## FORM D – INFORMED CONSENT DOCUMENT

| **Volunteer Name:** | |
|---|---|

**BROOKE ARMY MEDICAL CENTER/59TH MEDICAL WING/**
**NAVAL MEDICAL CENTER SAN DIEGO/MADIGAN ARMY MEDICAL CENTER**
**INFORMED CONSENT DOCUMENT**
[Adult, Child (14-17 years of age)]

| **Title of Protocol/Project:** | **Mentors Offering Maternal Support (M-O-M-S™): A Prenatal Program Building Maternal Self-Esteem, Coping, and Resilience and Decreasing Depression** |
|---|---|
| **FWH #:** | FWH20170069H |

**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 about the study and ask them any questions you may have for them. You may also wish to talk to others (for example, 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 procedures of the study and what the study is about, including the 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 it is finished, your decision will not affect your eligibility for care or any other benefits to which you are entitled. 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's for this study are:

| **PI Name and Degrees:** | **Rank:** | **Branch:** | **Department and Base:** |
|---|---|---|---|
| Karen L. Weis, PhD, RNC, FAAN | Col (ret) | N/A | University of the Incarnate Word |
| Jacqueline Killian, PhD | Lt Col | USAF | Science & Technology 59MDW JBSA Lackland |

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**STUDY SPONSOR:**
Joint Program Committee – 5 (JPC-5); Military Operational Medicine Research Program/711th USAF Human Performance Wing (HPW)

*Non-Profit Sponsor or Federal Agency:*
JPC-5/711th HPW, a federal agency that promotes scientific research, is funding this study (i.e., the study sponsor). This organization is providing money to 59MDW and the University of the Incarnate Word, so that the researchers can conduct the study.

**PURPOSE OF THIS STUDY** (Why is this study being done?):
The purpose of this study is to investigate the impact of your participation in the M-O-M-S™ program on your overall pregnancy mental well-being and the relationship to pregnancy complications, birth outcomes and your maternal role satisfaction and parenting stress.

You are being asked to consider participation in the research study of the M-O-M-S™ program. Prenatal and postpartum mental well-being can be related to pregnancy and birth outcomes as well as your role as a mother. Participating in this study provides an opportunity to not only test the impact of the M-O-M-S™ program on your well-being but it allows us to gather pre-and postpartum data on pregnancy psychological health for active duty women and wives/partners of active duty members across all the services.

This study will enroll approximately 2862 subjects, with approximately 954 subjects to be enrolled at each study site over a period of 33 months. The study will be conducted at Joint Base San Antonio (Lackland/SAMMC) in San Antonio, TX, Joint Base Ft. Lewis-McChord (Madigan) in Tacoma, Washington, and Naval Medical Center San Diego (NMCSD) in San Diego, CA so that we may gather data across all of the services.

You have been selected to participate in this study because you are at least age 18 or older, speak English, in your first trimester of pregnancy, 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.

**PROCEDURES:**
If you decide to take part in this research study, you will be asked to sign this consent form. Participation in this study requires that you participate beginning in your first trimester of pregnancy through delivery, and for approximately 6 months postpartum. As a participant, you will be randomly assigned to either the M-O-M-S™ intervention program (treatment group) or receive traditional prenatal care group without the M-O-M-S™ component (control group).

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**SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY:**

To determine whether you will be assigned to the M-O-M-S™ intervention program (treatment group) or a traditional prenatal care group with the M-O-M-S™ component (control group), *randomization* will be used.

*With randomization:*

When it is determined that you are eligible for the study you will be assigned by chance (like flipping a coin) to one of 2 study groups.

If you are a member of the treatment group (M-O-M-S™ intervention), while receiving prenatal care, you will also attend 10 sessions aimed at decreasing pregnancy concerns and building coping skills through supportive relationships with experienced military mothers and the other participants in the group. You will receive a "Birth of a Mother" manual designed to guide open discussion during the course of the sessions.

If you are randomized to the control group, you will not attend the support intervention sessions but continue your prenatal care as directed by your provider.

Whether you are randomized to the treatment group (M-O-M-S™ intervention) or control group (traditional prenatal care) you will be asked to complete a booklet containing 8 questionnaires during your first prenatal appointment, and at approximately 12, 16, 24, and 32 weeks during your pregnancy. Following delivery you will be given questionnaire booklets to complete at approximately 1, 3, and 6 months postpartum. These questionnaire booklets will take approximately 30 minutes to complete.

A research assistant working on the project will coordinate with you to determine the best time to meet you and provide you with the booklet of questionnaires to complete. You will receive a phone, text, and/or email contact reminding you of the need to complete questionnaires and to allow approximately 30 minutes prior to your appointment (or other determined time) for questionnaire completion.

**RISKS OR DISCOMFORTS:**

There is minimal risk for participating in the study. While completing the questionnaires you may feel brief distress generated by the questions. When reading or completing the "Birth of a Mother" manual, you may experience increased loneliness for your husband/partner particularly if he is deployed. The support group is designed to provide support during your pregnancy. If you are in the control group and you feel you need help, the research team members are available to offer assistance.

If an investigator feels at any time that you are at risk of self-harm, you will be given a direct referral to a provider within the Mental Health Services. Complete confidentiality for active duty pregnant women cannot be guaranteed. Importantly, Mental Health Service appointments do not have any connection with the study or your participation in the study.

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There is the potential risk for loss of confidentiality, although every effort will be made to protect your confidentiality. Every effort is made to safeguard the information you provide. The researchers will use only password protected computers. The demographic information you provide will be entered into a computer spreadsheet and the paper copies will be shredded. None of the questionnaires you complete will contain personal identifiable information but coded with a number assigned to you during the course of the study. All materials associated with the study will be kept in a locked file cabinet accessed only by the Primary Investigator, the Research Assistants, and Program Director.

Everyone taking part in this study will be watched carefully for any risk or discomfort. However, the Principle Investigator and research personnel are not your healthcare provider. Always let your provider or nurse available at your obstetrical appointment know immediately if you need help and referrals will be made.

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

**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?**
If you decide to withdraw from this study early, please discuss your decision with the principal investigator. There is no risk to you if you withdraw early from the study.

**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.
- Failure to attend M-O-M-S™ sessions and/or complete questionnaire booklets as scheduled.
- The researcher decides that continuing your participation is not in your best interests.
- You become ineligible to participate.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

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If you lose your status as a military health care beneficiary, you can no longer be included in the study. Please let the Principal Investigator and study staff know as soon as you become aware of your situation.

**BENEFITS:**

A benefit of participation in the study is the bi-weekly classes that offer mentored, peer support for women in the treatment group. If you are assigned to the control group, a benefit will be access to a team of nurses willing to help you or obtain the help you need. Though benefits are anticipated as part of the study, there may not be any direct benefit to you based on your study participation.

**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 study site beyond any scheduled standard of care appointments. You are allowed to bring your children to the M-O-M-S™ classes.

**PAYMENT (COMPENSATION):**

You will not receive any monetary compensation (payment) for participating in this study.
All participants consented into the study will receive a "1st year infant" calendar. Participants completing all components of the prenatal portion of the study will receive an Infant Feeding Kit. Participants completing all of the prenatal and postpartum components of the study will receive an infant sensory tool.

**POTENTIALLY BENEFICIAL ALTERNATIVES TO STUDY PROCEDURES OR INTERVENTIONS:**

The alternative to the M-O-M-S™ program is the standard prenatal appointment schedule and procedures as outlined in the DoD Pregnancy guidelines. Participants in the treatment group will receive the standard prenatal appointment schedule in addition to the M-O-M-S™ program.

**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 medical science. You will not be personally identified; all information will be presented as anonymous data.

Your de-identified records may be reviewed by the research personnel assigned to this study. Only personnel assigned to University of the Incarnate Word, DoD, military services, and other government agencies, 59 MDW Institutional Review Board, or areas of having oversight of human research may have access to your records.

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This study is being conducted at multiple military locations. Therefore, sharing of the information between sites is necessary, but the following procedures will occur to ensure privacy and confidentiality of all information. The transfer of any participant key information will only occur through a password protected and encrypted system. Only individuals assigned to the study will have access to the passwords and will be able to review or access the participant key information. Transfer of participant questionnaire booklets for the purpose of putting the information into the dataset will only occur in person. The questionnaire booklets will not contain any identifiable information apart from your assigned code. All data entered into dataset for analysis is identified only by a participant code.

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 information about you collected on this study will be kept in an electronic database, which will be double password-protected, firewall-protected and access-restricted to people involved in this study. As soon as possible, any link between your identity and the research information will be destroyed which means research information about you will be permanently de-identified. Personal identifying information will be destroyed no later than at the closure of the study. The research information collected about you for this study will not be used for any additional research activity beyond what you have approved by signing this consent.

The study staff advises that you protect your copy of the informed consent document. A breach of confidentiality could occur if you inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate action to assist you.

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

**ENTITLEMENT TO CARE:**

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. If you believe that you have been harmed, notify the researchers as soon as possible. You may also need to tell your regular doctors. If you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may also contact the 59 Authorized Institutional Official (AIO), 210-292-3355 or Brooke Army Medical Center (BAMC) Protocol Coordinators, 210-916-2598 or BAMC Judge Advocate 210-916-2031.

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Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations. If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study. No blood or tissue samples will be taken as part of this study.

***For California Participants Only***

**California Experimental Subject's Bill of Rights**

(a) Be informed of the nature and purpose of the experiment.

(b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

(c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

(d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

(e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

(f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

(g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

(h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

(i) Be given a copy of the signed and dated written consent form as provided for by Section 24173 or 24178.

(j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

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**CONTACT INFORMATION:**

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

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

Principal Investigators:

| | | |
|---|---|---|
| Dr. Karen Weis | Duty Phone: 210-829-3987 | After-Hours Phone: 850-362-9227 |
| Lt Col Jacqueline Killian (Joint Base San Antonio) | Duty Phone: 210-292-0027 | After-Hours Phone: 757-810-0686 |

Alternate Contact:
Associate Investigators:

| | | |
|---|---|---|
| Dr. Monica Lutgendorf (Naval Medical Center San Diego) | Duty Phone: 619-532-7020 | After-Hours Phone: 619-723-8719 |
| Megan Petersen (Madigan Army Medical Center) | Duty Phone: 253-969-1338 | |

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/ST CRD, 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 59 MDW AIO at 210-292-3355.

All oral and written information and discussions about this study have been in English, a language in which you are fluent. If you agree to participate in this research study, please sign this section. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction.
- Your consent to participate in this study is given on a voluntary basis.

A signed copy of this form has been given to you.

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**PARTICIPANT'S SIGNATURE** **DATE**

_____

**PARTICIPANT'S PRINTED NAME**

_____

**PARTICIPANT'S ADDRESS (street, city, state, zip)**

_____ _____ (____) _____ -_____

**ADVISING INVESTIGATOR'S SIGNATURE** **DATE** **PHONE#**

_____

**PRINTED NAME OF ADVISING INVESTIGATOR**

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