University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: February 10, 2015
IRB Study # 13-3848
Title of Study: Pregnancy Eating Attributes (PEAS)
Principal Investigators: Anna Maria Siega-Riz and Myles Faith*
***Principal Investigator Department**: Nutrition
***Principal Investigator Phone number**: (919) 966-7230
***Principal Investigator Email Address**: mfaith@unc.edu
Co-Investigators: Kyle Burger (Nutrition), Alison Stuebe MD, Wanda Nicholson MD (SOM).

Funding Source and/or Sponsor: NIH National Institute of Child Health and Human Development (NICHD)

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent 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. You 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 relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do 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 understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You 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?

The purpose of this research study is to examine 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. Excessive weight gain during pregnancy has been linked to adverse outcomes for both the mother and infant. The study addresses this public health problem by examining how women respond to and value food rewards and their behavioral control related to dietary intake during pregnancy and its effect on weight gain during pregnancy and weight in the postpartum period. It also examines pregnancy complications and the weight of the baby in the first year of life.

You are being asked to be in the study because you are pregnant with one child and are within

the age and gestational age range.

Are there any reasons you should not be in this study?
You should not be in this study if you have pre-existing diabetes; a non-singleton pregnancy (i.e. twins, triplets, etc.); an eating disorder; a chronic illness or medication requirement that could affect your diet or weight; a psychosocial condition such as bipolar, schizophrenia, major affective disorder, or substance abuse. If, during your pregnancy, you are found to have a medical condition that affects your diet or are diagnosed with a serious medical condition, you may be asked to stop taking part in the study.

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

How long will your part in this study last?
Your involvement will last from the first 8-12 weeks of your pregnancy to 1 year postpartum. Assessments will be conducted at the initial 8-12 week visit, at 16-22 weeks, 28-32 weeks, at delivery, and at 4-6 weeks, 6 months, and 1 year postpartum. Most of the questionnaires will be completed online at your convenience but the clinic samples and body measurements collected on the day of your visit may take up to 45 minutes.

What will happen if you take part in the study?
Study assessments will be conducted prenatally at 8-12 weeks, 16-22 weeks, and 28-32 weeks; at delivery, and at 4-6 weeks, 6 months, and 1 year postpartum. Data to be collected will include self-report questionnaires, 24-hour dietary recalls, medical record data, weight, height, waist, hip, and arm circumferences and skin fold measurements. We will collect blood at the 3 pregnancy visits and at the 12 month visit. We will also collect urine and stool collections (see table below Study Schedule diagram). The amount of blood collected at each interval is 30ml (about 2 tablespoons) except for the 16-22 week visit when we will collect 40ml (almost 3 tablespoons). We ask that you come in fasting (no food for 8 hours) for the 16-22 week and 12 month postpartum sample. See the schedule below for more details. You may also be asked to participant in substudies in the future.

Enroll (8-12 wks)	16-22 wks	28-32 wks	Delivery	4-6 wks postpartum	6 months postpartum	12 months postpartum
Blood (30ml)	Fasting blood (40ml)	Blood (30ml)	Cord blood (10ml)		Mom stool	Fasting blood (40ml)
	Urine, Stool				Baby stool	
Mom measurements	Mom measurements	Mom measurements		Mom measurements		Mom measurements
				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. These questionnaires assess what types of foods eat or have in the home (10-30 minutes per assessment); how much pleasure you get from eating (5-10 minutes per assessment), other dietary habits and general behavior (5-8 minutes per assessment), exercise and quality of life (5-10 minutes per assessment) and questions about feeding your baby (5-10 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 every assessment. We anticipate that you will spend 30-50mins at each of the 7 assessments filling out questionnaire online at your own pace. You may choose not to answer a question for any reason. If you score high on the Edinburgh Postnatal Depression Scale (EPDS) or indicate self-harm, a member of the research team will let your primary care provider know.

Biomedical Data and Medical Record Capture

Data on your past pregnancies, health status, medication use, genetic screening, how this pregnancy progressing (including labs, ultrasound data and pregnancy complications) will be extracted from the electronic medical record.

Weight and height will be assessed at all visits. Assessment of body composition using skin fold measures (thigh, triceps, subscapular, abdominal, and supra-iliac) and circumferences (waist, hip, upper arm) will be obtained at selected study visits. For the infant, weight at birth, 6, and 12 months will be measured, as well as length, skinfold measurements, and head, abdominal, and mid-arm circumference.

All biologic samples will be collected and frozen for analysis at a later time. Samples will be kept indefinitely at the specimen repository (bank) at the NICHD (National Institute of Child Health And Development) for analyses including but not limited to fasting glucose, insulin, lipid profile, C-Reactive Protein, interleukin-6, TNF-α, adiponectin, carotenoids, cortisol, and genetic data. Every attempt will be made to have the collection of these samples take place at the same time as routine prenatal/postpartum sample collection. However it may require an additional sample collection.

You will be asked to report on the occurrence and frequency of nausea/vomiting during pregnancy, and any treatment for nausea/pregnancy. You will also be asked to report demographic information including education level, family income, household composition, marital status, and race/ethnicity.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. There is little chance you will personally 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 child outcomes. We will provide you with the results of your measurements and diet intake at the end of the study if you would like to see the results.

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. Participants may experience minor discomfort during collection of blood samples. The collection of blood samples will be done at the same time as routine prenatal/postpartum clinic procedures whenever possible. It is possible that parts of the questionnaires used for data collection will contain topics that women feel are sensitive and thus

could cause some minor distress. However, you have the right to refuse to answer any questions.

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

How will information about you 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 information and your specimens that are collected as part of this study. The authority to collect this information is under 42 USC 285g. 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 on line. 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 consent form will go in to your medical record.

What if you want to stop before your 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 you receive anything for being in this study?
You will be receiving a total of $400 for taking part in this study. You will receive $50 each for the first and third prenatal visits and the first postpartum visit; $75 for the second prenatal and second postpartum visit, and $100 for the final postpartum visit, for a total of $400 for completion of all visits. You will also be reimbursed for parking costs associated with a study visit.

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

Who is sponsoring this study?
This research is funded by 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 have questions about this study?

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

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your 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.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent

University of North Carolina at Chapel Hill
Consent for Storing Biological Specimens <u>With</u> Identifying Information

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Consent Form Version Date: July 8, 2014
IRB Study # 13-3848
Title of Study: Pregnancy Eating Attributes (PEAS)
Principal Investigators: Anna Maria Siega-Riz and Myles Faith*
***Principal Investigator Department**: Nutrition
Principal Investigator Phone number: (919) 966-7230
Principal Investigator Email Address: mfaith@unc.edu
Co-Investigators: Wanda Nicholson, Alison Stuebe, Kyle Burger, Karen Dorman

Funding Source and/or Sponsor: NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

Study Contact Telephone Number: (919) 966-2550
Study Contact Email: karen_dorman@med.unc.edu
*Primary contact

<u>What are some general things you should know about research?</u>
Research is designed to gain scientific information that may help other people in the future. You may not receive any direct benefit from participating. There also may be risks.

You may refuse to take part in research. If you are a patient with an illness, you do not have to be in research in order to receive treatment.

Details are discussed below. It is important that you understand this information so that you can make an informed choice. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

<u>What is the purpose of this specimen repository or "biobank?"</u>
Research with blood, tissue or body fluids (specimens) can help researchers understand how the human body works. Research can also answer other questions by using specimens. Researchers may develop new tests to find diseases, or new ways to treat diseases. In the future, research may help to develop new products, such as drugs. Specimens are commonly used for genetic research. Sometimes researchers collect and store many specimens together and use them for different kinds of research, or share them with other scientists; this is called a specimen repository or "biobank."

The purpose of this particular repository or biobank is to store specimens for future research. Your blood, urine, and stool samples, as well as your child's cord blood and stool samples, will be stored in the NICHD bio-repository for analyses of biological factors that may help predict weight gain and/or weight retention. The specimens will also be stored to obtain genetic information that will be used to look for a relationship between genetic factors and food attitudes and body weight

<u>How will the specimens be collected?</u>
Your blood, urine, and stool will be collected by the research staff during your study visits as specified in the main consent form that you have signed.

What will happen to the specimens?
Your and your child's samples will be frozen and sent to the NICHD bio-repository to be stored for future research. The samples will be labeled with a unique identifier code which will link your samples to your data on a secure database. Only authorized study staff will have access to the database.

What are Genome Wide Association Studies (GWAS)?
The National Institutes of Health (NIH) has established a national database that will hold information from many individuals across the country, including medical information and genetic information. Your blood and tissues contain genes which are made of DNA that is unique to you. If coded information about you is sent to this national database, access will be controlled and limited to other researchers.

What are the possible benefits to you?
Benefits to you are unlikely. Studies that use specimens from this repository may provide additional information that will be helpful in understanding more about the influence of food on weight gain and retention during pregnancy.

What are the possible risks or discomforts involved with the use of your specimens?
Participants may experience minor discomfort during collection of blood samples. The collection of blood samples will be done at the same time as routine prenatal/postpartum clinic procedures whenever possible.

There is a risk of breach of confidentiality. If this research involves genetics, there is also a potential risk for some of your relatives and other members of your ethnic group, since they share some of your genetic makeup.

Will there be any cost to you for storage of the specimens?
There will be no cost to you for the storage and use of the specimens for research purposes.

Will you receive anything for the use of your specimens?
The payment schedule is outlined in the main consent. You will not receive anything more for storage of the samples.

Who owns the specimens?
Any blood, body fluids, or tissue specimens obtained for this purpose becomes the exclusive property of the NIH and the University of North Carolina at Chapel Hill. These organizations may retain, preserve or dispose of these specimens and may use these specimens for research that may result in commercial applications. There are no plans to compensate you for any future commercial use of these specimens.

How will information about you 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 information and your specimens that are collected as part of this study. 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. Information from your medical records may be stored along with your specimens(s). You will be asked to sign a separate form ("HIPAA authorization") to allow researchers to review your medical records.

The specimens may be shared with researchers at this or other NIH institutions. Research studies may be done at many places at the same time. Your personal identifying information will not be sent to other researchers.

You will not be identified in any report or publication about research using your specimens. 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. This is very unlikely, but 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 could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

A Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Will researchers seek approval from you to do future studies involving the specimens?
By signing this consent form, you are giving your permission for researchers to use your specimens as described above. Current and future research is overseen by a committee called the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of research participants. In some cases, the IRB may require that you be re-contacted and asked for your consent to use your specimens in a specific research study. You have the right, at that future time, not to participate in any research study for which your consent is sought. Refusal to participate will not affect your medical care or result in loss of benefits to which you are entitled.

Will you receive results from research involving your specimens?
Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.

Can you withdraw the specimens from the research repository?
If you decide that you no longer wish for the specimens to be stored, you should contact the researchers on the front page of this form. It is best to make your request in writing.

Any analysis in progress at the time of your request or already performed prior to your request being received by the researcher will continue to be used as part of the research study. Once the researchers have been notified, your remaining specimens would be destroyed. If you do not make such a request, the specimens may be stored forever. The researchers may choose to destroy the specimens at any time.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from having your specimen collected. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. However, by signing this form, you do not give up any of your legal rights.

Who is sponsoring this research?
This research is funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). 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 have questions about this research?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research subject?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by e-mail to IRB_ subjects@unc.edu.

Subject's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate. I agree to my specimen(s) being stored with the identifying code(s).

_____ _____
Signature of Research Subject Date

_____
Printed Name of Research Subject

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent

University of North Carolina at Chapel Hill
HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

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IRB Study # 13-3848

Title of Study: Pregnancy, Eating Attributes (PEAS)

Principal Investigator: Myles Faith
Mailing Address for UNC-Chapel Hill Department: 2105-A McGavran Greenberg Hall, CB:7435**;** Chapel Hill, NC 27599-7435

This is a permission called a "HIPAA authorization." It is required by the "Health Insurance Portability and Accountability Act of 1996" (known as "HIPAA") in order for us to get information from your medical records or health insurance records to use in this research study.

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1. If you sign this HIPAA authorization form, you are giving your permission for the following people or groups to give the researchers certain information about you (described below):

Any health care providers or health care professionals or health plans that have provided health services, treatment such as physicians, clinics, hospitals, including but not limited to the UNC Health Care System and government health agencies.

2. If you sign this form, this is the health information about you that the people or groups listed in #1 may give to the researchers to use in this research study:

Any information in your medical records that relates to your participation in this research. These records might include information about mental health, drug or alcohol use, HIV/AIDS or other communicable diseases, or genetic testing. Other information includes: medical and pregnancy history, information about your current pregnancy and delivery and your newborn's hospital course.

3. The HIPAA protections that apply to your medical records will not apply to your information when it is in the research study records. Your information in the research study records may also be shared with, used by or seen by collaborating researchers, the sponsor of the research study, the sponsor's representatives, and certain employees of the university or government agencies (like the FDA) if needed to oversee the research study. HIPAA rules do not usually apply to those people or groups. If any of these people or groups reviews your research record, they may also need to review portions of your original medical record relevant to the situation. The informed consent document describes the procedures in this research study that will be used to protect your personal information. You can also ask the researchers any questions about what they will do with your personal information and how they will protect your personal information in this research study.

4. If this research study creates medical information about you that will go into your medical record, you may not be able to see the research study information in your medical record until the entire research study is over.

5. If you want to participate in this research study, you must sign this HIPAA authorization form to allow the people or groups listed in #1on this form to give access to the information about you that is listed in #2. If you do not want to sign this HIPAA authorization form, you cannot participate in this research study. However, not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will not stop unless you stop it in writing.

7. You have the right to stop this HIPAA authorization at any time. You must do that in writing. You may give your written stop of this HIPAA authorization directly to Principal Investigator or researcher or you may mail it to the department mailing address listed at the top of this form, or you may give it to one of the researchers in this study and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

8. You will be given a copy of this signed HIPAA authorization.

_____ _____

Signature of Research Subject Date

_____

Print Name of Research Subject

For Personal Representative of the Research Participant (if applicable)

Print Name of Personal Representative: _____
Please explain your authority to act on behalf of this Research Subject:

_____

I am giving this permission by signing this HIPAA Authorization on behalf of the Research Participant.

_____ _____

Signature of Personal Representative Date