University of North Carolina at Chapel Hill
Parental Permission for a Minor Child to Participate in a Research Study

Consent Form Version Date: January 20, 2016
IRB Study # 13-3848
Title of Study: Pregnancy Eating Attributes (PEAS)
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Funding Source and/or Sponsor: NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

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What are some general things you and you child should know about research studies?
You are being asked to allow your child to take part in a research study. To join the study is voluntary.

You may refuse to give permission, or you may withdraw your permission for your child to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Your child may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your or your child's relationship with the researcher, the health care provider, or the University of North Carolina-Chapel Hill. If your child is a patient with an illness, your child does not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you and your child understand this information so that you and your child can make an informed choice about being in this research study.

You will be given a copy of this consent form. You and your child should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
Since you, the mother, are a part of this research study you are aware that the purpose of this research study is to learn how, why and how much women eat during pregnancy and how their thoughts, values and beliefs related to food influence their weight gain during pregnancy and the

postpartum period.

We are asking permission to enroll your child in this study to collect information about his/her health, take measurements of weight, height and skin fold thickness as well as a stool specimen when the child is six months of age.

Are there any reasons your child should not be in this study?
Your child should not be in this study if they experience a problem that requires a prolonged hospital admission after birth.

How many people will take part in this study?
There will be approximately 450 people in this research study.

How long will your child's part in this study last?
Your child's part in the study will last from delivery to 1 year postpartum. The clinic samples and body measurements of both you and your child on the day of a visit may take up to 45 minutes. Questionnaires about your baby will be mostly completed online at your convenience.

What will happen if your child takes part in the study?
Study assessments for your child will be conducted at 4-6 weeks, 6 months, and 1 year postpartum. Data to be collected will include self-report questionnaires about your baby, medical record data, weight, length, circumferences and skin fold measurements. We will collect 10ml (about 2 teaspoons) of your child's cord blood at delivery. We will also collect stool samples. Please see the schedule below for more details.

Delivery	4-6 wks postpartum	6 months postpartum	12 months postpartum
Cord blood (10ml)		Baby stool	
	Baby measurements	Baby measurements	Baby measurements

Questionnaires

Self-report questionnaires will be web-based and you will be able to complete them online using a secure connection at the study website. The questionnaires related to your child will assess questions about feeding your baby (5-10 minutes per assessment). Importantly, we have separated the questionnaires across your time in the study, so you don't have to fill out all of the questions at each assessment, we anticipate that you will spend about 40 minutes at each of the assessments filling out questionnaire online at your own pace. You may choose not to answer a question for any reason.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. There is little chance your child will benefit from being in this research study. However, information obtained from this study can help to shape programs for pregnant woman to help them eat better and gain weight appropriately during pregnancy so that they can have a healthy pregnancy and healthy child.

What are the possible risks or discomforts involved from being in this study?
The primary risks associated with a study of this type are threats to privacy and confidentiality. Risks will be minimized by use of a secure data server and assignment of unique study ID code instead of your name on all study records. There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You and your child will be given any new information gained during the course of the study that might affect your willingness to continue your child's participation in the study.

How will information about your child be protected?
Once you enroll in the study, you will be assigned a unique study ID number. That number will be used to identify your baby's information and his/her specimens that are collected as part of this study. The authority to collect this information is under 42 USC 285g and 45, CFR Part 42, Subpart D. The list that links you to the unique study ID number will be kept separately, in a locked cabinet in a locked office. All study information will be stored on a password-protected computer that only study staff will have access to.

As part of this research study, you will be asked to fill out questionnaires online. We will provide access to the website containing the questionnaires but then you will be able to change your password for the security of your data. All data will be stored with your study ID and no one will be able to access your data except the staff associated with the research study.

No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. The Privacy Act does apply to this study (Privacy Act System of Records Notice (SORN) # 09-25-0200 http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm). If disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety. A copy of this assent form will go in to your medical record.

What if you or your child wants to stop before your child's part in the study is complete?
You can withdraw from this study at any time, with no impact to your care or the care of your baby. The investigators also have the right to stop your participation at any time. This could be because you have had a change in your eligibility or because the entire study has been stopped.

Will your child receive anything for being in this study?
The reimbursement associated with this study is explained in detail in the consent form you have already signed. There is no additional payment for your child's participation.

Will it cost you anything for your child to be in this study?
It will not cost anything to be in this study.

Who is sponsoring this study?
This research is funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. This means that the research team is being paid by the sponsor for doing

the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you or your child has questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If there are questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, contact the researchers listed on the first page of this form**.**

What if there are questions about your child's rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your child's rights and welfare. If there are questions or concerns about your child's rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Parent's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to allow my child to participate in this research study.

_____
Printed Name of Research Participant (child)

_____ _____
Signature of Parent Date

_____
Printed Name of Parent

_____ _____
Signature of Research Team Member Obtaining Permission Date

_____
Printed Name of Research Team Member Obtaining Permission