*East Carolina University*

# Informed Consent to Participate in Research

Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: ENHANCED by Mom-Pediatrics
Principal Investigator: Dr. Linda May, MS, PhD
Institution/Department or Division: Division of Surgical Sciences
Address: 1851 MacGregor Downs Rd, MS 701, Greenville, NC 27834
Telephone #: 252-737-7072

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Researchers at East Carolina University (ECU) study problems in society, health problems, environmental problems, behavior problems and the human condition. Our goal is to try to find ways to improve the lives of you and others. To do this, we need the help of volunteers who are willing to take part in research.

## Why is this research being done?

The purpose of this research is to help improve the health of mothers and their children. The decision to take part in this research is yours to make. By doing this research, we hope to learn what activities during pregnancy affect, or do not affect, the health and growth of your child.

## Why am I being invited to take part in this research?

You are being invited to take part in this research because you have recently delivered your baby. If you volunteer to take part in this research, you will be one of about 80 women to do so.

## Are there reasons I should not take part in this research?

If you do not believe that you want your infant and yourself to participate in the measurements, then you should not participate in this study.

## What other choices do I have if I do not take part in this research?

You can choose not to participate. If you would like to find out the body composition or heart health of your child, then you can contact your child's pediatric clinic.

## Where is the research going to take place and how long will it last?

The research procedures will be conducted at an ECU clinic that houses the MRI. During the length of the study, you will need to go to the ECU clinic up to two times. The total amount of time you will be asked to volunteer for this study is approximately 2 hours during 1-2 visits.

## What will I be asked to do?

You are being asked to do the following:

- At 1 month of age, we will take the following measures: weight, BMI, body fat with calipers, and body measures (arm, leg, waist) to determine your child's body fat amount.
- At 1 month of age, your child will have an MRI done by a health professional to determine bone, fat, and muscle mass. This will be done from neck to feet.
- At 1 month of age, we will have a health professional do an ultrasound of your baby's heart to record heart measures to determine his/her heart health.

- At 1 month of age, we will have a health professional do a pediatric ECG to determine how healthy your baby's heart is in relation to your activity.
- At 1 month of age, we will take a small amount of blood (about 1 Tablespoon) from your child.
- At 1 month of age, we will have you complete: nutrition & activity questionnaires for you and your baby.

## What possible harms or discomforts might I experience if I take part in the research?

There are possible risks (the chance of harm) from this research. Your child will have a brief moment of discomfort during the blood draw. Your child may experience slight discomfort due to the sticky tape for the EKG recording. Your child may experience minor discomfort during the body fat measure as this involves 3 pinches on the skin; this feeling will be minor and temporary.

## What are the possible benefits I may experience from taking part in this research?

There are no direct benefits for participating in the study.

## Will I be paid for taking part in this research?

We will provide $50 gift card to thank you and your child for participating in this study.

## What will it cost me to take part in this research?

Dr. May's research funds will pay the costs of all procedures, if not covered by your insurance.

## Who will know that I took part in this research and learn personal information about me?

To do this research, ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- Any agency of the federal, state, or local government that regulates human research. This includes the Department of Health and Human Services (DHHS), the North Carolina Department of Health, and the Office for Human Research Protections
- The University & Medical Center Institutional Review Board (UMCIRB) and its staff, who have responsibility for overseeing your welfare during this research, and other ECU staff who oversee this research.
- People designated by Vidant Medical Center and Vidant Health;
- Additionally, the following people and/or organizations may be given access to your personal health information and they are: qualified research study staff.

## How will you keep the information you collect about me secure? How long will you keep it?

Once data is entered into the database, then it will be de-identified with a 3 digit number. Only Dr. May will hold a separate database with the identifiers; this will be kept in case of research audits. The database with identifiers will be kept password-protected file on Pirate drive. All de-identified data will be kept on a password-protected file within the protected Pirate drive file as well. The de-identified data will be kept on the password protected server. Upon publication only group, de-identified data will be presented.

## What if I decide I do not want to continue in this research?

If you decide you no longer want to be in this research after it has started, you may stop at any time. You will not be penalized or criticized for stopping. You will not lose any benefits that you should normally receive. A written or verbal statement must be given to Dr. May.

## Who should I contact if I have questions?

The people conducting this study will be available to answer any questions concerning this research, now or in the future. You may contact the Principal Investigator at 252-737-7072 (M-F days, between 7am-4pm).

If you have questions about your rights as someone taking part in research, you may call the Office for Human Research Integrity (OHRI) at phone number 252-744-2914 (days, 8:00 am-5:00 pm). If you would like to report a complaint or concern about this research study, you may call the Director of the OHRI, at 252-744-1971.

**Is there anything else I should know?**
We would also like to continue to follow you and your child after this visit. You may be contacted in the future for further measures of you and your child.

**I have decided I want to take part in this research. What should I do now?**
The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I know that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

_____ _____

**Participant's Name (PRINT) Signature Date**

**Person Obtaining Informed Consent**: I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person's questions about the research.

_____

**Person Obtaining Consent (PRINT) Signature Date**

_____

***Principal Investigator (PRINT) Signature Date***
***(If other than person obtaining informed consent)***

**As the parent or guardian of _____,**
**(Write your child's name)**

☐ **I grant my permission for Dr. May to include my child in her research project regarding mother and child health. I voluntarily consent to Dr. May using any of the data gathered, about me and my child, for her study. I fully understand that the data will not affect the health or services I, or my child, receive. The information will be kept completely confidential, and will be used only for the purposes of her research study.**

☐ **I do NOT grant my permission for Dr. May to include my child's data in her research project regarding mother and child health.**

**Signature of Parent/Guardian:_____ Date:_____**