Women & Infants | A MEMBER OF Care New England

Women & Infants Hospital of Rhode Island

Informed Consent for Research

Project Title:	Timed ambulation and outcomes in patients with gestational diabetes	
Principal Investigator:	**Anna Whelan, MD**	Telephone: **(401) 274-1122 x47463**
Supported by:	**Division of Maternal Fetal Medicine**	

Key Information for Research

- You are being asked to take part in a research study because you have been diagnosed with gestational diabetes and you plan to receive your care at the Diabetes in Pregnancy Program.
- The **purpose** of this research study is to assess how different levels of activity effect pregnancy outcomes in patients with gestational diabetes
- Your participation includes wearing a device to track your activity levels at all times when awake, weekly check-ins with research staff during your pregnancy and allowance of study team to collect pregnancy and reproductive health information from medical records, and entry of this information into our database.
- Your information, without any identifiers, may be **used in future research studies** or distributed to other researchers for future studies without additional informed consent.
- There are no direct benefits to you participating in this study however this may benefit other women like you in the future from information learned from this study. For complete description of benefits, see detailed consent form.
- The risks of this study include: 1) use of your time for consent process and 2) use of your information in a database for research use 3) breach of confidentiality from the use of your data
- **Your participation is voluntary** and it is up to you to decide to participate.
- If you decide to **not participate** in this research project, **you will not lose any services, benefits or rights you would normally have before this research study.**
- The person in charge of this study is **Dr. Anna Whelan** of Women & Infants Hospital, Department of Obstetrics & Gynecology. If you have any questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: **(401) 274-1122 x47463.**
- If you have any questions or concerns about your rights as a volunteer in this research, contact Women & Infants Hospital Director of IRB Administration between 8:00am and 5:00pm, Monday-Friday at 401-453-7677.

Introduction

Please read this form carefully. The purpose of this form is to provide you with important information about you taking part in a research study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If any of the statements or words in this form are unclear, please let us know. We would be happy to answer any questions. You have the right to discuss this study with another person who is not part of the research team before making your decision whether or not to be in the study.

Taking part in this research study is up to you. If you decide to take part in this research study we will ask you to sign this form. We will give you a copy of the signed form. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff. The person in charge of this study is Dr. Anna Whelan. We will refer to this person as the "researcher" throughout this form.

A. The Nature, Duration and Purpose of This Trial:

What is the purpose of this study?

The purpose of this study is to see how different levels of activity effect pregnancy outcomes in patients with gestational diabetes

Why am I being asked to take part in this research?

We are asking you to take part in this study because you have been diagnosed with gestational diabetes and are planning to receive care in conjunction with the Diabetes in Pregnancy Program through the Division of Maternal Fetal Medicine

About 84 subjects will take part in this research study at Women and Infants Hospital (WIH).

How long will I take part in this study? How much of my time will this research take?

If you agree to take part, your participation will last for the remainder of your pregnancy. You will be in touch with the research team weekly or biweekly when you review your blood sugars with the diabetic nurses. Your participation in the study will end after you are admitted for delivery of your baby, however the research team may still access your and your baby's medical records to obtain follow-up information on you and your baby.

B. The Means By Which The Study Is To Be Conducted:

What will I be asked to do? What will happen if I take part in this research study?

If you agree to take part in this study, you will be randomly assigned to one of two groups, one group which will be instructed on a specific timing of exercise and another which will be provided routine activity counseling. You will be provided with a FitBit device which you will wear on your wrist every day during the study period during all waking hours. Your activity monitor will be connected to a free app on your phone and the data from your app will be reviewed by the research team on a weekly or biweekly basis for the remainder of your pregnancy. The study will end when you are admitted to the hospital to have your baby.

What are the study procedures?

If you agree to take part in this study, we will ask you to sign the consent form before we do any study procedures. Routine prenatal diabetes care: you will continue to meet with your doctors, the diabetes nurse educators during your participation in the study. Nutrition counseling: you will continue to meet with the registered dietician regularly during your participation in the study
The study-related procedures include:

1. Activity monitoring: you will be asked to wear an activity monitor during all waking hours (you will need to plug it into the charger when you are sleeping). The monitor will be linked to an application on your smartphone. You will then share the data from your monitor with the research team on a weekly or biweekly basis. The research team will be able to view your following recorded data which is uploaded via your FitBit application on your phone:
    a. Number of steps taken
    b. Distance walked
    c. Type and timing of exercise
    d. Calories burned
2. Review of medical records: the study researchers will be able to access your and your baby's medical records to obtain information about your pregnancy, delivery and diabetes.

Randomization
We will assign you by chance, like a coin toss, to one of two study groups. You will be either assigned to a scheduled activity group or to routine activity group. You and the researcher cannot choose your study group. You will have equal chances of being assigned to either study group.

C. The Risks, Hazards, and Discomforts of the Study:

Will there be any risks of taking part in this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

Privacy and re-identification risks

We will be collecting information about you and your baby. While every effort will be made to keep this information private, there is a small risk that others could see sensitive personal information about you. Through all stages of data collection, storage, sharing, and analysis, your privacy and confidentiality will be protected, with these exceptions: the research team is required to report child abuse and neglect, or substantial risk of harm to self or others to state or local authorities.

A number of efforts will be made to keep your information confidential. These are outlined in the Privacy and Confidentiality of this form. Despite these efforts, it may be possible to identify you based on the information in these databases and other public information (including information you tell people or post about yourself). The risk of this happening is currently very low.

It is possible also that someone could get unauthorized access or break into the system that stores information about you. Every precaution will be taken to minimize this risk.
There also may be other privacy risks that we have not foreseen.

D. The Possible Benefit or Lack of Benefit to Myself:

Are there any benefits from being in this research?

You may or may not benefit from taking part in this study. We cannot guarantee or promise that you will receive any direct benefit by participating in this study. Possible benefits to you include improved control of your blood sugars during pregnancy. The knowledge gained from this study may help doctors determine better ways to take care of patients with diabetes during pregnancy.

E. The Possible Alternative Procedures:

What alternatives are available? If I do not want to take part in this research study, what options do I have?

You may choose not to take part in this research study. Participation in this study is voluntary. If you choose not to take part, you will receive normal prenatal care.

What if I want to stop? Can I stop participation?

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason. No matter what you decide, there will be no penalty or loss of benefit to which you are entitled. If you decide to withdraw from this study, the information that you have already provided will be kept confidential. You cannot withdraw information collected prior to your withdrawal.

Your data may be stored and shared for future research. They may be shared with researchers/institutions outside of WIH without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to

identify and destroy them. Therefore, you will not receive any results or financial benefit from future research done on your samples or data.

F. Financial Information

Who is funding this research study?

The Division of Maternal Fetal Medicine at Women & Infants Hospital of Rhode Island is funding this study.

Please ask **Dr. Anna Whelan** if you have any questions about how this study is funded.

Will I be paid for my participation?

You will not be paid for your participation; however you will be able to keep the activity monitoring device after completion of the study.

Will it cost me anything to participate?

While you are in this research study, the cost of your routine clinical care will be billed to you/your insurance company in the usual way. If your insurance does not pay for all the costs, you will be responsible for the remaining costs, including any co-payments and deductibles as required by your insurance. If you do not have insurance, you will be responsible for the costs of taking part in this study.

WIH has programs to help uninsured and underinsured families see if financial assistance is available. If you need financial assistance, you can talk with a financial coordinator.

G. Privacy and Confidentiality

How will you keep my information protected/confidential?

We will keep the records of this study confidential by only using the minimal information necessary and by removing all information that can be linked to you from the records**.** The study data will be stored at the hospital on a protected network. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The following people or groups may review your study records for purposes such as quality control or safety:

- The Researcher and any member of her research team
- Authorized members of Woman and Infants Hospital who may need to see your information, such as administrative staff members and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study)

The study data will be stored on a secured web-based database called REDCap.

The results of this study may also be used for teaching, publications, or presentations at professional meetings to inform other doctors and health professionals. We will keep your

identity private in any publication or presentation about the study. If your individual results are discussed, your identity will be protected by using a code number or pseudonym rather than your name or other identifying information.

By law, WIH is required to protect your private information. The investigator and staff involved in the study will keep your private information collected for the study strictly confidential. Please refer to the section at the end of this document titled "Authorization to Use or Disclose Health Information for a Research Study" that explains more specifically how your personal information will be protected.

If, during your participation in this study, we have reasonable cause to believe that child abuse is occurring, this will be reported to authorities as required by law. The researcher will make every reasonable effort to protect the confidentiality of your research information. However, it might be possible that a civil or criminal court will demand the release of identifiable research information.

If, during your participation in this study, we have reason to believe that you are at risk for harming yourself or others, we are required to take the necessary actions. This may include notifying your doctor, your therapist, or other individuals. If this were to occur, we would not be able to assure confidentiality.

Who can I contact if I have questions or concerns about the research, or if I have questions about my rights as a research subject?

If you have questions about the study, call the study doctor, **Dr. Anna Whelan,** at (401)274-1122. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at Women & Infants Hospital has reviewed and approved this study. The IRB reviews at all research studies and makes sure research subjects' rights and welfare are protected. If you want to speak with someone ***not*** directly involved in this research study, you may contact the Director of IRB Administration at Women and Infants Hospital at (401) 453-7677. You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Women & Infants | A MEMBER OF Care New England

Women & Infants Hospital of Rhode Island

HIPAA Authorization

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

Project Title:	Timed ambulation and outcomes in patients with gestational diabetes		
Principal Investigator:	**Anna Whelan, MD**	Telephone:	**401-274-1122**
Supported by:	**Division of Maternal Fetal Medicine**		

What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. **HIPAA** (Health Insurance Portability and Accountability Act of 1996) is United States legislation that provides data privacy and security provisions for safeguarding medical information. Under these laws, the Women and Infants Hospital cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the institution or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form for consent and authorization. Authorization is separate from and in addition to informed consent, although the two forms may be combined into one document. This form describes the different ways that WIH can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by WIH it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

By signing this document, you are permitting Women & Infants Hospital (WIH) and the doctors, nurses and other staff involved in this research to use your personal health information collected about you for research purposes within our institution. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you. You are also allowing WIH staff to disclose your personal health information to outside organizations or people involved with the processing of this study as described in this document.

Why is my health information needed?

The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent. If you sign this document, you give WIH permission to collect, use or disclose (release) your health information that identifies you for the research study described above.

What health information will be used and disclosed as part of this research?

The health information that we may use or disclose (release) for this research includes:

- Information from your medical records at WIH including information about your pregnancy, delivery and postpartum care.
- We will also collect information about how your baby does after delivery and if they have any complications or need any special care.

Who may use or disclose my health information during the research?

Researchers and others need to review and/or record your research records to conduct this research, assure the quality of the data and to analyze the data. The health information listed above may be used by and/or disclosed (released) to:

The health information listed above may be used by and/or disclosed (released) to:

- Members of the research team and other authorized staff at WIH;
- People from agencies and organizations that perform independent accreditation and oversight of research.

WIH is required by law to protect your health information. The research staff will only allow access to your health information collected for this study to the groups listed above for the purposes stated. By signing this document, you authorize WIH to use and/or disclose (release) your health information for this research. Some of those persons or organizations listed above who receive your health information may not be required to protect it in accordance with Federal privacy laws (such as the Privacy Rule). If permitted by law, they may be allowed to share your information with others without your permission.

Federal and state law requires us to review any inadvertent disclosure (release) or inappropriate access of your health information that we become aware of. If we become aware your information has been inadvertently disclosed (released) or inappropriately accessed, Compliance Services at Care New England will complete an investigation to determine if there is a breach of your individual health information that requires us to notify you.

Am I required to sign this Authorization?

You do not have to sign this Authorization. Your decision to sign or not sign this form will not affect your standard medical treatment, payment or enrollment in any health plans or affect your eligibility for benefits. However, if you choose not to sign this form, you may not take part in this research study.

Women and Infants Hospital will continue to provide you with health care services even if you refuse to sign this authorization form.

Can I withdraw my Authorization?

You may change your mind and revoke (take back) this Authorization at any time.

If you revoke this Authorization, you may no longer participate in the research described in this Authorization.

Even if you revoke this Authorization, WIH and Dr. Anna Whelan may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. Your request to revoke this Authorization becomes effective when WIH receives it.

To revoke this Authorization, you must submit a request in writing to the investigator:

Dr. Anna Whelan
101 Dudley Street
Providence, RI 02905

Does my Authorization Expire?

This Authorization does not have an expiration date.

Optional Elements of Authorization

- Your health information will be used or disclosed when required by law.
- Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.
- No publication or public presentation about the research described above will reveal your identity without another authorization from you.
- If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Will you be able to access your records?

You will be able to request access to the information we collect from you for the study when the study is completed. During your participation in this study, you will not be able to access the results of the tests, surveys, and evaluations we do for the research study. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you research information that is not part of your medical record.

Signature Page
Consent to Take Part in this Research and Authorization to Use and Disclose Health Information for the Research

SIGNATURE OF PERSON OBTAINING AUTHORIZATION
The research study and consent form have been explained to you by:

_____
Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent/Authorization Date

SIGNATURE OF SUBJECT
By signing this form, you are indicating that you have read the information in this consent form including risks and possible benefits; You have been given the chance to ask questions and your questions have been answered to your satisfaction; and you agree to participate in the research study and agree to allow your health information to be used and shared as described above. If you don't agree to the collection, use and sharing of health information, you cannot participate in this study.

_____
Name of Subject

_____ _____
Signature of Subject Date

PARENTAL PERMISSION

By signing this form, you are indicating that you have read the information in this consent form including risks and possible benefits; You have been given the chance to ask questions and your questions have been answered to your satisfaction; and you agree to allow your child to participate in the research study and agree to allow your child's health information to be used and shared as described above. If you don't agree to this collection, use and sharing of health information, you cannot participate in this study.

_____ _____
Signature of Parent Date