FORM D – INFORMED CONSENT DOCUMENT

Volunteer Name: _____

99th MEDICAL GROUP

Protocol Title: Frequency Specific Microcurrent for the treatment of diastasis recti

FWH20190124H

KEY INFORMATION ABOUT STUDY PARTICIPATION: You are being asked to consider participation because you are an Active Duty or a DoD beneficiary female aged 18 years or older and are 12 to 24 hours postpartum. The purpose of this study is to see if using a microcurrent device helps treat diastasis rectus abdominus. Once you are deemed eligible to participate, you will be randomized (like flipping a coin) into 1 of 2 groups receiving either sham (fake) microcurrent therapy or frequency specific microcurrent therapy. Both groups will be asked to wear the microcurrent device while they are in the hospital for 11 hours and 32 minutes. We will measure your inter-rectus distance using ultrasound at your screening visit, after your microcurrent therapy, at your 2 week well baby visit, and your postpartum visit. In addition, at your postpartum visit, we will also ask you to complete 3 questionnaires regarding the rating of your lumbar and pelvic pain, how you feel about your body image, and how your bladder, bowel, or vaginal symptoms or conditions have affected your activities, relationships, or feelings. These questionnaires will take approximately 10 minutes to complete. The risks associated with this study include an accidental breach of confidentiality since we will be gathering identifiable information from you. The risks related to the use of ultrasound include a skin sensitivity or allergic reaction to the gel and discomfort with the ultrasound exam. Additionally for the microcurrent therapy group, you may experience the following: nausea, discomfort with the microcurrent treatment, skin sensitivity after treatment, skin damage, your condition may worsen, and if the device malfunctions, it could give you an inadvertent electric shock (similar to a mosquito bite). If you choose not to participate in this study, standard of care options for the treatment of diastasis include, but are not limited to, exercise and surgery.

Diastasis recti: A separation between the left and right side of the abdominal muscles. Your abdominal muscles cover the front surface of your belly area. This condition is common in women who have given birth. We will measure the separation between your abdominal muscles using a measurement called Inter-rectus distance. This entails applying ultrasound gel to your belly and using an ultrasound machine and a tape measure to measure the distance between these muscles.

Microcurrent Device: We will be using the Inspirstar microcurrent stimulator TENS device. It is an FDA approved portable hand-held device used for the symptomatic relief of chronic pain. It generates low current intensity pulses in the ranges of 20μA (microampere) to 400μA. In this study, we will be using a treatment range of 100-300μA microcurrent. Microampere is an electric current measured by amound per second. In most cases, patients cannot even feel the treatment from the micorcurrent therapy. If you were to experience an inadvertent electrical shock (similar to a mosquito bite), this may cause slight discomfort.

Placebo: We will be using the Inspirstar microcurrent stimulator TENS device. We will place the microcurrent pads on your body and turn the microcurrent device on placebo mode which mean no treatment will be

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delivered.

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 an Active Duty or 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:

Shalease Adams, DO, Capt, USAF, 99MDG/Family Medicine Residency.

STUDY SPONSOR: Air Force Medical Support Agency, a federal agency that promotes scientific research, is funding this study (i.e., study sponsor). This organization is providing money to 99MDG so that researchers can conduct the study.

PURPOSE OF THIS STUDY (Why is this study being done?)**:** You are being asked to consider participation because you are an Active Duty or a DoD Beneficiary female aged 18 years or older, and you are 12-24 hours postpartum. The purpose of this study is to see if using a microcurrent therapy device helps treat your pain from diastasis rectus abdominus.

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.

This study will enroll approximately 116 subjects at Nellis AFB, over a period of two 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 Shalese Adams, the Principal Investigator (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

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procedures for the 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. 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 including pregnancy history.
- We will collect your demographic information.

Study Assignments: You will be randomized (like flipping a coin) into one of two research-related treatment groups receiving either microcucrrent therapy or sham (fake) microcurrent therapy. For both groups, we will place the electrodes on your belly and turn the machine on. It will run for a total of 11 hours and 32 minutes.

Visit 1 (while you are still in the hospital-may be the same day as screening visit):
- We will apply ultrasound gel to your belly and measure your inter-rectus distance (distance between the left and right side of the abdominal muscles) using ultrasound and a tape measure.
- You will receive treatment according to your study assignment group.
- You will be instructed to leave the microcurrent in place until the treatment is over. Research personnel will retrieve the microcurrent box after the completion of the treatment.
- We will apply ultrasound gel to your belly and measure your inter-rectus distance (distance between the left and right side of the abdominal muscles) using ultrasound and a tape measure.

Visit 2- Week 2-4 (2 week well baby visit that occurs 2-4 weeks postpartum):
- We will apply ultrasound gel to your belly and measure your inter-rectus distance (distance between the left and right side of the abdominal muscles) using ultrasound and a tape measure.

Visit 3- Week 4-12 (postpartum visit that occurs at 4-12 weeks postpartum):
- We will apply ultrasound gel to your belly and measure your inter-rectus distance (distance between the left and right side of the abdominal muscles) using ultrasound and a tape measure.
- You will be asked to complete the Body Image States Scale (takes approximately 5 minutes to complete).
- You will be asked to complete the Pelvic Floor Impact Questionnaire Scale (takes approximately 5 minutes to complete).
- You will be asked to complete the Defense and Veterans Pain Rating Scale for lumbar and pelvic pain Scale (takes approximately 5 minutes to complete).

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 microcurrent electrodes 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 taking part in this research study.

Ultrasound: *Less Likely and not serious:*
- Skin sensitivity or allergic reaction to the gel

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- Discomfort with the ultrasound exam

Microcurrent: *Less Likely and not serious:*

- Discomfort with microcurrent treatment
- Skin sensitivity after treatment
- Skin damage
- Condition may worsen
- Nausea
- If the device malfunctions, it could give you and inadvertent electrical shock similar to a mosquito bite.

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

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.

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.

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 see if using a microcurrent device helps treat diastasis rectus abdominus pain in postpartum females. The potential benefit from your participation may include an improvement in your diastasis, improvement in abdominal wall functionality, reduction of pain, improvement in body image, and improvement in urogynecologic (pelvic floor and bladder) symptoms, 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.

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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 therapies, including but not limited to, exercise and surgery to fix your diastasis. 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 & 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 99MDG 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.

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REPOSITORY OF DE-IDENTIFIED 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 "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. 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 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 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, 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

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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 will be available to answer any questions concerning procedures throughout this study.

Shalease Adams, DO, Capt, USAF, 99MDG/Family Medicine Residency
Phone: (702) 653-3298, Off-Duty Phone: (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 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**

_____
PRINTED NAME OF ADVISING STUDY STAFF

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