UNIVERSITY OF WISCONSIN-MADISON
Research Participant Information and Consent Form

Title of the Study: Contributions of the Maternal-Fetal and Microbiome Interactions and Circulating Fetal DNA from Maternal Plasma and Cervical and Vaginal Fluid

Principal Investigator: Maureen Durkin, PhD, Dr PH (phone: 608-263-7507)

DESCRIPTION OF THE RESEARCH

You are invited to participate in a research sub-study to the National Children's Study about the genetic information such as DNA that is present in women during pregnancy and in babies during the prenatal period and soon after birth.

You have been asked to participate because you are participating in the Vanguard Phase of the National Children's Study.

The purposes of the research are to learn how early in pregnancy it is possible to find genetic information about babies from a pregnant woman's blood, and to better understand how to measure genetic information about the many normal bacteria and other small organisms that are present in the bodies of both women during pregnancy and their newborn babies over time.

This study will include approximately 100 pregnant women or women trying to conceive from Waukesha County who are participating in the Vanguard Phase of the National Children's Study and the babies resulting from these pregnancies.

In addition to the samples obtained at regularly scheduled National Children's Study visits in your home or at our clinic, we will schedule one visit for you with a nurse practitioner at Waukesha Memorial Hospital, up to 2 visits in your home or the Wisconsin Study Center for blood draws, and two visits in your home after your baby's birth to collect saliva and stool samples.

WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this sub-study, you will be asked to contribute the following kinds of samples that are in additional to the 2 blood samples from you and the cord blood sample being collected for the larger National Children's Study:

1. Blood samples from you at up to two additional time points [1 during pregnancy & 1 after the birth). This can be performed in either your home or at the Wisconsin Study Center office. We will draw up to 20 ml blood (4 teaspoons) at each draw.

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0647). Do not return the completed form to this address.

2. Fluid and cells from inside your vagina. This will require you to visit Waukesha Memorial Hospital during the third trimester of your pregnancy where a trained nurse-practitioner will examine your vagina and cervix and collect the samples.
3. Saliva/buccal (cells from the inside of the cheek) swab collected from the mouth of your child, with a cotton swab, after birth only if we are unable to collect cord blood at delivery. As part of the NCS, you already gave us permission to collect umbilical cord blood after your infant is born. We would like to analyze some of the cord blood specifically for this sub-study. It would not require any additional procedures.
4. Placenta surface culture or swab after it has been delivered.
5. Stool samples from your child's diaper at three time points: soon after birth, 1 month and 6 months. Your participation in this sub-study will require a total of up to two hours and twenty minutes of your time, in addition to travel time for one visit to Waukesha Memorial Hospital. There will be a total of five data collection sessions, and each one will take between 15 and 30 minutes.

ARE THERE ANY RISKS TO ME?

There is a small risk of bruising or discomfort from a blood draw.

Some subjects may experience embarrassment and/or physical discomfort at having the vaginal exam.

There is a small risk that some information could be disclosed to someone outside of the project or that, at some point, information stored in the controlled access databases could in some way be linked back to a specific subject.

Since we are collecting genetic information, you should be aware that despite the recent passage of a federal law that bars genetic discrimination in employment and some types of insurance, the use by others of genetic information from the study of the samples we collect could possibly impact you negatively in some way. For example, there is a very small risk that genetic information obtained by this study could be used by law enforcement officials to try to learn more about your or your family members for the purpose of a criminal investigation. To minimize this risk, all samples will be labeled with Study codes and will be stored and transported securely. All identifying information associated with the samples will be kept separate and securely at the Study office.

The intent of this study is not to discover anything unrelated to the study purpose. However, we want all participants who agree to home visits to know that if concerns about a problem that could result in serious harm to you or another individual (e.g., abuse, neglect, domestic violence) are identified at the visit we would report concern to the senior member of this research study (Dr. Maureen Durkin) and the Institutional Review Board overseeing this study. Additionally, certain field staff members are mandatory reporters of child abuse and neglect and are required by law to report any suspected child abuse and neglect to the proper authorities. This is the one instance where we may not be able to keep information about you that we collected for the research study confidential.

IRB Approval Date: 10/10/2011
Date IRB Approval Expires: 10/9/2012
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In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Maureen Durkin at 608-263-7507 if you are injured or for further information.

ARE THERE ANY BENEFITS TO ME?

We don't expect any direct benefits to you or your child from participation in this study. The information you provide will help scientists to develop methods that can be used to discover things affecting children's health beginning in the prenatal period and continuing after birth.

WILL I BE COMPENSATED FOR MY PARTICIPATION?

You will receive $50 for your participation in the vaginal sampling and $25 for any blood collected independent of the Vanguard Phase of the NCS. We will also reimburse you mileage for travel to and from the Study Center and/or Waukesha Memorial Hospital at $0.485/mile and childcare expenses will be reimbursed at $7.00 for each hour if needed.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Identifiable information about you and your child will not be shared outside the study. The information gathered about you and your child will be protected with safeguards that protect all of your information within the NCS. This includes use of participant number codes to separate your identity from the data collected and written statements from all study personnel promising to keep your information confidential. Only coded data will be shared with research partners at the Medical College of Wisconsin, the University of Pittsburg, Yale University, University of California-Irvine, and Baylor College of Medicine. If information about this study is published, your name will not be used. Only group characteristics will be published.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS?

You may ask any questions about the research at any time. If you have questions about the research after you leave today you should contact the Principal Investigator Maureen Durkin, PhD, Dr PH at 608-263-7507.

If you are not satisfied with response of research team, have more questions, or want to talk with someone about your rights as a research participant, contact the UWHC Patient Relations Representative at 608-263-8009 or University of Wisconsin Medical Foundation Patient Relations Representative at 800-552-4255 or 608-821-4819.

Your participation is completely voluntary. If you decide not to participate or to withdraw from the study it will have no effect on any services or treatment you are currently receiving.

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Your signature indicates that you have read this consent form, had an opportunity to ask any questions about your participation in this research and voluntarily consent to participate. It also indicates that you as the parent of the child agree to allow your child to participate after birth. You will receive a copy of this form for your records.

Name of Participant (please print):_____

Signature: _____ Date: _____

Name of Person Obtaining Consent (please print):_____

Signature: _____ Date: _____

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