

What You Should Know about Enrolling Your Child in the National Children's Study (NCS) Vanguard Study

Parental Permission Form for Child from Birth to 6 Months of Age



HEALTH GROWTH ENVIRONMENT

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- Thank you for participating in the National Children's Study (NCS) Vanguard Study. Your family is unique and critical to the success of this research study. With your help, the NCS will learn more about how our physical, social, and family environments affect the health, growth and development of our children.
- We hope your child will be one of thousands of children from across the United States helping us learn what will improve our children's health. Although what we learn in the NCS Vanguard Study may not help your child or your family right now, the things we learn may help people in the future.

- Now, we will tell you more about the kinds of information we would like to collect from you about your child when your child is born and ask for your permission to collect information about your child from birth to 6 months of age. We will also tell you about samples we would like to collect from your child and ask for your permission to collect them.
- Your child's participation in the NCS Vanguard Study is your choice. You can decide whether your child takes part or not. You and your child can leave the Study at any time and you can decide not to answer certain questions, or not to give certain samples.

Sponsors

The National Children's Study is led by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development of the National Institutes of Health (NIH) in collaboration with a consortium of federal government partners.

What is the goal of the National Children's Study (NCS)?

- The goal of the NCS is to improve the health of all children in the United States.
- The NCS will help us learn more about how our physical environment (including air and dust), social surroundings (our neighborhoods and communities), and family life:
 - Affect how children grow, and
 - Help children stay healthy.
- The NCS has several stages. The first stage is called the NCS Vanguard Study.
 - The purpose of the NCS Vanguard Study is to help guide the design of the NCS Main Study.
- The next stage is called the NCS Main Study.
 - This phase of the NCS will look at how our genes act together with our environment to influence health, growth, and development.
- About 100,000 children from all over the United States will be in the NCS Main Study.
- You are being asked for permission for your child to participate in the NCS Vanguard Study.

Why is the NCS important?

- The NCS is important because it will help us understand how we can improve our children's health.
- It is one of the largest ever research studies of children's health and development.
- With your help, we can learn more about how our physical, social and family environments affect children's health, growth, and development while they are young and when they become adults.
- The Study may also help us better understand why some children develop obesity, diabetes, autism, learning disabilities, asthma, or other problems.

What kind of study is the NCS Vanguard Study?

- The NCS Vanguard Study is an observational study.
- This means that we will not:
 - Ask you or your child to change what you normally do.
 - Ask you or your child to take any medicines or drugs.
- We will follow children from birth to age 21 by:
 - Visiting with you and your child at home and maybe at other places where your child spends a lot of time. We may ask you to visit us at a clinic or another location near you.

- ▶ Asking questions about you and your child and where you live and work.
- ▶ Collecting samples from you and your child (like blood, urine, and saliva) and from your home (like dust and air).

How many children will be in the NCS Vanguard Study?

- ▶ About 5,000 children will be in the NCS Vanguard Study.
- ▶ We are also asking those caring for the children in the Study to participate.

How long will the NCS Vanguard Study last?

- ▶ The Study will follow children until they are 21 years old.
- ▶ This parental permission form is asking for your permission to enroll your child in the NCS Vanguard Study from birth to about 6 months of age.
- ▶ Around the time that your child turns 6 months old, we will ask you for permission for your child's continued participation in the Study through the age of majority.

What is involved in taking part in the NCS Vanguard Study for the first few months after the birth of my child?

- ▶ While you are in the hospital or birthing center and after your baby is born, we would like to collect your child's cord blood and placenta.
 - ▶ We will work with the hospital, clinic, or birthing center staff to collect the umbilical cord blood. Blood is collected from the umbilical cord shortly after it is separated from the baby. The procedure takes about 5 minutes.
 - ▶ If you have decided to participate in a cord blood bank program to store your child's umbilical cord blood, we will not collect any umbilical cord blood for the Study.
- ▶ We would also like to collect a small amount of blood (up to 7 drops) from your child's heel soon after birth. We will work with hospital staff to collect this sample when they collect the baby's blood for routine tests.
 - ▶ No additional heel sticks will be performed on your child to collect this blood sample.
- ▶ All samples will be collected by trained medical professionals who know how to collect blood safely.
- ▶ We may ask you if we can take pictures of your child.
- ▶ During your time in the hospital or soon after you get home, we would like to ask you some questions.
 - ▶ This interview will take about 15 minutes to complete. We will ask you about

yourself, your child and your child's birth, and your plans for after your child is born.

- ▶ If there are questions you do not want to answer, you can skip them and your child can still be in the Study.

Will I need to do anything after I go home?

- ▶ We will give you an Infant Medical Care Log and ask you to write down some information when you take your child to the doctor.
 - ▶ We will ask you some questions about these doctor visits when we talk to you on the phone or visit you in person.
- ▶ We will contact you to arrange a phone interview with you when your child is about three months old.
- ▶ We will schedule another visit with you and your child when your child is around 6 months old.

What about genetic information?

- Genetic information is collected to help us learn how genes affect our children's health and how our physical environment and experiences affect the way our genes work.
- If you agree, we will get information about your child's genes. We will get this information from the samples that we collect from your child. We will store your child's samples and analyze them in the future.
- The risks associated with genetic analyses are unknown. In some cases the results of these genetic analyses may identify the risk of getting an illness or being a carrier of an illness. We will do our best to keep all results confidential.
 - ▶ There is a law that helps protect people from most kinds of health insurance and employment discrimination on the basis of genetics. This law is called the Genetic Information Nondiscrimination Act (GINA). GINA does not protect people against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.
- Some people have concerns about genetic information for cultural or religious reasons. If you do not want us to conduct genetic analyses, let us know. You can tell us not to do genetic analyses and your child can still be in the Study.

What will the NCS Vanguard Study do with all this information?

- We will use what we learn in the NCS Vanguard Study to inform the NCS Main Study and to achieve the goal of the NCS to improve the health of all children.
- The NCS Vanguard Study may use the information and samples we get from your

child during the NCS Vanguard Study in several ways. Researchers may use this information to find out:

- ▶ What questions and procedures will work best in the NCS Main Study.
 - ▶ How children’s genes, surroundings, and experiences work together to affect growth, development, and health.
 - ▶ How some conditions that appear later in childhood and adulthood begin in early childhood.
- By agreeing to let your child be in the NCS Vanguard Study, you are agreeing to allow the use of your child’s information and samples for:
 - ▶ The NCS Main Study.
 - ▶ Future studies on children’s health and human development. Future studies might be done by other approved researchers.
 - We will store the information and samples that participants provide indefinitely.
 - ▶ We may combine your child’s data and genetic information with data from other research studies or information sources to answer important research questions. To do this, we may share genetic information through a secure national research database.
 - In the future, scientists could develop new technologies or products based on the information and samples we collect from your child for the Study. Your child will not receive any money that may result from the development of such technologies or products.

How can I find out about the results of the NCS Vanguard Study?

- We will share what we learn overall from the NCS Vanguard Study. We will keep in touch with you through newsletters, on our website and in other ways.
- If tests we do during a visit show results important for your child’s health care, we will share them with you at that time. For example, we will give you information about your child’s height, weight and blood pressure when we measure them.
- We plan to analyze your child’s biological and environmental samples in the future.
 - ▶ At this time, we do not know when analyses will be done, which analyses will be done and when information from the analyses will be available.
- The analyses we will do on the samples will help us understand how the physical, social, and family environments, genes and other factors affect health and disease.
- These analyses are not intended to help guide your child’s health care.
- In case any results of these analyses do turn out to be vital to your child’s health care, we have a process in place for deciding this and telling you. We work with a group of doctors, scientists, and community members who advise us about analyses that could provide information vital to your child’s health care.
- If we do identify results that provide vital information directly related to your child’s

health care, we will discuss options for sharing this information with you.

How will the NCS Vanguard Study protect my child's information?

- Study records that identify your child will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access.
- We will make our best effort to protect your child's privacy and keep information you provide confidential by:
 - ▶ Using a number code to label all samples and other information instead of your child's name.
 - ▶ Keeping your question responses, results and other information about your child in a secure computer or locked file cabinet within a locked office.
 - ▶ Storing your child's samples in a secure place.
 - ▶ Reviewing all of the ways we store your child's information to improve how we protect your child's privacy.
 - ▶ Improving the ways your child's information is secured by using new technologies.
- We require researchers to keep your child's information safe. Researchers who want to use your child's information must:
 - ▶ Be authorized by the NCS and the Federal government to receive and store study information.
 - ▶ Protect your child's privacy by combining your responses and your child's information with that of other participants when reporting results.
- The NCS has gotten a Certificate of Confidentiality from the U.S. Department of Health and Human Services (HHS). This legal document says that the Study does not have to give out your child's personal information, even if ordered to do so by a judge or court.
 - ▶ If you give a person or an organization written permission to see the information you gave the Study about your child, we cannot use the Certificate of Confidentiality to protect your child's information from that person or organization.

When might the NCS Vanguard Study share my child's information?

- The NCS needs to share your child's information to do the research described by this informed consent form.
 - ▶ The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development runs the National Children's Study.

- ▶ We hire groups and organizations to do work for the Study such as collecting, storing and analyzing data. These groups must be authorized by the Study to protect your child's information in ways described by Federal Privacy Regulations.
- The NCS may need to share your child's information to protect public health and safety.
 - ▶ If we learn that you or someone else is harming your child or others around your child, we may be required by law to report this to the police or a social services agency in your community.

What are the possible benefits of my child's participation in the NCS Vanguard Study?

- Taking part in the NCS Vanguard Study will not improve your child's health right now. But the Study may help us learn things about health that could benefit all of us—including your children and grandchildren—in the years to come.
- If your child needs medical or social services, we will give you names and contact information for people and agencies that can try to help.

What are the possible risks or burdens to my child and to his or her community from being in the NCS Vanguard Study?

- The immediate risks from the NCS Vanguard Study are the same as those in routine health care.
- The heel stick blood sample may cause your child a small amount of pain. Infants sometimes feel brief pain when blood is taken, and there is a very small risk of infection, bruising, or bleeding.
- There is no pain associated with collection of cord blood or the placenta.
- We may learn information about adoption or parentage (biological fatherhood or motherhood) of your child. We will not give out any information about parentage to you or anyone else.
- Although we are taking many steps to protect your child's information, there is always a chance that your child's information or identity or that of your family members could be disclosed. Such disclosures may also occur if you share information yourself or agree to have your child's research records released.
- We will continue to review and improve the ways we keep your child's information private.
- We will get information about your child's health, community, and your child's race and ethnicity. We will make files with this information available to approved researchers. In addition to the risks to individuals, the risks of providing information about racial or community groups are unknown. There is a possibility that specific Study findings will be associated with particular racial and ethnic groups.

Will I be paid for taking part in the birth visit, sample collections from my child, and follow-up phone call?

- We will give you about \$25 to \$100 in cash or gift cards to thank you each time you participate in a Study visit.
- We may also give you small gifts like a tote bag, water bottle, picture frame, or other small items to thank you for being in the Study.

What is the alternative to taking part in the NCS Vanguard Study?

- The alternative to taking part in the NCS Vanguard Study is not taking part in the Study.

What if I want my child to leave the NCS Vanguard Study?

- You can choose to have your child leave the NCS Vanguard Study at any time.
- If your child leaves the Study, we will not ask for any new information, but we will keep using the information you have already given us about your child and the samples we have collected from your child.
- If you want us to destroy any of your child's unused samples, you can ask us to do so and we will.
- Leaving or not taking part in the Study will not affect your child's access to health care or any other benefits your child may be receiving, like those from Social Security, Medicaid, WIC, or the Supplemental Nutrition Assistance Program.

What if my child and I move?

- We would like to keep in touch with you as long as the NCS Vanguard Study is collecting information and your child is still participating in the Study.
- We hope you will tell us whether you are planning to move so your child can still be part of the Study in your new home.
- If you move and forget to tell us, we will try to get in touch with you. We will use the information you have given us about family members and friends, as well as publicly available information.
- If we get in touch with you, we will ask whether you want your child to continue to be part of the Study.

Will it cost me anything for my child to be in the NCS Vanguard Study?

- No. There is no cost to you for your child's participation in the NCS Vanguard Study.
- The Study will pay for all procedures done as part of the NCS Vanguard Study. Any future analyses done on your child's samples as part of the NCS Vanguard Study will also be paid for by the NCS.

Does the NCS Vanguard Study pay for health care for my child?

- The NCS Vanguard Study cannot and will not pay for health care or mental health services for your child. If your child needs medical or social services, we will give you names and contact information for people and agencies that can try to help.
- The information we collect is for research purposes only. Being part of the NCS Vanguard Study does not take the place of your child's usual doctor or clinic visits.

If my child is part of the NCS Vanguard Study, will my child have to join other studies?

- If your child is part of the NCS Vanguard Study he or she does not have to join any other studies.
 - We may invite your child to be in other studies connected with the NCS.
 - If your child is invited to be in other studies, you can always say no.

What if the media wants to talk with me about my child's participation in the NCS Vanguard Study?

- The NCS will not tell the media anything about the identities of Study participants.
- Because of the importance of the Study, reporters may go to communities where the Study is being done. They may ask participants whether they want to talk about their experiences with the Study.
- If you are contacted by reporters, you can decide whether you want to talk to them. If you do talk to a reporter, he or she can write about anything you say. What you say will be public information. The organization that the reporter works for will have control over any information and material you give it.
- If you talk with the media or post on social media websites about your child's Study experience, your child's participation in the Study will be public knowledge. When this information becomes public, it will be harder for the Study to protect the privacy of your child's information and the information of other participants from your community.

Who can I contact if I have questions about the NCS Vanguard Study?

- If you have questions now, you can ask the Study representative who gave you this parental permission form.
- You may call the NCS toll free at 1-877-865-2619 at any time if you have questions. Ask to speak with a member of the Study staff or to the principal investigator, Dr. Steven Hirschfeld. If you have questions about your child's rights as a research participant, you may call the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Institutional Review Board at 301-496-8370.

Important things to remember about being in the NCS Vanguard Study.

- After reading this parental permission form, we hope you will decide to allow your child to participate in the NCS Vanguard Study.
- We will ask you to sign a page that says you have given your permission for your child to be in the Study.
- You decide what questions to answer. You can also decide what samples to give from your child. If you decide not to answer some questions or give some samples, your child can still be in the Study.
- No matter what you decide now, you and your child can leave the Study at any time.
- Before you decide, you may want to talk with your family, friends, or doctor about your child taking part in the Study.
- You will receive a copy of this parental permission form.
- We will ask you for ongoing permission for your child's participation in the rest of the Study around the time that your child turns 6 months old.

Thank you for taking the time to learn about the NCS Vanguard Study.

