

Fetal DNA and Microbiome Study Consent

We are conducting a small-scale pilot study to figure out how the National Children's Study (NCS) should look at fetal DNA and the human microbiome, specifically in pregnancy. Please review this information and feel free to ask any questions before you agree to take part in this pilot study.

Purpose

There are two parts to this project; the first is looking to see if fetal DNA is present and at which levels in maternal blood and in cervical fluid before, during and after pregnancy.

The second part is looking at the pregnancy microbiome. The purpose of this study is to establish what microbes are present during labor in "normal" pregnancies in the last month, and compare those to "preterm labor" labor microbes in the 6th through 9th month. By making this library of microbes from pregnancies, we will later be able to discover how that microbe library changes when there are problems like preterm labor in pregnancies.

For this pilot study, we will collect specimens from the vagina, placenta, your baby's meconium, and your baby's stool at one and six months of age. We will collect these samples from 75 participants.

Please remember

- Being in this pilot study is your choice.
- If you are part of the NCS, your participation in this pilot study will not affect your participation in the NCS. If you decide not to answer some of our questions, collect certain types of samples, or if you decide to leave this pilot, you may still participate in the NCS.
- If you leave this pilot study, we won't ask you any new information, but we'll keep using information and samples you've already given us.
- If you decide you don't want us to keep your information before the samples are studied, you can ask us to destroy it. If we have already studied the samples, we will not destroy the information we learned from them, but we will not do any more research on your samples.
- You can also tell us if you don't want your samples to be used for genetic tests. However, we can't destroy samples that we're already studying.
- We won't give you any results of the test performed at this visit.
- We will not use your name or any of the other information we record from your medical record. We will label all of the samples we take from you and from your baby with code numbers. The information on how the samples are labeled will be kept in a locked file cabinet that is located in a locked office. No one except the Study staff involved in this pilot study will have access to that information. We will also use these code numbers to identify the information that we learn from your samples.
- After this pilot study is over, we will keep any remaining sample in storage so that researchers can possibly use it in the future. However, the samples will stay numbered with code numbers and not any of your own information. We will make sure that no one uses these samples for any type of research that is not consistent with the research described in this consent form.

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.

- If you tell us or we see that a child is being abused or neglected, or if we learn from our visit that you are a danger to yourself or others, we must report this to the police or local social service agency.

What will happen during this substudy?

After you have had an opportunity to have your questions answered and told us you are interested by signing this consent form, we will have you visit with a nurse practitioner for a speculum exam. This trained medical professional will take several samples from your vagina using simple swabs (like a Q tip) and from your cervix using Dacron swabs. We will look in your medical record and record certain information on your general health history, your due date, and other background information.

We will call you throughout the last two months of your pregnancy to remind you to call our study staff when you come into the hospital in labor. At the time you deliver your baby, we will also use a simple swab (like a Q tip) to take samples from your vagina and the baby's side of the afterbirth. We will also take a sample from your baby's first bowel movement (or meconium). Sometimes, it can take an hour or more for the first bowel movement, at which time we will collect it from your baby's diaper in the nursery.

We will give you kits to help you collect some of your baby's stool. When your baby is one month old, you will collect a small amount of your baby's stool from your baby's diaper and mail it to us. You will repeat this when your baby is between two and six months old. Our study staff will help you remember by calling to remind you to send us these samples.

Potential Risks and Discomforts

- You may feel some embarrassment when we take the samples.
- You may have some discomfort during the sample collection.
- Your vagina may feel slightly irritated after collection.

We will be studying you and your fetus' genetic material, or mitochondrial DNA. Therefore when we study the DNA from your samples, we will generate data about a very limited part of your entire genetic material (also called your genetic code). Despite the steps we take to protect this information about your genetic code, there is a risk that somebody could learn some information and you and then try to use it to discriminate in some way against you or your family members. For example, genetic data from this study could possibly be used by a disability, life, or long term insurance company to deny you coverage, or by law enforcement officials to try to learn more about you or your family members for the purpose of a criminal investigation. The risk of this happening is currently very small, but as technology advances, there may be new ways to do this that we cannot foresee now.

We may share your information with the Department of Health and Human Services (HHS), hospital or university representatives, or other public health agencies if we are required to as part of an audit or evaluation.

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand more about fetal DNA and the human microbiome and how it relates to pregnancy health and disease and children's health.

Alternatives

You may choose not to participate in this substudy.

Subject Costs and Payment

You will not be asked to pay any costs related to this research. To thank you for your time, we will give you \$25 for the first sample (vaginal swab) and an additional \$25 for the second infant stool sample.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study. You will be given a copy of this form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

Consent Signature Form

- I have received information about the Fetal DNA and Microbiome Study.
- I understand what is involved and what the risks and benefits are if I join this part of the Study.
- I understand that my biological samples will be stored in a secure facility and that the Study will protect my samples.
- I understand that test results from my samples will not be given to me.
- I understand that my samples may be used for a variety of tests, including genetic tests.
- I understand that I may leave the study at any time.
- I have asked and received answers to all my questions about the Study.
- I understand that I may ask further questions at any time and that I will receive a copy of this consent form for my records.

I choose to join the Fetal DNA and Microbiome Adjunct Study.

Participant

Printed Legal Name of Participant: _____

Signature of Participant: _____ Date: ____/____/____

Parent/Legal Guardian (if participant is a non-emancipated minor)

I have received information about joining the "Joining the Fetal DNA and Microbiome Adjunct Study," which explains the nature and purpose of this study. I give my permission for _____ to take part in the Study if she agrees to be a part of it.

(name)

Printed Legal Name of Parent/Legal Guardian: _____

Signature of Parent/Legal Guardian: _____ Date: ____/____/____

Witness (if required)

I observed the data collector explain "Joining the Fetal DNA and Microbiome Adjunct Study" to the participant and she signed or marked this form.

_____ Date: ____/____/____

Signature of Witness

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____ Date: ____/____/____