



What if we could improve children's respiratory health by changing the bacteria that live in their airways?

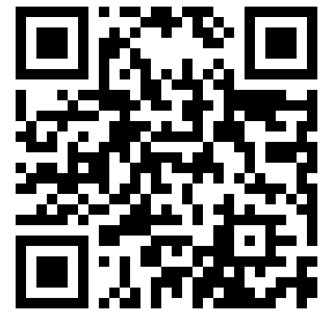
MOTHER SEED STUDY INFORMATION BOOKLET

The Center for Asthma Research at Vanderbilt University Medical Center (VUMC) is recruiting participants for the “MOmodification Of THE Early-Life Respiratory Microbiome Through Vaginal SEEDing” (MOTHER SEED) study.

Study Purpose and Background

What is the main purpose of this study?

The main purpose of this study is to evaluate if vaginal seeding of a child's nose is feasible and safe procedure.



What is vaginal seeding?

Vaginal seeding involves swabbing a baby's body part (such as the nose) with the mother's vaginal fluids (that is, secretions from the mother's vaginal area) soon after birth by cesarean section (C-section).

Babies born vaginally are covered with their mother's vaginal fluids. These fluids are present at birth in the child's nose, mouth, and skin. Some studies have suggested that these fluids could be a source of “good” bacteria, which could help in the development of a child's immune response (that is, how a child's body defends itself against infection or reacts against different exposures). In contrast, babies born by C-section are not exposed to the bacteria present in the mother's vaginal fluids. This could explain why children born by C-section seem to have a higher risk for developing some common respiratory diseases later in life (such as bronchiolitis, hay fever, or asthma).

The idea behind vaginal seeding of a child's nose is that this procedure could transfer some good bacteria from a mother to her baby after birth by C-section, thus trying to imitate what happens when a child is naturally exposed to the mother's vaginal fluids during a vaginal delivery.

Who should participate?

Pregnant women with a history of a prior C-section, scheduled to undergo a repeat C-section at VUMC, and planning to have general pediatric care for their child at one of the VUMC locations may be eligible to participate in this study.

What should you expect?

If you are eligible for the study, your child may be randomly assigned to receive an intervention called "vaginal seeding". This intervention involves swabbing your baby's nose with your vaginal secretions soon after birth. This is done to expose cesarean-born babies to the same bacteria they would have been exposed to at birth if they were born by vaginal delivery.

You will not be able to choose or know the group that your baby is assigned to for the duration of the study.

There will be several study visits while you are pregnant, around the time your child is born, and throughout your child's first year of life.

Each study visit will include specific study activities, which mainly consist of collecting information and samples from you and your child.

You can find a timeline of the study visits and activities at the end of this document.

What type of information will we collect from you and your child?

For this study, information will be collected by asking you questions, reviewing your and your child's medical records, and performing limited physical exams on you and your baby.

Some of the information we will collect through these methods include personal data (such as names, dates of birth, home addresses, phone numbers, and email addresses), sociodemographic characteristics (such as household income, level of education, and

type of insurance), environmental and lifestyle exposures (such as plans for breastfeeding, daycare attendance, and use of tobacco products, drugs, or alcohol), past and current medical history (including history of sexually transmitted infections), family history, medication use and immunization history, and information on the course of your pregnancy, child's birth's characteristics, child's development, and any health issues you or your child may have.

You can find out what we learn from the information we collect at the end of this document.

What type of samples will we obtain from you and your child?

The type of samples that we will collect from you include blood, urine, and vaginal samples. The type of samples that we will collect for your child include nasal, stool, and urine samples.

You can find out what we learn from the samples we collect at the end of this document.

How long will you be in the study?

We will follow you and your child throughout the pregnancy and until your child is one year old.

Where will the study take place?

Study visits will be mainly conducted in person or at around scheduled prenatal care visits or well-child visits at VUMC locations.

Why should you participate?

Your participation will help us learn about the potential interventions to change the bacteria living in the nose of children born by C-section.

Study Compensation

You will be compensated up to \$450 for your participation.

Study Funding

Funding for this study is provided by the National Institutes of Health (NIH).

To Get More Information

For more information about this study, please contact or visit us at:

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Website: <https://www.vumc.org/motherseed>



Thank you!


Families like yours make this research possible.




motherseed

MODIFICATION OF THE EARLY-LIFE RESPIRATORY
MICROBIOME THROUGH VAGINAL SEEDING

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 <https://www.vumc.org/motherseed>

What do we learn from the information and samples we collect?



TO BE COLLECTED FROM THE PARTICIPATING MOTHER

Questionnaires and review of medical records



We will collect information that will help us determine if you are eligible for the study and if this study is appropriate for you and your child.

Vaginal Swab



One of these will be used for the vaginal seeding of your child's nose. The others will be used to examine your vaginal flora or microbiome and to measure the acid level in your vaginal area.

Blood Sample



This will be used to test you for certain sexually transmitted infections.

Urine Sample



This will be used to test you for certain sexually transmitted infections.

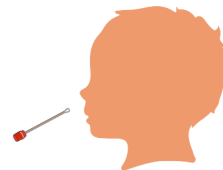
TO BE COLLECTED FROM THE PARTICIPATING CHILD

Questionnaires and review of medical records



We will collect information on your child's health and any health issues he/she may have.

Nasal Samples



These will be used to examine your child's nasal flora or microbiome and to assess his/her immune response.

Stool Sample



This may be used to examine your child's gut flora or microbiome or to assess his/her immune response.

Urine Sample



This may be used to assess your child's immune response.