Meets 2018 Common Rule Requirements

San Antonio Institutional IRB (SA IRB)

CONSENT TO PARTICIPATE IN RESEARCH

Title: *Effects of a Prenatal Mental Health Support Intervention on Maternal and Fetal Physiologic Response*

Principal Investigator: *Lt Col Robert Brady, MD*

Sponsor/Funded by: *Uniformed Services University (Sponsoring Office)*

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

The purpose of this study is to investigate the association between overall pregnancy well-being on pregnancy complications, placental effects and birth outcomes. We will expand the on-going M-O-M-S™ program, a prenatal intervention that supports active-duty women and wives/partners of DoD beneficiaries, and explore the relationships between mental health in pregnancy and the associated physiological effects on the placental tissue with and without an early prenatal support intervention. This study will enroll approximately 150 participants. All Active Duty and DoD beneficiary pregnant women that are not dependent daughters, 18 years of age or older, who are receiving obstetrical care within the San Antonio Military Health System are invited to participate.

If you participate in this study, you will be randomized to the either the control group (prenatal care without M-O-M-S™ program) or the treatment group (M-O-M-S™ with prenatal care). All participants will complete a prenatal booklet at several timepoints throughout your pregnancy. You can choose to complete the questionnaire booklets electronically, or in paper. We will also obtain peripheral blood samples throughout your pregnancy which we will attempt to collect during your scheduled prenatal lab appointments and will collect tissue samples from your placenta following delivery. We will collect birth outcomes data being retrieved from both yours and newborn infant's electronic medical record. All data we collect (booklets, lab samples, placenta tissue samples, and birth outcomes) will all be de-identified and coded with your study participant number. Women randomized to the M-O-M-S™ program will attend 10 sessions, lasting 1 hour, every other week comprised of ten, one hour facilitated group discussion and support sessions held prenatally, focused on decreasing pregnancy anxiety and depression, and building self-esteem.

Your participation is voluntary, and you are consenting for a research study. There is no direct benefit to you for participating in this study, though your participation we hope the information learned from this study may help future patients. The findings from this study, as applicable, will be used to update the VA/DoD Clinical Practice Guideline for Pregnancy Management and as norming data for assessment tools used within the DoD. Additional details are discussed in the sections below.

There is minimal risk for participating in this 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. There is no risk to you if you withdraw early from the study.

Your decision will not affect your future care at the San Antonio Military Health System. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

Please tell the researchers if you are taking part in another research study.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are pregnant, entering care in the first trimester, and receiving obstetrical care and delivering at Brooke Army Medical Center (BAMC), are at least age 18 or older, speak English, you are either a wife or DoD beneficiary (Active Duty, retiree) partner to a military service member, or you are an active duty member yourself, or you are either a wife or DoD beneficiary (Active Duty, retiree) partner to a military retiree or you are a military retiree yourself.

The purpose of this study is to investigate the association between pregnancy well-being on pregnancy complications, placental effects and birth outcomes.

There will be about 150 people taking part in the study at the San Antonio Military Health System, Brooke Army Medical Center (BAMC), over a period of 20 months and continued birth outcomes data collection for approximately 12 months after.

The study is looking at prenatal maternal anxiety and depression which have been implicated as possible risk factors for preterm birth and other poor birth outcomes. Research efforts in the investigation of reproductive health, especially as it relates to mental health of active-duty servicewomen, female veterans, or wives of service members is limited. We will expand the on-going M-O-M-S™ program, a prenatal intervention that supports active-duty women and wives/partners of DoD beneficiaries, and explore the relationships between mental health in pregnancy and the associated physiological effects on the placental tissue with and without an early prenatal support intervention.

At the end of this research study the clinical results, including research results about you will not be shared with you.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you take part in this study, you will need to provide some information so that the Investigator can confirm that you qualify for the study. This is called the “Screening Process”.

You are eligible to participate in this study if you are a pregnant woman, entering care in the first trimester, and receiving obstetrical care and delivering at Brooke Army Medical Center (BAMC), are at least age 18 or older, speak English, you are either a wife or DoD beneficiary partner to a military service member, or you are an active duty member yourself, or you are either a wife or DoD beneficiary partner to a military retiree or you are a military retiree yourself.

4. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

If you decide to take part in this research study, you will be asked to do the following:

- Sign this consent form & HIPAA form.
- You will be randomized to the treatment arm (M-O-M-S™) or the control group (prenatal care in accordance with the woman's prenatal, obstetrical clinical practice guidelines without M-O-M-S™). If randomized to the control group will not receive any peer support from the M-O-M-S™ program but will receive prenatal care based on the clinical guidelines for the obstetrical clinic.
- You will complete a booklet containing questionnaires at entry into the study, and at 16, 24, 28 and 32 weeks of pregnancy. You can choose to complete the questionnaire booklets electronically, or in paper. The questionnaire booklets will take approximately 30 minutes to complete. Research personnel working on the project will coordinate with you to determine the best time to meet you and provide you with the booklet of questionnaires if you elect to complete them by paper. If you choose to complete them electronically, a one-time link to complete them at each time point will be sent to your email account. It is totally anonymous. The questionnaire booklet will have a participant number (code) specifically assigned to you, but it does not have your name on it.
- A 2.5ml tube of study specific maternal peripheral blood sample will be collected throughout your regularly scheduled prenatal blood draw at 4-10, 16-20, and 28-32 weeks gestation. The approximate amount of blood drawn for your regularly scheduled prenatal draw is 15-20ml + 2.5ml for research (total 17.5-22.5ml), which is dependent on what lab tests are being conducted during each regularly scheduled prenatal blood draw. In the case of missing or damaged specimens, the determination will be made if you can still provide the specimen within the correct study timeframe. If so, you can elect to provide the additional sample. If you choose to refuse the research lab draw for the study, then we will withdraw you from the study. The blood samples will coded with your participant number. The coded blood samples will be collected and analyzed to quantify RNA and protein expression levels for inflammatory, cytokine, oxidative stress and hormone biomarkers. The samples will be frozen and transported to the 59MDW Clinical Investigations & Research Support (CIRS) Laboratory at JBSA-Lackland for storage. The aliquoted serum will be analyzed by the USUHS/59MDW Joint Microphysiology Lab located at Wilford Hall Ambulatory Surgical Center (WHASC). After analyzing, the serum samples will be stored in a biorepository at CIRS for future analyses.
- Following delivery, placenta tissue will be collected. Your placenta tissue will be transported to BAMC Pathology in a labeled tissue container and "Labor and Delivery Placenta Pathology Submission Form" that is attached per normal standard procedures. Once at the pathology laboratory, the appropriate lab research personnel will be notified and the specimen will be given the participant number for study purposes and tissue specific collection will occur. The placenta will undergo the usual examination in accordance with local standard operating procedures. Additionally, the coded placental tissue slides will be processed and collected by BAMC research personnel. The coded

placental tissue slides will be evaluated by Dr. Brady (PI) and sent to Dr. Bustamante at the University of the Incarnate Word (UIW) for further review.

- After the specimens are reviewed, sections of the placenta will be taken and flash frozen. The flash frozen tissue will be prepared for shipment to 59 MDW Clinical Investigations & Research Support (CIRS) for storage. The placental tissue specimens will be analyzed at the USUHS/59MDW Joint Microphysiology Lab located at Wilford Hall Ambulatory Surgical Center (WHASC) JBSA-Lackland. Once analysis has been run on the specimens at , one of three things will occur: 1) the tissue will be destroyed, 2) the tissue will be maintained as a coded, de-identified specimen within a tissue repository at CIRS, and/or 3) de- identified/non-coded slides will be maintained for medical student use at UIW School of Medicine. The tissue will be maintained until the completion of all data analyses as re-analysis might occur.
- If you desire to have your placenta, you can complete a tissue request form and obtain the placenta from the BAMC Pathology Department. This process is required whether you participate in the study or not. If your physician requests evaluation of your placenta, this will occur in conjunction with the research study evaluation.
- Following delivery, we will collect birth outcomes data being retrieved from both yours and newborn infant's electronic medical record. The information obtained from you and your child's electronic medical record will be de-identified, coded and securely maintained on a password protected computer with a secured study folder.

5. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

There is minimal risk for participating in this study. If you choose to take part in this study, there is a risk that associated with your pregnancy, you could experience emotional distress or anxiety that may affect your well-being or unborn infant. There may be feelings of isolation, particularly if one's husband/partner is away. Both of which are common feelings during your pregnancy but may be increased when completing the questionnaires. For your venipuncture, you may have a bruise or be sore at this site where blood is drawn. There is also a slight possibility of infection at the site where the blood is drawn. Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

Your personal information (the questionnaire booklets and demographic data) are securely maintained on an electronic database that is double password-protected, firewall-protected, and access-restricted to people involved in this study. The paper documents will be locked in a file cabinet in a locked office, as part of the research record. Only members of the research team, listed on the research protocol, will have any access to the information.

As soon as possible, any link between identity and the research information will be destroyed which means research information about you will be permanently de-identified. Personal identifying information and identifiable bio-specimens will be destroyed no later than at the closure of the study. The research information and bio-specimens collected will not be used for any additional research activity beyond what has been described in this consent.

All coded (de-identified specimens) will be stored as a part of an IRB approved Data/Tissue repository for the purposes of this study at the *59MDW Clinical Investigations & Research*

Support (CIRS) Laboratory at Joint Base San Antonio Lackland and will be handled and disposed of in accordance with Federal regulations upon termination of the repository. No individual, investigator, institution or agency will have access to this database without permission of the Pl, Dr. Robert Brady, and the currently assigned CIRS Laboratory Protocol Coordinator for the Repository, and where applicable, the San Antonio Institutional Review Board (SAIRB). Your data will not be released or shared with anyone outside the project.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

There is no direct benefit to you for participating in this study, though your participation we hope the information learned from this study may help future patients. The findings from this study, as applicable, will be used to update the VA/DoD Clinical Practice Guideline for Pregnancy Management and as norming data for assessment tools used within the DoD.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Your alternative is not to participate in this research. You will not be penalized or lose benefits to which you would otherwise be entitled as a DoD beneficiary. Your decision to not participate will not affect your future care at the San Antonio Military Health System.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

Yes, you will receive a MOMS™ pregnancy calendar after consenting to participate in the study. In addition, when you actively continue to participate, in either the intervention or control portion of this study, you will be entered into a quarterly gift card drawing for one of five $50 gift cards. There will be approximately 7 quarterly gift card drawings.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Principal Investigator:
Lt Col Robert Brady, MD
Pathology BAMC
robert.o.brady.mil@health.mil

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

Uniformed Services University of the Health Sciences (USUHS), a federal agency that promotes scientific research, is funding this study (i.e., the study sponsor). This organization is providing money to the 59MDW and the Geneva Foundation. The Geneva Foundation will allocate the funds so that the researchers can conduct the study.

12. SOURCE OF FUNDING:

Sponsoring Office: Uniformed Services University of the Health Sciences
USUHS Award No: HU00012220065

13. LOCATION OF THE RESEARCH:

The place of performance is at the following location(s):

- Brooke Army Medical Center (BAMC), Fort Sam Houston, TX

14. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

None.

15. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:
https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2005.pdf

The members of the research team will keep your research records. These records may be looked at by staff from the San Antonio Institutional Review Board (IRB), research personnel assigned to the study, the DoD Higher Level Review as part of their duties, and other government agencies that oversee human research. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Individual data access as well as privileges will be clearly delegated, audited, and monitored by research team. A copy of this consent will be stored by the investigator in a locked file cabinet in a locked office, as part of the research record. 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 identity and the research information will be destroyed which means research information about you will be permanently de-identified. Personal identifying information and identifiable bio-specimens will be destroyed no later than at the closure of the study. The research information and bio-specimens collected about you for this study will not be used for any additional research activity beyond what you have approved by signing this consent.

If you are assigned to the treatment group (MOMS™ Intervention), we also ask that each of you respect the privacy of everyone here and not share or repeat what is said here in any way that could identify anyone here. However, since someone in the group may not obey instructions to keep all comments confidential, we recommend that you avoid saying anything that you don't want to be repeated outside the group. We ask your cooperation in protecting the privacy of the comments made within this session by not saying anything that would identify you or other participants.

There will be appropriate data sharing agreements in place between the data owner(s) and all appropriate parties involved in the handling of data.

Complete confidentiality cannot be promised for military personnel because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

- *Brooke Army Medical Center (BAMC), Fort Sam Houston, TX*
- *San Antonio Institutional Review Board*
- *University of the Incarnate Word, San Antonio, TX*
- *Uniformed Services University of the Health Sciences (USU), Bethesda, MD*

Those listed above will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

16. LONG TERM USE OF DATA

The investigator has requested to save selected data collected from your participation in this research study for possible use in future research. By consenting to participate in this study, you agree to allow us to maintain your de-identified research data indefinitely. This future research may be in the same area as the original study, or it may be for a different kind of study.

Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

Future Use of Biologic Specimens: The investigators in this study are asking for your permission to store your samples described above (Section 4) for future use in other research studies. The specifics of these future research studies are unknown at this time, but these studies will frequently be in the area of maternity, immunological, inflammatory and hormone biomarker changes.

Your samples would be stored with the following information: participant number, date and time of specimen collection and specimen type. Other examples of information that makes your stored PHI/PII both identifiable and/or coded data will be data such as name, Social Security Number, gender, birth date, age, treatment dates, surgical procedures, and post-surgery outcomes. The PHI/PII information needed to identify your coded specimens is maintained in an electronic database, which will be double password- protected, firewall-protected, and access-restricted to people involved in this study. This is considered identifying information and can be traced back to you as the donor.

The storage (bank) area is maintained at the 59MDW Clinical Investigations & Research Support

(CIRS) Laboratory at Joint Base San Antonio Lackland. The CIRS Laboratory Protocol Coordinator for the Repository is responsible for the storage bank. The coordinator's phone number is: 210-292-0083. Future research investigators requesting portions of your samples from the bank must have the approval of the Protocol Coordinator and also must have a research protocol for their newly proposed research study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants). It is possible these other researchers will request approval from an IRB to contact you in the future.

Some future research studies may include genetic testing of your samples stored at the bank. The research might include whole genome sequencing. Since storage (banking) of biologic specimens for future genetic testing is still undergoing development, the benefits and risks of genetic testing are not fully known at this time. It is believed that the risks are very low. Using new technology, information about your DNA structure (genetic information) gained from your banked samples can be used to indicate risk for developing certain diseases. This genetic information is unique to you and may indicate changes in your future health status or life expectancy, or that of your children and other relatives. These discoveries could be stressful and cause psychological difficulties or family problems. It is also possible that during future research, people of your ethnic background may be found to be at more risk for certain diseases. This could stigmatize your ethnic or cultural group.

Release of personally identifiable genetic information may pose a possible risk of discrimination or increased difficulty in obtaining certain types of insurance for you and your family members. The Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110-233) also known as "GINA" is a federal law that prohibits discrimination in health insurance coverage and employment based on genetic information. However, GINA does not apply to employers with fewer than 15 employees. GINA's protections in employment do not extend to the US military. Nor does it apply to health insurance through the TRICARE military health system, the Indian Health Service, the Veterans Health Administration, or the Federal Employees Health Benefits Program. Lastly, the law does not cover long term care insurance, life insurance or disability insurance.

Potential risk would occur if the confidentiality of your data is breached. Because of the consequences of a breach of confidentiality, every effort will be made by the bank to protect your privacy. The storage bank's procedures to protect the confidentiality of your data includes: any information needed to identify your coded specimens is maintained in an electronic database, which will be double password- protected, firewall-protected, and access-restricted to people involved in this study. No individual, investigator, institution, or agency will have access to this database without permission of the Pl, Dr. Robert Brady, and the currently assigned CIRS Laboratory Protocol Coordinator for the Repository, and where applicable, the San Antonio Institutional Review Board (SAIRB). The Protocol coordinator is responsible for all PHI and PII data stored in the repository. Only de-identified data (data that meets the HIPAA standards for removing direct identifiers or information) will be released to investigators with an IRB-approved research study, so tracing specific information back to the donor of the data should not be possible. Recipient investigators may only receive limited data sets under a Data Use Agreement (DUA) including the information necessary to conduct their IRB-approved research. All recipient investigators requesting data from the storage bank must have approval from the bank Manager and must have a research study approved through a DoD Institutional Review Board (IRB) and/or the San Antonio Institutional Review Board (SAIRB).

Your samples will enter the repository bank by the study research personnel or project

coordinator signing and verifying packaging. The blood and tissue samples will be coded, frozen and transported in cooled storage containers from BAMC to CIRS at Lackland. Your coded blood samples and flash frozen placenta samples will be stored in a freezer at BAMC pathology lab until they are packed by the PI and/or pathology resident into storage boxes appropriate for transport to the Clinical Investigations & Research Support (CIRS). The Project coordinator and/or the research personnel will sign the specimens and verify packaging. They will be responsible to ensure the specimens are taken directly to the CIRS lab, where they will be signed in accordance with CIRS STCL OI 40A-003.

Your samples could be stored indefinitely at the bank, or until none is left to use. Generally, you will not be provided with the results of the future studies using your samples from this bank. This is typically the case because the research results at that early point will not have a clear meaning for or direct clinical benefit to you.

You may request that your specimen be withdrawn from the bank at any time if you decide you no longer want to participate. This can be done by notifying the bank Manager listed above.

Your biospecimens (even if identifiers are removed) may be used for commercial profit. You will not share in this commercial profit.

17. USE OF INFORMATION AND SPECIMENS

Participation in this study will also require that you complete a prenatal booklet containing at entry into the study, and at 16, 24, 28 and 32 weeks of pregnancy. You can choose to complete the questionnaire booklets electronically, or in paper. The questionnaire booklets will take approximately 30 minutes to complete. Also choosing to participate means that you elect to allow access to your child's medical records to obtain information on your child's birth outcomes (ie: weight, height, gender, delivery type, birth complications). Your child's protected health information will be used for the purpose of evaluating stress in pregnancy (both physical and emotional) to changes in the placenta. Delivery-specific information necessary in evaluating the placenta will be obtained from your child's electronic medical record. The information obtained from your child's electronic medical record will be coded and securely maintained on a password protected computer with a secured study folder. Only members of the research team, listed on the research protocol, will have any access to the information. At the conclusion of the study, all documents will be shredded.

During this research study, you will be asked to provide the following types of samples (biological specimens): serum blood, placental tissue, histology slides from placental tissue. The placental tissue will be collected which poses the possibility of determining the identity of both mother and baby through the placental tissue (which there is-DNA).

While this study is on-going, your samples will be handled in accordance with this study's protocol and applicable regulations at the following laboratory: 59MDW Clinical Investigations & Research Support (CIRS) Laboratory at Joint Base San Antonio Lackland.

When this study is over, your samples will be disposed of in the following manner: in accordance with Federal regulations and local laboratory procedures. In accordance with the authorization within this consent, once the tissue has been analyzed and run, one of three things will occur: 1) placental tissue and blood samples will be destroyed, 2) the placental tissue and blood samples

will be maintained as coded specimens within a repository at CIRS, and/or 3) coded placental tissue histology slides will be maintained for medical student use at the University of the Incarnate Word (UIW), School of Medicine. If you decide to withdraw from the study, any identifiable data and remaining portion of your identifiable or coded blood and placenta tissue samples will be destroyed. However, any coded, de-identified data already obtained by researchers from your sample will continue to be used for data analysis, as discussed in this consent.

The information and/or specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

The investigators are asking for your permission to store your histology slides of the placenta tissue at UIW for future use in research studies/student training. The actual placenta tissue samples and blood samples will remain stored at 59MDW Clinical Investigations & Research Support (CIRS) Laboratory at Joint Base San Antonio Lackland. The histology slides will be packed by the PI and/or pathology resident on the study in accordance with bio-specimen requirements. The information needed to identify you to your coded specimen is maintained in an electronic database, which will be double password-protected, firewall-protected, and access-restricted to people involved in this study. The storage of the histology slides are maintained at the UIW. Dr. Blandine Bustamante is responsible for histology slide storage.

Other research investigators requesting portions of histology slide samples must have the approval from UIW and must also have a research protocol for this newly proposed study that has been reviewed and approved by an Institutional Review Board (IRB), a committee responsible for protecting research subjects. It is possible researchers from this study will contact you in the future with your written authorization to add follow-up information at the storage bank. Any histology slide samples you have donated which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the investigators, sponsors and/or others. However, donors of tissues do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

18. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding." We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.

We will also give information about this incidental finding to your primary doctor, or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious

- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

19. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled. Choosing to withdraw will not affect your continued care at the San Antonio Military Health System.

You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

20. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

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 as a DoD beneficiary. There is no risk to you if you withdraw early from the study.

Should you choose to withdraw, you must notify a research team member right away. If you decide to no longer participate in this research study, the researcher may use or share your health information that is already collected if the information is needed for this study.

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.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

21. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

If you think that you have a research-related injury, notify your Principal Investigator immediately using the contact information in the section below.

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 authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

22. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Lt Col Robert Brady, MD
Phone: 210-916-2956
Mailing Address: Brooke Army Medical Center, Dept of Pathology, 3551 Roger Brooke Drive, Fort Sam Houston, TX 78234

San Antonio IRB (SAIRB) Human Research Protection Program (HRPP) Office
The Human Research Protection Program Office Point of Contact and/or Human Protections Administrator (HPA) will be available to answer questions or discuss concerns you may have about this research study.

Human Protections Administrator/HRPP (SAIRB HRPO)
Phone: 210-916-2000 OR 210-916-2598

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at:

Mailing Address:
SA-IRB, Brooke Army Medical Center
MCHE-ZQ; Department of Quality and Safety
3551 Roger Brooke Drive, Building 3667
JBSA, Ft. Sam Houston, TX 78234

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

SIGNATURE OF PARTICIPANT

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

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

Protocol # C.2023.018 FWH20190163H

Principal Investigator (PI) Name and Rank: Lt Col Robert Brady, MD

Corps and Service/Organization: USAF 59MDW, BAMC Dept of Pathology

Title of Research Study: Effects of a Prenatal Mental Health Support Intervention on Maternal and Fetal Physiologic Response

I. Purpose of this Document

An Authorization is your signed permission to use or disclose your health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or disclose your health information with a valid Authorization. The MHS is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force. A valid Authorization must include the core elements and required statements as contained in this document.

Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information.

II. Authorization

The purpose of this study, Effects of a Prenatal Mental Health Support Intervention on Maternal and Fetal Physiologic Response, is to investigate the association between overall pregnancy well-being on pregnancy complications, placental effects, and birth outcomes. We will expand the on-going M-O-M-S™ program, a prenatal intervention that supports active-duty women and wives/partners of DoD beneficiaries, and explore the relationships between mental health in pregnancy and the associated physiological effects on the placental tissue with and without an early prenatal support intervention. For future research purposes the de-identified coded placental tissue samples and maternal serum blood samples will be stored at the 59MDW CIRS in an IRB approved data/tissue repository.

A. What health information will be used or disclosed about you?

Your protected health information that may be used or disclosed about you in this study includes: Name, Demographic information (ie: age, race/ethnicity, rank, marital status, deployment information, etc.), Medical History with direct identifiers, Address, Phone Number, E-mail address, Dates, Last 4 SSN and Health Plan Beneficiary Number.

The protected health information (PHI) will be accessed from GENESIS, the Military Health System (MHS) patient documentation system. Your protected health information that is collected to track data

over time will be de-identified and coded with a study number and maintained by a using a master log with participant name and your assigned study number. Your medical information, (which may include prenatal history, birth outcomes, placental tissue sample results), will be collected for the purpose of evaluating stress in pregnancy to changes in the placenta and maternal serum blood stress levels. Pregnancy and delivery- specific information necessary for evaluating the placenta and maternal serum blood samples will be obtained from your medical record. The questionnaires collected are not maintained with any identifiable information. They are only identifiable by your study number. Your personal information are securely maintained on a password protected computer with a secured study folder, and/or in a locked file cabinet in the private secured office of the nurse researcher.

No data will be shared outside the DoD with any identifiable PHI. Only members of the study team will be permitted to use the health information accessed within the MHS at the Military Treatment Facility (MTF) where you enroll for the study. The disclosure of your protected health information is necessary in order to be able to conduct the research project described. Only members of the research team, listed on the research protocol, will have any access to the information.

Records of your participation in this study may only be disclosed in accordance with state and federal law, including the Privacy Act (5 U.S.C. 552a) and the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (45 CFR 160 & 164). Note: Protected health information of military service members may be used or disclosed for activities deemed necessary by appropriate military command authorities to ensure the proper execution of the military mission.

B. Who will be authorized to use or disclose (release) your health information?

The Military Treatment Facilities (MTFs) where you have received care over the past five years.

C. Who may receive your health information?

Those listed below will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

- Authorized members of the research study team
- Brooke Army Medical Center (BAMC), Fort Sam Houston, TX; 59MDW, Lackland AFB, TX; Department of Defense representatives
- San Antonio Institutional Review Board
- Human Research Protection Office representatives (HRPO)
- Research collaborators at the University of the Incarnate Word, San Antonio, TX; Uniformed Services University of the Health Sciences (USU), Bethesda, MD
- State and Federal Government representatives, when required by law

You need to be aware that some parties receiving your protected health information may not have the same obligations to protect your protected health information and may re-disclose your protected health information to parties not named here. If your protected health information is re-disclosed, it may no longer be protected by state or federal privacy laws. Any data shared outside the Research Study Team will be de-identified.

D. What if you decide not to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you will not be allowed to participate in the research study. The MHS **will not** condition (withhold or refuse) treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this Authorization.

E. Is your health information requested for <u>future</u> research studies?

Yes, your health information *<u>is</u>* requested for future research studies as specified below:

For future research purposes the de-identified coded placental tissue samples and maternal serum blood samples will be stored in an IRB approved data/tissue repository at the 59MDW CIRS located at JBSA Lackland. The coded research information gained from your participation in this study will aid in future research looking at prenatal maternal anxiety and depression which have been implicated as possible risk factors for preterm birth and other poor birth outcomes. Research efforts in the investigation of reproductive health, especially as it relates to mental health of active-duty servicewomen, female veterans, or wives of service members is limited. We will explore the relationships between mental health in pregnancy and the associated physiological effects on the placental tissue with and without an early prenatal support intervention. You will not be personally identified in future research, publications or presentations; all information will be presented as anonymous data.

Your health information will not be used for future research studies unless you give your permission by initialing your choice below:

____ I give permission to use my health information for future research studies

____ I *<u>do not</u>* give permission to use my health information for future research studies

F. Can you access your health information during the study?

To maintain the integrity of this research study, you will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you will have access to your health information that the MHS maintains in a designated record set. A designated record set means a set of data that includes health information or billing records used in whole or in part by your health care providers at the MHS to make decisions about you. If it is necessary for your care, your health information will be provided to you or your health care providers.

G. Can you revoke this Authorization?

- You may change your mind and revoke (take back) your Authorization at any time. However, if you revoke this Authorization, any person listed above may still use or disclose any already obtained health information as necessary to maintain the integrity or reliability of this research.
- If you revoke this Authorization, you may no longer be allowed to participate in this research study.
- If you want to revoke your Authorization, you must write to:

  Lt Col Robert O. Brady, MD at Robert.o.brady.mil@health.mil

H. Does this Authorization expire?

Yes, it expires at the end of the research study, unless you have agreed in writing to maintain your coded data/tissue specimens in the 59 MDW CIRS Data/Tissue Research Repository for future research.

I. What else may you want to consider?

- No publication or public presentation about the research described above will reveal your identity without another signed Authorization from you.
- If all information that does or can identify you is removed from your health information, the remaining de-identified information will no longer be subject to this Authorization and may be used or disclosed for other purposes.
- In the event your health information is disclosed to an organization that is not covered by HIPAA, the privacy of your health information cannot be guaranteed.

Signature of Research Participant or Personal Representative:

Your signature acknowledges that:

- You authorize the MHS to use and disclose your health information for the research purposes stated above.
- You have read (or someone has read to you) the information in this Authorization.
- You have been given a chance to ask questions, and all of your questions have been answered to your satisfaction.

_____ _____

Participant Signature Date

_____

Participant Printed Name

If the personal representative signs on a participant's behalf, then the personal representative must provide verification of their authority under applicable state law.

_____ _____

Personal Representative Signature Date

_____ _____

Personal Representative Printed Name Description of the Personal Representative's Authority