IRB #: _____
IRB APPROVAL DATE: _____
EXPIRATION DATE: _____

Subject Consent Form

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

STUDY TITLE

EFFECTS IF A BEDTIME SNACK ON FASTING BLOOD SUGAR LEVELS IN PATIENTS WITH GESTATIONAL DIABETES

Key Summary of Information

We are inviting you to take part in a research study about how a bedtime snack will influence blood sugar levels in patients with gestational diabetes. 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 determine if a bedtime snack improves fasting blood sugar levels in patients with gestational diabetes. You will be randomized to a group that eats a mixed protein-carbohydrate snack at bedtime or a group that does not. You will be enrolled in this study from between 24 to 33 weeks gestation until the time that you deliver your baby. After you deliver your baby, the study team will collect information about you and your baby from your medical record, until the time both you and your baby are discharged from the hospital, or up to 42 days after delivery.

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

The information that will be obtained from this study will contribute to advancements in the field of Obstetrics and Gynecology and will help future researchers determine the best methods of managing gestational diabetes.

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

You might choose not to participate because you want to choose whether you eat a bedtime snack. You may also choose not to participate if you do not wish to use continuous glucose monitoring or undergo a finger stick test for blood sugar testing.

For a complete description of the risks of this study, please refer to detailed consent form.

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 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.

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

STUDY TITLE

Effects of a Bedtime Snack on Fasting Blood Sugar Levels in Patients with Gestational Diabetes

INVESTIGATORS

Marwan Ma'ayeh, MD; Morgan Scaglione, MD
Macon and Joan Brock Virginia Health Sciences at Old Dominion University

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine whether a mixed protein-carbohydrate snack leads to improved blood sugar levels in patients with gestational diabetes.

WHY ARE YOU BEING ASKED TO TAKE PART?

You are being asked to participate in this research project because you are a pregnant woman between 24 weeks 0 days and 33 weeks 6 days gestation who has been diagnosed with gestational diabetes.

This is a research study. This study includes only people 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 134 people will take part in this study. We will need you to be in the study for until you deliver your baby.

Clinically relevant research results will not be disclosed to participants, including any that might apply individually.

WHEN SHOULD YOU NOT TAKE PART?

If you have any of the following conditions or are taking any of the medications listed below, you should not take part in this study:

- If you are currently on anti-diabetic medication, like metformin or insulin
- Known major fetal anomaly or chromosomal abnormality

Additionally, if you are allergic to the snacks involved in the study (see next page for full list), you should not take part.

WHAT IS INVOLVED IN THE STUDY?

You will be "randomized" into one of the study groups described below. This means that you will be assigned into a group by chance. It is like flipping a coin. A computer program may do this - neither you nor the investigator will be able to choose what group you will be in. You will have an equal chance of being placed in any group.

The following are standard procedures that will be done because you will be in this study:

For the no bedtime snack group:

- Standard diabetic counseling, which you will receive even if you do not participate in this study

The following are experimental procedures that are being tested in this study:

For the bedtime snack group:

- Standard diabetic counseling, plus instructions to eat a specific snack with ~15 g of carbohydrates before bed
- The snack can be:
    - 1 Tbsp peanut butter with 3 Triscuits;
    - 1 Tbsp almond butter with 1 Graham Cracker; or
    - 3 Tbsp of Planters® Trail Mix

Your blood sugar levels will be collected via continuous glucose monitoring or finger stick test. We will need you to follow your cohort's procedures for the remainder of your pregnancy.

There will be a follow-up visit one week after your enrollment, where you will be asked to fill out a survey about your experience.

We will also collect data on your pregnancy outcomes, including information on the health of your baby following delivery. We will collect outcome information until you and your baby are discharged from the hospital. We are collecting this data because your blood sugar control is important to your baby's health, so we want to track the relationship between average blood sugar and infant outcomes.

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.

Data is mixed on whether a bedtime snack leads to better fasting glucose levels. Some studies show that fasting glucose levels deteriorate with a bedtime snack, which is a risk associated with participation in this study.

There also may be other side effects that are unknown and we cannot predict.

For more information about risks and side effects, ask the investigator or contact 757-446-7900.

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. Eating a snack before bed may lead to better fasting blood glucose levels. 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 not to participate in this research study. You may eat a bedtime snack without taking part in this study.

Please talk to your regular doctor or health care provider about these and other options.

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 persons 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
Maternal medical, surgical, obstetrical, and social history; maternal and fetal outcomes	Sentara EPIC medical records	Principal investigator and research team members	Conducting the research study
Maternal medical, surgical, obstetrical, and social history; maternal and fetal outcomes	EVMS Medical Group Allscripts medical records	Principal investigator and research team members	Conducting the research study

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 continue to be used. To cancel your approval, you must notify Marwan Ma'ayeh, MD in writing at 825 Fairfax Avenue, Norfolk VA 23507.
- Your approval for the sharing of personal information about you for this study does not expire 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, Macon & Joan Brock Virginia Health Sciences at Old Dominion University Institutional Review Board and the Office for Human Research Protections (OHRP).

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?

You are responsible for the costs associated with buying the bedtime snacks.

You will receive no payment for taking part in this study.

What If You Get Injured?

In the case of injury or illness resulting from this study, emergency medical treatment is available and will be provided by Sentara Norfolk General and paid for by your insurance. Further medical care and/or hospitalization resulting from this injury or illness will be charged to your insurance.

Macon & Joan Brock Virginia Health Sciences at Old Dominion University and Sentara Norfolk General Hospital will 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.

What About the Collection of Data?

You are in a study where data is collected as part of your participation in the research study. This data will not be used or distributed for future research studies by the investigator or other researchers. After all of the study testing is complete, the data and specimens will be destroyed.

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.

The investigator may decide to take you off this study if you cancel your approval or it is in the best interest of your health.

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

Whom Do You Call if You Have Questions or Problems?

For questions about the study, contact the investigator, Dr. Ma'ayeh, 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, Dr. Marwan Ma'ayeh at 757-446-7900. You may also contact Betsy Conner, director, Macon & Joan Brock Virginia Health Sciences at Old Dominion University Human Subjects Protection Program and IRB office, at (757) 446-5854.

FDA Clinical Trial Registration

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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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