Magee-Womens Hospital
of University of Pittsburgh Medical Center
Department of Obstetrics, Gynecology, and Reproductive Sciences

STUDY TITLE: Family Check-Up Heart

KEY INFORMATION

- You are being asked to be in a research study.
- It is up to you to decide whether or not to participate.
- This page is to give you information to help you decide whether or not to participate.
- More detailed information is provided in the rest of this document.
- If you have questions please contact:

Janet Catov, PhD, MS
412-692-8504
catovjm@mwri.magee.edu

Daniel Shaw, PhD
412 624-1836
casey@pitt.edu

The goal of Family Check-Up Heart is to find out if a heart health program combined with a home visitor program to support new parents is effective. All mothers who sign up for this study will receive the home visiting program. Some mothers will be chosen at random to get information about healthy eating, weight loss, smoking, and how to monitor their own weight and blood pressure.

If you agree to be in this research study:

- You will be asked to answer questions about how you and your baby are doing. The questions take about 60 minutes to complete.
- You will be asked to give permission to collect information from medical records.
- You will be contacted about meeting with a trained Family Check-up Coach for an initial meeting, assessment, and Feedback Session. Your Coach may talk with you about topics, such as child development, parenting, breastfeeding, nutrition, and more.
- We will measure your and your baby's weight and blood pressure. You *may* be given a body weight scale and a blood pressure device that sync to your phone. Your readings will be sent to the study team so we can learn if this program affects your weight and blood pressure.
- You may be asked to enroll in The Pittsburgh Study Early Childhood Collaborative.

There may be risks involved in participating in this research study:

- Some of the questions may make you uncomfortable; you may skip these if you want.
- Our study team will be very careful to protect the information you give us, but there is a small risk that someone outside of the study team may find out your answers to the questions.
- You may not receive any benefit from participating in this research.

For more information about the Family Check-Up Heart Study please read the rest of this consent form.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: **Family Check-Up Heart**

Principal Investigators:

Janet Catov, PhD, MS
412-692-8504
catovjm@mwri.magee.edu

Daniel Shaw, PhD
412 624-1836
casey@pitt.edu

Who is being asked to take part in this research study?

We would like to invite you to participate in the Family Check-Up Heart study. In this research study, you will be offered the **Family Check-Up program** to support parents and their young children. We are asking pregnant women and birthing people who recently delivered a baby, are Medicaid-eligible, and live in Allegheny County to participate in the study. We will ask 150 mothers to participate in this study.

If you agree to participate in the Family Check-Up Heart study, you will be offered one of two programs: the traditional version of the **Family Check-Up** or **the Family Check-Up Heart** program. The Family Check-Up Heart program includes all the parts of the traditional Family Check-Up program plus additional parts related to heart health. You will be randomly selected to receive one of these two programs.

For both programs, a Family Check-Up family coach will meet with you for a "check-up" about your child's development and behavior and how to improve your own well-being to support your child's development. The Family Check-Up typically takes place over the course of 3-5 sessions, each about an hour long. These meetings take place at your home or wherever is most convenient for you, including virtually online.

What procedures will be performed for research purposes?

Home visiting services:

- A trained Family Check-Up family coach will spend time getting to know you and your child during an "Initial Interview."
- **Assessment**:
  - Questionnaires: You will complete questionnaires about your child and family relationships, such as your well-being, social support, as well as various health topics including smoking, pregnancy, physical activity, diet, sleep, and more.

- Measurements: Assessments also include measurement of your blood pressure, body mass index, diet quality, exercise, and smoking. We will also measure your child's length and weight.
- Mother-Baby interactions: An important part of the assessment is the family interaction tasks, where you and your child will take part in activities like playing together with toys and puzzles. The Family Check-Up family coach will then highlight parenting strengths during the third meeting, called the Feedback Session.

- **Feedback Session**: The Family Check-Up family coach will meet with you for a conversation about strengths and challenges for your child and family as a whole. You'll be invited to set goals for you and your child to support and maintain strengths, and to address any areas of concern.
- **If you are randomly selected to participate in the Family Check-Up Heart program:**
  - You will also receive feedback about healthy eating and weight loss, stress management, and smoking. You will also learn how to monitor your own weight and blood pressure.
  - **Bluetooth data collection**: You will receive the following bluetooth-enabled devices to keep: A body weight scale, a blood pressure cuff, and a Fitbit. Your weight, blood pressure, and physical activity readings and data will be sent back to the study team to learn about how our program impacts your cardiovascular health.
- After the Feedback Session, you have the option to continue meeting with your family coach to support your child's development and improve parental well-being.
- **Follow up.** We will contact you again after about 6 months to complete a similar survey, meet with your Family Coach and take blood pressure and body mass index measurements for you and your child.

Are there any risks or benefits from participating in this research?

We do not expect any risks or discomforts from participating in the home visiting component of the Family Check-Up study. You may feel uncomfortable answering personal questions. You may refuse to answer any question that makes you uncomfortable.

As with any study, there is also a risk of a breach of confidentiality. This may include any part of your study record. The study team takes every precaution to keep your records confidential. The study team does its best follow up with you by your preferred contact method. Please know there are some additional risks of breach of confidentiality when communicating via email or text.

Participating in the Family Check-Up Heart study may lead to possible health risks from increasing physical activity. Please do not make any major dietary or physical activity challenges without first consulting your primary care provider.

What are possible benefits from taking part in this study?

You will not receive any direct benefit from participation in this research study. However, the results of this research could be of considerable benefit to women, including participants in this study, and to society. Referrals to other types of services will be provided if needed.

Who will know about my participation in this research study?

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

New Information

We will tell you about any new information that we learn that may cause you to change your mind about staying in the study.

Confidentiality & Medical Records

All records pertaining to your involvement in this research study will be stored in a locked file cabinet in the office of the research staff. Electronic information is stored behind firewalls and have specific access permissions. A case number (ID) will indicate your identity on these records. This information will be accessible to the investigators and their research staff listed on the first page of this document. Individuals from the agencies funding this research may review the records as part of their ongoing audit of this project, which will not include any identifiable information. Any information about you or your hospital treatment, including the information we are asking to abstract from your medical records, will be handled in a confidential (private) manner consistent with other hospital medical records and will be labeled with the case number when added to your research records. You will not be specifically identified in any publication of research results.

Bluetooth Data

We are asking your permission to access and use your bluetooth data from the body weight scale, the blood pressure cuff, and the Fitbit via the apps and cloud storage associated with each device. No method of transmitting or storing data is completely secure and there is a risk of third parties unlawfully intercepting or accessing transmissions or private communications. If you do not have secure internet access, we do not encourage the use of unsecured networks. Our research staff can create a personal secure hotspot for the transmission of data to the research team during a home visit. Each device uses

data encryption and they have their own data security terms and privacy policies. You are responsible for reading and understanding the terms and conditions of the privacy policies that apply to your use of these bluetooth-enabled devices.

Medical records
As part of this research study, we are asking your permission to use your medical records to learn if you are eligible to be in this study, to compare early pregnancy or pre-pregnancy blood pressure readings to the findings from this study, and to learn about specific pregnancy conditions that may benefit the most from cardiovascular health programs. We will collect information past, present, and future. We will keep all your records confidential. We will abstract information about pregnancy, diagnosis, medical history, medical procedures, and results of other tests done as part of standard medical care. This identifiable medical record information will be made available to members of the research team and your permission is valid for an indefinite period of time (your permission does not expire). We will not add any information to your medical record unless we contact you.

You can withdraw your permission to allow the research team to review your medical records in writing to Dr. Catov and Dr. Shaw at any time. Any information obtained about you up to that point will continue to be used by the research team.

Usage of data in the future
We will store your data indefinitely. We may share data with other researchers or agencies not on this list, under the direction and approval of Drs. Catov and Shaw. Information collected as part of this study and released to any secondary investigators are stripped of identifiers and cannot be linked back to you.

In the future, we may contact you for new research studies you may be eligible for, including The Pittsburgh Study Early Childhood Collaborative, which is led by PI Dr. Daniel Shaw.

Who will have access to identifiable information related to my participation in this research study?
In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in the research study:

If you enroll in The Pittsburgh Study Early Childhood Collaborative, you agree to share your identifiable research records to the study team, which is led by PI Dr. Daniel Shaw. Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn

that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Information sharing with our study sponsor
Authorized representatives from the sponsor of this research study, may review and/or obtain de-identified information (which may include identifiable medical information) related your participation in this research study for the purpose of monitoring the accurate and the completeness of the research data and for performing required scientific analyses of the research data.

Will participating in the Family Check-Up program cost my family anything?
No. The Family Check-Up programs are free and there is no cost to you or your insurance.

Will I be paid for my participation in this study?
You will be paid $20 after completing the survey, an additional $20 when you complete the Family Check-Up assessment with your Family Coach, and another $30 when you complete the Feedback Session for a total of $70. In addition, when your child is about 6 months old, you will receive $30 for completing the last assessment. If you are not randomly selected to participate in the Family Check-Up Heart program, you will also receive a new Fitbit at the end of the 6-month assessment when you complete the study.

Payment to participants is considered taxable income regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a "Form 1099 – Miscellaneous" with the IRS and provide a copy to the taxpayer. We are required to give your name and social security number to the Accounting Office. Participants who do not provide a social security number may still participate in the research, but the IRS requires that 26% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 74% of the expected payment.

Is my participation in this research study voluntary?
Your participation in this research study, to include the use of your identifiable information for the purposes described above, is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your or your child's current or future medical care at a UPMC or affiliated health care provider or your current or future relationship with a health care insurance provider. You may withdraw from the study for any reason, at any time.

What happens if I believe I was injured because of taking part in this study?
If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for

injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

Withdrawal from the study

You can withdraw from this research study at any time. Any identifiable research information obtained as part of this study prior to the date that you withdrew your consent will continue to be used by the investigators for the purposes described above. If you want to withdraw, notify the study team. Your decision to withdraw will have no effect on your current or future relationship with the University of Pittsburgh or UPMC.

It is possible that you may be removed from the research study by the researchers if you do not respond to our attempts to contact you after you have signed this form. We will attempt to contact you for several weeks before making this decision. If you are withdrawn from participation in this research study, you may continue to be enrolled in the general home visiting program.

Who do I contact for more information?

If you have any questions or concerns at any time you may contact Dr. Catov at 412-692-8504 (email: catovjm@mwri.magee.edu) or Dr. Shaw at 412 624-1836 (email: casey@pitt.edu). Any questions you have about your rights as a research participant will be answered by the Institutional Review Board Office of the University of Pittsburgh (1-866-212-2668). You will be given a copy of this consent form.

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Electronic Consent

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints during this study, and they will be answered by a qualified individual or by the investigator(s). I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. A copy of this consent form will be given to me.

□ I give my consent for myself and my child to participate in this research study which includes HIPPA authorization to use and share de-identified information from my and my child's medical records for the purpose described above.

Child's Name: _____ Birthdate: ____ / _____ / _____ (mm/dd/year)
(First, middle initial, last name) (Child Birth Date)

Parent's Name: _____ Birthdate: ____ / _____ / _____ (mm/dd/year)
(First, middle initial, last name) (Parent Birthdate)

Relationship to Child: _____

Answer to ONE of 3 questions from drop-down box:

What is your mother's maiden name?
In what city were you born?
What high school did you attend?

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Written Consent

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints during this study, and they will be answered by a qualified individual or by the investigator(s). I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. A copy of this consent form will be given to me.

Child's Name: _____ Birthdate: ____ / _____ / _____ (mm/dd/year)
(First, middle initial, last name) (Child Birth Date)

Parent's Name: _____ Birthdate: ____ / _____ / _____ (mm/dd/year)
(First, middle initial, last name) (Parent Birthdate)

Relationship to Child: _____

Printed Name of Child Participant: _____

I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. By signing this form, I consent for myself and my child to participate in this research study which includes HIPPA authorization to use and share de-identified information from my and my child's medical records for the purpose described above.

_____	_____
Parent's or Guardian's Name (Print)	Relationship to child
_____	_____
Parent or Guardian Signature	Date

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CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered and will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Name of Person Obtaining Consent (Print)	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date