Subject Consent Form

Macon & Joan Brock Virginia Health Sciences at Old Dominion University *Institutional Review Board*

STUDY TITLE:
Glucose Control in Type 2 Diabetes in Pregnancy

We are inviting you to take part in a research study about pregestational Type 2 diabetes, where we hope to examine the effect of physical activity on glucose levels in pregnant patients. This page is intended to provide you with key information to help you decide whether or not to participate. The detailed consent form follows this page. Please ask the research team questions. If you have questions later, the contact information for the principal investigator in charge of this study is below.

WHAT IS THE PURPOSE, WHAT ARE THE PROCEDURES, AND WHAT IS THE DURATION OF THIS STUDY?

The purpose of this study is to evaluate the effect of physical activity on glucose control in pregnant patients with pregestational Type 2 diabetes. Participants will be randomized to one of two groups. Each group will receive one of two types of counseling regarding physical activity. Both groups will complete a fasting blood draw and urine sample at enrollment and then between 34 and 36 weeks gestation for the testing of metabolomics. All participants will also have an evaluation of body composition at these two time points. Depending on the gestational age at enrollment, participation will last between 8 weeks and 37 weeks. All participants will receive a continuous glucose monitor and Fitbit for use and data collection. Additionally, electronic medical records will be accessed to confirm eligibility criteria. Any data collected from electronic medical record will be de-identified.

WHAT ARE SOME REASONS YOU MIGHT CHOOSE TO PARTICIPATE IN THIS STUDY?

The primary reason for choosing to participate in this study is to contribute to maternal diabetes research. This study is a very low risk study and will provide physicians with information to better counsel patients with gestational diabetes.

WHAT ARE SOME REASONS YOU MIGHT CHOOSE NOT TO PARTICIPATE IN THIS STUDY?

Some reasons to not participate in this study is inconvenience with exercise participation.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

If you decide to take part in the study, it should be because you really want to volunteer for it. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer. You are free to withdraw from the study at any time.

WHAT IF YOU HAVE QUESTIONS OR CONCERNS?

For questions about the study, contact the investigator, Marwan Ma'ayeh, at MaayehMG@odu.edu

For questions about your rights as a research participant, contact a member of the Institutional Review Board through the Institutional Review Board office at (757) 446-8423.

Please continue to the next page for detailed information about the study.

STUDY TITLE
Glucose Control in Type 2 Diabetes in Pregnancy

INVESTIGATORS
Marwan, Ma'ayeh, M.D. Macon and Joan Brock Virginia Health Sciences at Old Dominion University
Morgan Scaglione, M.D. Macon and Joan Brock Virginia Health Sciences at Old Dominion University
George Saade, M.D. Macon and Joan Brock Virginia Health Sciences at Old Dominion University

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to better understand the effect of exercise on pregestational Type 2 diabetes in pregnancy.

WHY ARE YOU BEING ASKED TO TAKE PART?
You are being asked to participate in this research project because you are pregnant and have a known or new diagnosis of Type 2 Diabetes.

This is a research study. This study includes only individuals who choose to take part. Please take your time to make your decision and feel free to ask any questions you might have.

WHAT ARE SOME IMPORTANT DETAILS ABOUT THIS STUDY?
At this local site about 40 people will take part in this study. You may be withdrawn from the study if the provider no longer deems that participation is in your best interest. Participation in this research study will not affect any other aspect of your care. No inducements will be offered to terminate a pregnancy. Those engaged in this study will not take any part in decisions regarding termination of pregnancy and if you desire termination or have questions regarding the viability of your pregnancy, you will be referred to a non-investigator for appropriate care.
Clinically relevant research results will not be disclosed to you, including any that might apply individually.

WHEN SHOULD YOU NOT TAKE PART?
If any of the following conditions are true, you should not take part in this study:
- You are not pregnant
- You are pregnant with multiples (such as twin or triplet pregnancy)
- If you have not been diagnosed with type 1 or type 2 diabetes prior to pregnancy or in the first trimester
- You are unable to walk for up to 20 minutes at a time

WHAT IS INVOLVED IN THE STUDY?
You will receive standard counseling regarding physical activity in pregnancy, which includes recommendation for at least 150 minutes of moderate intensity aerobic activity per week in pregnancy. In addition to this, you will participate in post-prandial walks for 20 minutes after each meal (breakfast, lunch, and dinner). All participants will receive a continuous glucose monitor and

Fitbit. The continuous glucose monitor requires changing every 10 days, and you will be provided with continuous glucose monitors at no cost to you for the duration of your pregnancy. The EVMS Maternal Fetal Medicine Diabetes team will provide you with training on applying the continuous glucose monitoring as well as assist you with troubleshooting and replacing devices as needed. The Fitbit should be worn at all times, and not just at the time of exercise.
By participating in this study, you are agreeing to share your glucose monitor and Fitbit data via the share function electronically.
Both groups will be asked for a fasting blood draw and urine sample at enrollment and between 34 and 36 weeks gestation. An evaluation of body composition utilizing bioelectrical impedance analysis will also be performed at these two time points. This is a measurement of your body composition (water, fat mass, muscle mass). This procedure involves placing small adhesive patches on your skin that can measure electricity running through the body. You will not be able to sense the electricity being delivered or running through the body. This test will last approximately 10 minutes, and it allows us to determine your body's fluid, fat, and muscle content. All of these testswill be performed concurrently with a provider visit, and therefore no additional visit would be needed for this. The amount of blood that will be collected is approximately 1 tablespoon.
For the remainder of the study, the principal investigator and co-investigators will use electronic medical records to assess maternal, fetal, and metabolomic outcomes. All data will be de-identified.

What Are the Risks of the Study?

A risk associated with allowing your data to be saved is the release of personal information from your study record. We will strive to protect your records so that your personal information (like name, address, social security number and phone number) will remain private.
There are no known risks or discomforts related to the bioelectrical impedance analysis. Minor discomfort is associated with the placement and removal of the electrodes on your skin.
Having blood samples taken may cause some discomfort, bruising, minor infection, or bleeding. If this happens, it can be easily treated. While walking is low-impact, repetitive strain can lead to foot and ankle injuries. Pay attention to any discomfort or pain and notfiy a member of our research team if you have concerns.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. There is no guarantee that you will personally benefit from taking part in this study. We hope the information learned from this study will benefit other people with gestational diabetes in the future.

What Other Options Do You Have?

You may choose <u>not</u> to participate in this research study.

What about Confidentiality?

In conducting this research study, it may be necessary for the research team to send information about you and your health to individuals in other organizations. This information may include what we call "protected health information (PHI)," which includes personal information about you. It will be shared with others only as described below:

Description of Your PHI to Be Disclosed	Organization and Person (or their title) Disclosing Your PHI	Organization and Person (or their title) Receiving Your PHI	Purpose of Disclosure
MRN	EVMS: Dr. Marwan Ma'ayeh, M.D.	EVMS Research Team: Morgan Scaglione, M.D. George Saade, M.D.	To access chart regarding diabetes diagnosis.
Maternal, Fetal, and Metabolomic Outcomes	EVMS, CHKD, and Sentara: Allscripts, Powerchart, and EPIC	EVMS Research Team: Morgan Scaglione, M.D. George Saade, M.D.	To collect data on maternal, fetal and metabolomic outcomes during allotted study period.

All protected health information will be maintained in strict confidence as required by law. However, your protected health information may be disclosed if required by law. Once your protected health information is disclosed for research, such as to the sponsor, federal privacy laws may no longer protect the information.

- If you refuse to give your approval for your personal information to be shared as described in this consent form, you will not be able to be in this study. However, your choice will not affect any medical benefits to which you are entitled.
- By signing this consent form to participate in the study, you are allowing the research team to share PHI, as described in this consent form.
- You have the right to cancel your approval for the sharing of PHI. If you cancel your approval, you will have to leave the study. All information collected about you before the date you cancelled will not be used/continue to be used. To cancel your approval, you must notify Marwan Ma'ayeh in writing at 825 Fairfax Ave, Suite 310, Norfolk, VA 23507.
- Your approval for the sharing of personal information about you for this study expires at the end of the study.
- You also have the right to review your research records, or someone you designate may review your research records on your behalf, once the study has ended unless prohibited by law.
- Any research information in your medical record will become a permanent part of that document.

Your study records may be reviewed and/or copied in order to meet state and/or federal regulations. Reviewers may include, for example, an Macon & Joan Brock Virginia Health Sciences at Old Dominion UniversityInstitutional Review Board.

Information learned from this research may be used in reports, presentations and publications. None of these will personally identify you.

WHAT WILL PARTICIPATION IN THE STUDY COST OR PAY?

There are no costs to you associated with taking part in this study. The continuous glucose monitors and Fitbit devices will be provided at no cost to your or your insurance company during the pregnancy. The devices will need to be returned at the time of delivery.

WHAT IF YOU GET INJURED?

Macon & Joan Brock Virginia Health Sciences at Old Dominion Universitywill not provide free medical care for any sickness or injury resulting from being in this study. Financial compensation for a research related injury or illness, lost wages, disability, or discomfort is not available. However, you do not waive any legal rights by signing this consent form. No injuries are anticipated in this study.

WHAT ABOUT THE COLLECTION OF DATA/TISSUES/SPECIMENS?

You are in a study where identifiable date is collected as part of your participation in the research study. Right now, there are no plans to use the *data* for another research study. However, the identifiers might be removed and, after such removal, the *data* could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.
The blood draw and urine collected at enrollment and between 34 and 36 weeks gestation will be collected at an already scheduled clinic appointment. Therefore, no additional appointment will be needed for this. It will be drawn by phlebotomy staff or research nurses. The sample will be kept in a secure area until processing, at which point after processing it will stored at an EVMS repository de-identified. There will be no cost to you.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Taking part in this study is your choice. If you decide not to take part, your choice will not affect any medical benefits to which you are entitled. You may choose to leave the study at any time. If you do leave the study, discuss it with the investigator who will help you do so in the safest way. If you leave, the study it will not result in any penalty or loss of benefits to you.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Virginia law says that if you or anyone associated with the study is exposed to the other person's body fluids that might transmit the virus that causes AIDS or the Hepatitis B or C virus:

- The person whose body fluids were involved is deemed to have consented to testing for those viruses so that no further consent is necessary to test the person for these diseases; and,
- Those test results will be released to the person who was exposed and to the health department as required by Virginia law.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions about the study, contact the investigator, Marwan Ma'ayeh, M.D., at (757) 446-7900.

For questions about your rights as a research participant, contact a member of the Institutional Review Board through the Institutional Review Board office at (757) 446-8423.

If you believe you have suffered an injury as a result of your participation in this study, you should contact the principal investigator, Marwan Ma'ayeh at 757-446-7900. You may also contact Betsy Conner, director, Human Subjects Protection Program and IRB office at Macon & Joan Brock Virginia Health Sciences at Old Dominion University, at (757) 446-5854.

SIGNATURE

You will get a copy of this signed form. You may also request information from the investigator. By signing your name on the line below, you agree to take part in this study and accept the risks.

_____ Signature of Participant/	_____ Typed or Printed Name	_____ Relationship to Subject	___/___ /___ MM/ DD/ YY

STATEMENT OF THE INVESTIGATOR OR APPROVED DESIGNEE

I certify that I have explained to the above individual the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised and have witnessed the above signature. I have explained the above to the volunteer on the date stated on this consent form.

_____ Signature of Investigator or Approved Designee	_____ / _____ / _____ MM/ DD/ YY

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