATION (PII) DATA:** All de-identified research data will be kept at the Mike O'Callaghan Military Medical Center, Department of Family Medicine Residency and will be handled and disposed of in accordance with federal regulations. No unauthorized individual or agency outside of the 99MDG will have access to this database without permission of the "Nellis Acupuncture Research Data Repository (FWH20140048H)", Manager Col Paul Crawford and the Wilford Hall Ambulatory Surgery Center (WHASC) 59<sup>th</sup> 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. Your stored de-identified research data will be information such as gender, age, height/weight, medical history, and laboratory tests. 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 59<sup>th</sup> MDW IRB. Only de-identified data (no personal identifiers or information) will be released to recipient investigators, so specific information cannot 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 will not be able to request that your de-identified research data be withdrawn from the database repository since we will have no way of identify whom the data belongs to. If you have any questions, you can contact 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.

Choose one:

- NO: I do not authorize the storage of my de-identified research data in this repository.
- YES: I authorize the storage of my de-identified research data in this repository.

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Signature of Study Participant

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**CONTACT INFORMATION:**

**\*\*In the event of an emergency, dial "911" or immediately seek assistance at your nearest emergency room.\*\***

Principal Investigator (PI): The principal investigator and alternate member of research staff will be available to answer any questions concerning procedures throughout this study.

Title	Name	Duty Phone	After-Hours Phone
Principal Investigator	Matthew Snyder, DO, LtCol	(702) 653-3298	(702) 349-0452

Institutional Review Board (IRB): The 59 MDW Institutional Review Board (IRB), the 59 MDW committee that reviews research on human subjects, will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer at 210-292-4683. You can contact the IRB by calling the Chairperson of the 59 MDW IRB at 210-916-8251, or by mail to IRB at 59 MDW/STC, 1100 Wilford Hall Loop, Bldg 4430, JBSA Lackland, Texas 78236. 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 also contact the Mike O'Callaghan Military Medical Center Human Subject Research Protections Point of Contact, (702) 653-3298. 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 study, please 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 for your records.

\_\_\_\_\_  
**VOLUNTEER'S SIGNATURE**

\_\_\_\_\_  
**DATE**

\_\_\_\_\_  
**VOLUNTEER'S PRINTED NAME**

\_\_\_\_\_  
**ADVISING STUDY STAFF SIGNATURE**

\_\_\_\_\_  
**DATE**

\_\_\_\_\_  
**PRINTED NAME OF ADVISING STUDY STAFF**

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