FORM D – INFORMED CONSENT DOCUMENT

Volunteer Name:	

375th Medical Group/99th Medical Group
INFORMED CONSENT DOCUMENT

Title of Protocol:	A Comparison of Scar Infiltration, Scar Deactivation, and Standard of care for the Treatment of Chronic, Post-Surgical Pain after Cesarean Section in the Primary Care Setting: A comparative effectiveness trial.
FWH #:	FWH20190005H

KEY INFORMATION ABOUT STUDY PARTICIPATION: You are being asked to consider participation because you are a DoD beneficiary aged 18 years or older and have pain related to your Cesarean Section Scar (C-Section Scar). The purpose of this study is to compare whether an injection of lidocaine or receiving acupuncture is more effective in reducing pain in women with chronic pain related to the site of incision after C-Section compared to standard of care physical therapy. Once you are deemed eligible to participate, you will be randomized (like flipping a coin) into 1 of 3 groups. Group 1 will receive acupuncture needles inserted in the area around your C-section scar and remain in place for a duration of 20 minutes. Group 2 will receive a Lidocaine injection into the areas around your C-section scar tissue. Group 3 will receive standard of care physical therapy. Both groups will be asked some questions and asked to complete a few questionnaires at baseline, 4 weeks, 8 weeks, 16 weeks, and 20 weeks. The risks associated with this study include an accidental breach of confidentiality. Additionally for the acupuncture group the risks also include pain, bleeding from the acupuncture needles.

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

PI Name and Degrees:	Rank:	Branch:	Department and Base:
Jennifer Loomis, DO	Capt	USAF	375th MDG/Scott AFB O'Fallon Family Medicine Residency Clinic located at 3 St. Elizabeth's Blvd, Suite 4000, O'Fallon, IL

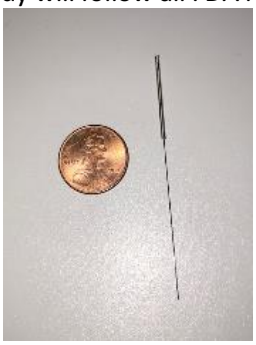
Office of Clinical Research Support Use Only:
FWH20190005H, ICD, Loomis, NS

PURPOSE OF THIS STUDY (Why is this study being done?)**:** You are being asked to consider participation because you are a DoD beneficiary aged 18 years or older and have pain related to your Cesarean Section Scar (C-Section Scar). The purpose of this study is to compare whether an injection of lidocaine or receiving acupuncture is more effective in reducing pain in women with chronic pain related to the site of incision after C-Section compared to standard of care physical therapy.

Lidocaine Injection: Lidocaine is used to relieve pain and numb the skin. Lidocaine will be injected into the areas around your C-section scar tissue, if you are randomized to this treatment group.

Acupuncture: Acupuncture needles will be inserted in the area around your C-section scar and remain in place for a duration of 20 minutes, if you are randomized to this treatment group.

Acupuncture is a method where doctors place small needles (see figure below) 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 c-scar pain). Landmarks on the body are easily identified and no equipment, other than the needles. The needles being used stay in place during your treatment and are then removed prior to the end of your appointment. The acupuncture needles used in this study are exempt from Food & Drug Administration (FDA) clearance or approval but the FDA has published safeguards for their use. This study will follow all FDA requirements for the safe use of these devices.



Standard of Care: Using the McKenzie protocol, which is a method used in routine physical therapy, if you are randomized into this treatment group.

The McKenzie protocol is a form of standard of care physical therapy in which the physical therapist tries to find a cause and effect relationship between the positions the patient usually assumes while sitting, standing, or moving, and the location of pain because of those positions or activities. The therapeutic approach requires a patient to move through a series of activities and test movement to gauge the patient's pain response. The approach then uses that information to develop an exercise program designed to centralize or alleviate the pain.

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 up to 4 visits with the study staff.

Office of Clinical Research Support Use Only:
FWH20190005H, ICD, Loomis, NS

This study will enroll approximately 60 subjects overall, with approximately 30 subjects at Scott AFB and 30 subjects at Nellis AFB, over a period of five years.

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 approximately 4 outpatient visits with Capt Jennifer Loomis, the Principal Investigator (PI), or study staff at Scott AFB or with Col Paul Crawford (Nellis PI) or study staff.

SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY: 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:

- 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, current email address, height, weight, obstetrical history, history of relevant pain and interventions.
- We will instruct you to discontinue any current acupuncture treatment that you are receiving.
- If you are active duty, we will also ask:
  - Have you or are you currently on a fitness restriction this condition.
  - If so, what are/were the dates of the restriction?

Randomization: You will be randomized (like flipping a coin) into one of three research-related treatment groups:
- Group 1: Acupuncture needles will be inserted in the area around your C-section scar and remain in place for a duration of 20 minutes.
- Group 2: Lidocaine will be injected into the areas around your C-section scar tissue.
- Group 3: Physical therapy utilizing the McKenzie protocol (standard of care)

Visit 1:

Group 1: Acupuncture Needles:
- We will ask if you have any changes to your medication list.
- We will weigh you.
- We will ask you what your expectations are regarding acupunctures effectiveness for chronic, post-surgical pain related to low transverse Cesarean Section.
- We will ask you to complete the following once before you receive acupuncture treatment and once after you receive acupuncture treatment for a total of 2 times during this visit:
  - You will be asked to complete the Defense and Veterans Pain Rating Scale (DVPRS)
  - We will instruct you to mark general area of your scar on pictures provided on the Patient and Observer Scar Assessment Score (POSAS) Patient Scale form.

Office of Clinical Research Support Use Only:
FWH20190005H, ICD, Loomis, NS

Group 2: Lidocaine Injection:

- We will ask if you have any changes to your medication list.
- We will weigh you.
- We will ask you what your expectations are regarding the lidocaine injections effectiveness for chronic, post-surgical pain related to low transverse Cesarean Section.
- We will ask you to complete the following once before you receive the lidocaine injection and once after you receive the lidocaine injection for a total of 2 times during this visit:
  - You will be asked to complete the DVPRS
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

Group 3: Physical Therapy:

- We will ask if you have any changes to your medication list.
- We will weigh you.
- We will ask you what your expectations are regarding physical therapy's effectiveness for chronic, post-surgical pain related to low transverse Cesarean Section.
- You will be given a study diary and instructed to track the dates and duration of your physical therapy treatments
- We will ask you to complete the following one time during this visit:
  - You will be asked to complete the DVPRS
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

Visit 2 (4 weeks after visit 1):

Group 1: Acupuncture Needles:

- We will ask if you have any changes to your medication list.
- We will weigh you.
- We will ask you to complete the following once before you receive acupuncture treatment and once after you receive acupuncture treatment for a total of 2 times during this visit:
  - You will be asked to complete the DVPRS
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

Group 2: Lidocaine Injection:

- We will ask if you have any changes to your medication list.
- We will weigh you.
- We will ask you to complete the following once before you receive the lidocaine injection and once after you receive the lidocaine injection for a total of 2 times during this visit:
  - You will be asked to complete the DVPRS
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

Group 3: Physical Therapy:

- We will ask if you have any changes to your medication list.
- We will weigh you.

Office of Clinical Research Support Use Only:
FWH20190005H, ICD, Loomis, NS

- We will review your study diary and document the dates and duration of your physical therapy treatments.
- We will ask you to complete the following one time during this visit:
  - You will be asked to complete the DVPRS.
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

Visit 3 (8 weeks after visit 1):

Group 1: Acupuncture Needles:

- We will ask if you have any changes to your medication list.
- We will weigh you.
- We will ask you to complete the following once before you receive acupuncture treatment and once after you receive acupuncture treatment for a total of 2 times during this visit:
  - You will be asked to complete the DVPRS
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

Group 2: Lidocaine Injection:

- We will ask if you have any changes to your medication list.
- We will weigh you.
- We will ask you to complete the following once before you receive the lidocaine injection and once after you receive the lidocaine injection for a total of 2 times during this visit:
  - You will be asked to complete the DVPRS
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

Group 3: Physical Therapy:

- We will ask if you have any changes to your medication list.
- We will weigh you.
- We will review your study diary and document the dates and duration of your physical therapy treatments.
- We will ask you to complete the following one time during this visit:
  - You will be asked to complete the DVPRS.
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

Visit 4 (16 weeks after visit 1):

Group 1: Acupuncture Needles:

- We will ask if you have any changes to your medication list.
- We will weigh you.
- We will ask you to complete the following once before you receive acupuncture treatment and once after you receive acupuncture treatment for a total of 2 times during this visit:
  - You will be asked to complete the DVPRS
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

Group 2: Lidocaine Injection:

- We will ask if you have any changes to your medication list.

Office of Clinical Research Support Use Only:
FWH20190005H, ICD, Loomis, NS

- We will weigh you.
- We will ask you to complete the following once before you receive the lidocaine injection and once after you receive the lidocaine injection for a total of 2 times during this visit:
  - You will be asked to complete the DVPRS
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

Group 3: Physical Therapy:

- We will ask if you have any changes to your medication list.
- We will weigh you.
- We will review your study diary and document the dates and duration of your physical therapy treatments.
- We will ask you to complete the following one time during this visit:
  - You will be asked to complete the DVPRS.
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

Visit 5 (20 weeks) (visit window plus or minus 1 week):

Group 1: Acupuncture Needles:

- We will ask if you have any changes to your medication list.
- We will weigh you.
- We will ask you what your reduction in pain severity as a percentage since you started the study.
- We will ask you if your expectations have been met regarding acupunctures effectiveness for chronic, post-surgical pin related to low transverse Cesarean Section.
- We will ask you to complete the following one time during this visit:
  - You will be asked to complete the DVPRS
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

Group 2: Lidocaine Injection:

- We will ask if you have any changes to your medication list.
- We will weigh you.
- We will ask you what your reduction in pain severity as a percentage since you started the study.
- We will ask you if your expectations have been met regarding the lidocaine injections effectiveness for chronic, post-surgical pin related to low transverse Cesarean Section.
- We will ask you to complete the following one time during this visit:
  - You will be asked to complete the DVPRS
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

Group 3: Physical Therapy:

- We will ask if you have any changes to your medication list.
- We will weigh you.
- We will review your study diary and document the dates and duration of your physical therapy treatments.
- We will ask you what your reduction in pain severity as a percentage since you started the study.

Office of Clinical Research Support Use Only:
FWH20190005H, ICD, Loomis, NS

- We will ask you if your expectations have been met regarding physical therapy's effectiveness for chronic, post-surgical pin related to low transverse Cesarean Section.
- We will ask you to complete the following one time during this visit:
  - You will be asked to complete the DVPRS.
  - We will instruct you to mark general area of your scar on pictures provided on the POSAS Patient Scale form.

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. You may experience a certain side effect many times, a few times, or only once or twice, if at all. Some side effects are more likely than others to occur. Side effects from this study will usually go away soon after the acupuncture needles are removed. Everyone taking part in this 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 acupuncture that is part of this research study.

Acupuncture Risks:

Likely and not serious:

- Pain
- Bleeding

Less likely and not serious:

- Infection
- Muscle cramps/spasms

Less Likely and serious:

- Transient vasovagal response to needling
- Bowel Perforation

Lidocaine Risks:

Likely and not serious:

- Pain
- Bleeding

Less likely and not serious:

- Infection
- Lidocaine toxicity

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

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 researchers.

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

Office of Clinical Research Support Use Only:
FWH20190005H, ICD, Loomis, NS

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.

ARE THERE RISKS RELATED TO WITHDRAWING FROM THE STUDY? There are no risks to you if you withdraw from this study. If you decide to withdraw from this study early, please discuss your decision with the principal investigator.

COULD YOUR PARTICIPATION END EARLY? The researcher may withdraw you from the study prior to the study's end 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.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.
- You become Pregnant

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 staffs know as soon as you become aware of your situation.

BENEFITS: The investigator has designed this study to learn if the addition of acupuncture or a lidocaine injection in comparison to standard of care treatment helps with reducing C-section scar pain but 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.

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 other medicinal therapies, such as Acetaminophen or Non-Steroidal Anti-inflammatory Drugs, Tricyclic Antidepressants, Gabapentin, Pregabalin, and Serotonin-Norepinephrine Reuptake Inhibitors for C-section pain. If medicinal therapy fails to manage symptoms, consultation for pain management specialists and/or surgical evaluation is often considered, as well. You may choose to receive any of these types of treatment options without participating in this 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 &

Office of Clinical Research Support Use Only:
FWH20190005H, ICD, Loomis, NS

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 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. 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. All research data will be kept in an electronic database, which will be double password protected, firewall-protected, encrypted, and access-restricted to people involved in this study. The research data will be coded. 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.

Office of Clinical Research Support Use Only:
FWH20190005H, ICD, Loomis, NS

REPOSITORY 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) 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 Principal 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 for research purposes 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 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 identifying 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.

_____

Signature of Study Participant

Office of Clinical Research Support Use Only:
FWH20190005H, ICD, Loomis, NS

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 an alternate member of the research staff will be available to answer any questions concerning procedures throughout this study.

Role	Location	Contact	Phone	Off-Duty Phone
Principal Investigator	Scott AFB	Capt Jennifer Loomis	(570) 877-2078	(702) 349-0452
Role	**Location**			
Associate Investigator	Nellis AFB	Col Paul Crawford	(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 call the Research Hotline at 210-292-5146 or Nellis Air Force Base Human Subject Research Protections Officer, (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 will be given to you for your records.

_____ _____

VOLUNTEER'S SIGNATURE **DATE**

_____

VOLUNTEER'S PRINTED NAME

_____ _____ (____)_____-_____

ADVISING STUDY STAFF'S SIGNATURE **DATE** **PHONE#**

_____

PRINTED NAME OF ADVISING STUDY STAFF

Office of Clinical Research Support Use Only:
FWH20190005H, ICD, Loomis, NS