V. 12-2019

#PBRC 2019-070

CONSENT TO PARTICIPATE IN A RESEARCH STUDY FOR A MINOR

INFORMED CONSENT - PART I

Title of Study: ***A weight maintenance program to promote fat loss during pregnancy in women with obesity "Healthy Mamas"***

Study Sponsor: ***National Institutes of Health***

Key Information:

- **Why am I being asked to review this form?**
  - You are being asked to give permission for your child to take part in a research study. This form is provided so that you may read and understand the reasons why you might or might not want your child to participate in the research. Your child's participation is voluntary.
- **What is the purpose, duration, and procedures of this study?**
  - The purpose of this research study is to study health outcomes of babies born to mothers who are enrolled in the "Healthy Mamas" study.
  - Your child's expected time in this study will be 1 day consisting of 1 study visit.
  - The procedures involved in this study include:
    - **Length, Weight, Head Circumference, and Abdominal Circumference**
    - **Body composition by PEA POD, Skinfold Thickness, and whole-body DXA scan**
    - **Stool collection**
- **What are the possible risks and discomforts?**
  - This study does not involve major risk to study participants. Most of the measurements performed in this study are routine assessments performed at baby wellness visits by a pediatrician.
  - Some possible risks and discomforts include:
    - **Body Composition by whole-body DXA scan**: The low energy X-ray used in the whole-body DXA scan emits radiation. The amount of radiation absorbed by the body during this procedure is very small. The level of radiation is less than a regular chest X-ray and is less than 2% of the background radiation associated with altitude such as living in Denver, CO. Although information regarding radiation exposure is not specifically available for children, the exposure for children is less because they are smaller in size.
    - **Lifetime Radiation Exposure**: We are exposed to radiation in the environment on a daily basis; however, some scientists have suggested that humans have a lifetime maximum exposure limit. Exposure to radiation is not without risk, but it is difficult to quantify the exact amount someone is exposed to. By participating in this study, your baby will be exposed to radiation that will add to this lifetime maximum exposure limit. If you believe your baby has

been exposed to a significant amount of radiation as part of your baby's daily life or due to treatment for a specific medical condition, you should notify the study team to discuss whether or not this study would be appropriate for your baby.

- **Body Composition by Skinfold Thickness:** There is no known risk of harm from this measure, although your baby may briefly experience a very mild discomfort resulting from the light pinch of skin with the caliper. This pinching sensation is about as uncomfortable as if you were to lightly take a pinch of skin between your fingers.

- A more comprehensive and detailed description of reasonably foreseeable risks to subjects are included later in Section 6 of the informed consent.

- **What are the possible benefits?**
  - We cannot promise any benefits from your child being in the study. You and your child's participation may help us gain knowledge on the role of nutrition during pregnancy on infant health outcomes.
- **If you choose not to give permission for your child to participate in the study, are there other choices?**
  - You have the choice at any time not to have your child participate in this research study.

Detailed Information:

1- Who is doing the study?

This is a Pennington Biomedical Research Center study. We expect about 100 babies born to women in the “Healthy Mamas” study, including 50 babies at Pennington Biomedical Research Center and 50 babies at California Polytechnic State University will be enrolled in this study. The study will take place over a period of 3 years. Your child’s expected time in this study will be 1 day.

2- Where is the study being conducted?

This study takes place at two sites in the United States including Pennington Biomedical Research Center in Baton Rouge, Louisiana and California Polytechnic Institute in San Luis Obispo, California.

3- What is the purpose of this study?

The purpose of this study is to study health outcomes of babies born to mothers who are enrolled in the “Healthy Mamas” study.

4- Who is eligible to participate in the study?

We are interested in studying the health outcomes of all babies born to mothers who are enrolled in the “Healthy Mamas” study, no matter what the health status of the baby is at birth. All babies born to mothers who are enrolled in the “Healthy Mamas” study are eligible to participate in the study. You should also be willing to collect your child’s stool for future research.

5- What will happen to your child if he/she takes part in the study?

The study involves 1 study visit when the baby is about 2 weeks old. Throughout your baby’s participation, study investigators and study staff are required by law to report any

suspicion of child abuse or neglect. The following table shows what will happen to your baby at the study visit:

	Newborn Visit (7-20 days old)
Informed Consent	X
Length	X
Weight	X
Head Circumference	X
Abdominal Circumference	X
Body Composition by PEA POD	X
Body Composition by Skinfold Thickness	X
Body Composition by Whole-Body DXA Scan	X
Stool Collection	X

Newborn Visit

After your baby is born, you will schedule a visit when your baby is 7 to 20 days old. This visit will occur at Pennington Biomedical and will take approximately 1 hour. The Newborn Visit may occur at the same time as the mother's Outcome Visit 4. If your baby is unable to schedule a visit within the visit window because of an extended hospital stay, the Newborn Visit will occur within 10 days of hospital discharge.

The testing at this visit includes the following procedures:

- **Length**: Your child will lie on a standard measuring board with his or her head held securely against a stationary board and legs extended fully. A moveable footboard will be adjusted to measure your child's length from the top of the head to the heel of the foot.
- **Weight**: Your child will be undressed including removal of the diaper and placed on an electronic scale to measure body weight.
- **Head circumference**: Your child's head will be held securely, and a tape measure will be placed around your child's head just above the ears.
- **Abdominal circumference**: A tape measure will measure around your baby's stomach just above the belly button.
- **Body Composition by PEA POD (about 10 minutes)**: Your child's body fat will be measured in a special infant chamber called a PEA POD. Your child will be undressed including removal of diaper during this procedure except for wearing a special soft lycra hat. The temperature inside the PEA POD is about 88°F, which is comfortable for an undressed newborn. Your child will be placed on a tray that slides into a clear plastic chamber. The amount of space occupied by your child will be measured. You will be able to see your child during the test through the clear top. This measurement takes 2 minutes.
- **Body Composition by Skinfold Thickness (about 5 minutes)**: The body fat under your baby's skin will be measured at 4 places on his or her body (on his or her arms, back, hip, and legs).A fold of his or her skin will be gently squeezed with a measuring device called a caliper.
- **Body Composition by Whole-Body DXA Scan (about 10 minutes)**: This scan measures the amount of bone, muscle, and fat in your baby's body. The

scan will be performed using a whole-body scanner. Your baby will be swaddled with a blanket, and we will ask you to remove all metal-containing objects from your baby's body. After your baby is swaddled and comfortable, your baby will be carefully positioned on the table. A scanner emitting low energy X-rays and a detector will pass along your baby's body. The scan takes approximately 2 minutes. For babies who are not able to rest quietly during the scan, we will make up to 3 attempts at the visit. This scan is for research purposes only and not for medical care.

- **Stool collection**: One stool sample from your baby will be collected to measure composition and bacteria activity if your baby produces a sample while you are completing the Newborn Visit. We will provide you with detailed instructions about how to collect your baby's sample. This sample will be collected for future research.

6- What are the possible risks and discomforts?

This study does not involve major risk to study participants. Most of the measurements performed in this study are routine assessments performed at baby wellness visits by a pediatrician.

- **Length**: There is no anticipated risk or discomfort associated with this measurement. This is a routine assessment at wellness visits from birth to 2 years old.
- **Weight**: There is no anticipated risk or discomfort associated with this measurement. This is a routine assessment at wellness visits from birth to 2 years old.
- **Head Circumference**: There is no anticipated risk or discomfort associated with this measurement. This is a routine assessment at wellness visits from birth to 2 years old.
- **Abdominal Circumference**: There is no anticipated risk or discomfort associated with this measurement.
- **Body Composition by PEA POD**: There is no anticipated risk or discomfort associated with this measurement.
- **Body Composition by Skinfold Thickness**: There is no known risk of harm from this measure, although your baby may briefly experience a very mild discomfort resulting from the light pinch of skin with the caliper. This pinching sensation is about as uncomfortable as if you were to lightly take a pinch of skin between your fingers.
- **Body Composition by Whole- Body DXA Scan**: The low energy X-ray used in the whole-body DXA scan emits radiation. The amount of radiation absorbed by the body during this procedure is very small. The level of radiation is less than a regular chest X-ray and is less than 2% of the background radiation associated with altitude such as living in Denver, CO. Although information regarding radiation exposure is not specifically available for children, the exposure for children is less because they are smaller in size. The radiation-induced cancer risk for whole-body DXA scans in infants is negligible according to the Health Protection Agency of the UK. We are

exposed to radiation in the environment on a daily basis; however, some scientists have suggested that humans have a lifetime maximum exposure limit. Exposure to radiation is not without risk, but it is difficult to quantify the exact amount someone is exposed to. By participating in this study, your baby will be exposed to radiation that will add to this lifetime maximum exposure limit. If you believe your baby has been exposed to a significant amount of radiation as part of your baby's daily life or due to treatment for a specific medical condition, you should notify the study team to discuss whether or not this study would be appropriate for your baby.

- **Stool Collection**: There is no anticipated risk for collecting a stool sample. Infants may experience irritation or discomfort from the plastic wrap which will line the diaper for the stool collection. If your infant experiences discomfort, the plastic wrap can be removed.
- **Stool Stored for Future Research**: There is no known risk associated with having your child's stool stored and analyzed.

In addition to the minimal risks listed above, your baby may experience a previously unknown risk or side effect.

Will I be notified if my child's images result(s) in an incidental finding?
During a research study, a researcher may notice something that he or she was not looking for. This is called an "incidental" or "unexpected" finding. These incidental findings are not directly related to the research. However, they may show important information about the health of a research volunteer.

Researchers may share some or all of their findings with you about your child. However, you may not learn about any findings for a very long time. If such findings occur, you will be notified by the medical investigator or trained study personnel and your child will be referred to a treatment facility for further testing and/or treatment.

It can be very upsetting to learn unexpected information about your child's health. This is especially true if you learn that your child may have or will develop a condition that has no treatment or cure. There is a chance that unexpected findings could affect your family or social relationships, change your family planning decisions, or affect you financially. Your child might need more tests and procedures to find out what the information really means. It's also possible that the information might be incorrect, so you would worry without cause.

7- What are the possible benefits?

We cannot promise any benefits from your child being in the study. If your child takes part in this study, he/she may help others in the future.

8- If you do not want your child to take part in the study, are there other choices?

You have the choice at any time for your child to not participate in this research study. If you choose for your child to not participate, any health benefits to which your child is entitled will not be affected in any way.

9- If you have any questions or problems, whom can you call?

If you have any questions about your child's rights as a research volunteer, you should call the Institutional Review Board Office.

10- What information will be kept private?

Every effort will be made to maintain the confidentiality of your baby's study records. However, someone from the National Institutes of Health, Pennington Biomedical Research Center, or California Polytechnic State University may inspect and/or copy the medical records related to the study. Results of the study may be published; however, we will keep your baby's name and other identifying information private. Other than as set forth above, your baby's identity will remain confidential unless disclosure is required by law.

Identifiable Private Information or Identifiable Biospecimens

Any identifiers might be removed from your child's identifiable information or identifiable biospecimens and that, after such removal, the information could be used for future research studies or given to another investigator for future research without additional informed consent from you or your child.

ClinicalTrials.gov

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.

Biospecimens and Commercial Profit

Your child's biospecimens including stool being collected for this study will not be sold or used to develop new drugs or other products that may result in commercial profit.

Whole Genomic Sequencing

Your child's biospecimens including stool being collected for this study will not include whole genomic, germline, somatic, or exomic sequencing. This means that the researchers have no plans to look at or try to "read" the protein information that makes up your genes (DNA) from your sample.

11- Can your child's taking part in the study end early?

The principal investigator or the study sponsor can withdraw your child from the study for any reason or for no reason. Possible reasons for withdrawal include inability to comply with study demand or medical concerns that would not be in your child's benefit to further participate. The sponsor of the study may end the study early.

If your child's participation in the research ends early because of the investigator or by your choice, termination procedures may need to be completed or follow-up data may need to be obtained to ensure your child's safety. The study staff will go over the details with you.

You may withdraw your child from the study at any time without penalty; however, all information Pennington Biomedical has previously collected cannot be removed from the study.

If you decide you would like to withdraw your consent, you must provide a written request to the Principal Investigator.

12- What if information becomes available that might affect your decision to keep your child in the study?

Significant New Findings

During the course of this study there may be new findings from this or other research. Significant new findings may affect your willingness to allow your child to continue participation. Information concerning any such new findings will be provided to you and your child.

Clinically Relevant Research Results

In this study, you will not be informed of any clinically relevant research results, including your child's individual results that may be discovered.

13- What charges will you or your child have to pay?

None.

14- What payment will your child receive?

Your child will not receive separate payment for completing this study. As detailed in the Adult Informed Consent, you will be compensated up to $525 for completion of the study.

15- Will your child be compensated for a study-related injury or medical illness?

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No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) is available from the Pennington Biomedical Research Center. In the event of injury or medical illness resulting from the research procedures in which your child participates, he/she will be referred to a treatment facility. Medical treatment may be provided at your expense or at the expense of your health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage. The Pennington Biomedical Research Center is a research facility and provides medical treatment only as part of research protocols. Should your child require ongoing medical treatments, they must be provided by community physicians and hospitals.