

What You Should Know about Being in the National Children’s Study (NCS) Vanguard Study

Informed Consent Form



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- You are caring for a child who is part of the National Children’s Study (NCS) Vanguard Study, and we would like you to be a part of it too. 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.
- The National Children’s Study is a research program with several stages. Different stages of the Study will run at the same time. We are currently in the first stage, called the NCS Vanguard Study. The NCS Vanguard Study will help us decide on the design of the next stage, called the NCS Main Study.
- We hope you will be one of thousands of participants 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 you or your family right now, the things we learn may help people in the future.
- Participating in the NCS Vanguard Study is your choice. You can decide to take part or not take part. You can leave the Study at any time, 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.
- We hope about 100,000 children from all over the United States will take part in the NCS Main Study.
- You are being asked 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 to change what you normally do.
 - Ask you or the child you take care of to take any medicines or drugs.
- Study activities include:
 - Visiting with you at home and maybe at other places where the child you take

care of 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 where you live and work.
- ▶ Collecting samples from you (like blood, urine, a swab from your mouth, 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 plans to follow children until they are 21 years old.
- The Study will collect information from adult caregivers while their child takes part in the Study.

What is involved in taking part in the NCS Vanguard Study?

- We will visit you at home, call, or send a letter to ask questions about you, the child you take care of, and your family. Sometimes we will ask you to visit a clinic or doctor's office for tests, exams, and measurements.
- Once the child you take care of is old enough, we will ask him or her questions, too.
- Because the NCS Vanguard Study will change over time, different families may be asked to take part in different Study activities.
- Before we do any Study activities, we will always explain what we are doing and will ask your permission first.
- If there are questions you do not want to answer, you can skip them and still be in the Study.

How many visits and contacts should I expect during the NCS Vanguard Study?

- We plan to visit you and the child you take care of at scheduled times over 21 years.
 - ▶ We plan to visit twice during the first year of the child's life.
 - ▶ We plan to visit once a year when the child is age 2 to age 5

- ▶ After that, we plan to visit about every 1 to 3 years.
- Between visits, we may call, e-mail, text or send a letter to:
 - ▶ Ask questions about the child's development and health; and
 - ▶ Confirm information like your address or phone number.

What kinds of information and samples will the NCS Vanguard Study collect?

- We will visit your home to collect information about you, the child you take care of, your health, your family medical history, and your physical, social, and family environments.
- We may ask to take your body measurements like height, weight, and blood pressure.
- We may ask you to answer questions or fill out forms about the child you take care of. For example, we may ask you to keep a diary about the food the child eats for several days.
- We may ask for your permission to look at your health information and medical records.
 - ▶ If you change your mind after you give us permission, we will stop getting new information from your medical records, but we will keep using the information we have already gotten.
- During some visits, we may ask for your permission to collect samples, like your blood, urine, a swab from your mouth, and saliva.
- Before we ask for any samples during a visit, we will:
 - ▶ Explain what type of samples we want and how much we will need.
 - ▶ Explain how we will collect the samples and any known risks of the collection.
 - ▶ Ask for your verbal permission to collect the samples.
- During some visits, trained staff will:
 - ▶ Use a needle to collect a small amount of your blood from a vein in your arm.
- We may also ask you to get some samples yourself. For example, by collecting:
 - ▶ A small amount of your urine in a cup.
 - ▶ A small amount of your saliva.
 - ▶ A swab from your rectum.
- During some visits, we may also ask for your permission to collect samples from your home, such as air, dust, noise level measurements, and water. For example,

we may have our staff collect:

- ▶ Dust samples from your vacuum cleaner or a dust cloth.
 - ▶ Samples of the water you drink.
- In addition, we may ask you to collect some dust samples yourself using a kit we provide.
 - If there are samples you do not want to give us, you can skip them and still be in the Study.

What about genetic information?

- Genetic information is collected to help us learn how genes affect our children's health. We also hope to learn how our physical environment and experiences affect the way our genes work.
- If you agree, we will get information about your genes. We will get this information from blood, saliva, and other samples you give us. We will store your samples and analyze them in the future.
- The risks associated with genetic analyses are unknown. In some cases, the results of these analyses may find the risk of getting an illness or being a carrier of an illness. We will do our best to keep all results private.
 - ▶ 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 do genetic analyses, let us know. You can tell us not to do genetic analyses and 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 you 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 be in the NCS Vanguard Study, you are agreeing to allow the use of your 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 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 you for the Study. You 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 health care, we will share them with you at that time. For example, we will give you information about your height, weight, and blood pressure when we measure them.
- We plan to analyze your 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, family environments, genes, and other factors affect health and disease.
- These analyses are not intended to help guide your health care.
- In case any results of these analyses do turn out to be vital to your 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 health care.
 - ▶ If we do identify results that provide vital information directly related to your health care, we will discuss options for sharing this information with you.

How will the NCS Vanguard Study protect my information?

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

When might the NCS Vanguard Study share my information?

- The NCS needs to share your information to do the research described in 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 information in ways described by Federal Privacy Regulations.

- The NCS may need to share your information to protect public health and safety.
 - If we learn that you or someone else is harming you, the child you take care of, or others around you, 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 being in the NCS Vanguard Study?

- Taking part in the NCS Vanguard Study will not improve your 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 you need 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 me and to my 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.
- Some of the questions we ask and some of the ways we get samples may make you feel uncomfortable. If you are uncomfortable, you can skip any part of the NCS Vanguard Study. You are in charge.
- Giving a blood sample may cause a small amount of pain. People sometimes feel brief pain when blood is taken. There is also a very small risk of infection, bruising, bleeding, or fainting.
- A visit to your home will probably take 2 to 4 hours. We will schedule these visits at a convenient time, but they may interrupt your daily routine. You can change the date or time of any scheduled visit at any time.
- We may learn information about adoption or parentage (biological fatherhood or motherhood) of the child you take care of. We will not give out any information about parentage to you, the child you care for, or anyone else.
- Although we are taking many steps to protect your information, there is always a chance that your 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 research records released.
- We will continue to review and improve the ways we keep your information private.

- We will get information about your health, your community, and your 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 being in the NCS Vanguard Study?

- We will give you about \$25 to \$100 in cash or gift cards to thank you each time you participate in a Study visit.
- From time to time, 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 to leave the NCS Vanguard Study?

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

What if I move?

- We would like to keep in touch with you as long as the NCS Vanguard Study is collecting information and you are still caring for the participating child.
- We hope you will tell us if you are planning to move so you 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 to continue to be part of the Study.

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

- No. There is no cost to you for being 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 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 family or me?

- The NCS Vanguard Study cannot and will not pay for health care or mental health services for you or your family. If you need 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 usual doctor or clinic visits.

If I am part of the NCS Vanguard Study, will I have to join other studies?

- If you are part of the NCS Vanguard Study you do not have to join any other studies.
 - We may invite you to be in other studies connected with the NCS.
 - If you are invited to be in other studies, you can always say no.

What if the media wants to talk with me about my participation or the participation of my child/the child I take care of 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 Study experience, your 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 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 informed consent 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 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 informed consent form, we hope you will decide to participate in the NCS Vanguard Study.
- We will ask you to sign a page that says you have decided to be in the Study.
- You decide what questions to answer. You can also decide what samples to give. If you decide not to answer some questions or give some samples, you still can be in the Study.
- No matter what you decide now, you can quit at any time.
- Before you decide, you may want to talk with your family, friends, or doctor about being in the Study.
- You will receive a copy of this informed consent form.

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

**National Children's Study: Vanguard Study
Informed Consent Signature Page for Adult Study Participation**

- The NCS Vanguard Study (the Study) staff has explained the purpose of the Study, the procedures involved, and the risks and benefits.
- I have asked all the questions I have now. I know who to contact if I have more questions.

I understand that:

- taking part in the Study is voluntary and I can leave the Study at any time.
- if I do not want to answer a question, give a sample, or do a part of the Study, I can skip it and still be in the Study.
- any biological samples and environmental samples that I provide will be stored in a secure facility and that the Study will control access to my samples.
- my data and samples will be used in the future to help researchers learn about children's health and human development.
- I will not routinely get results back from analyses done on my samples.

Please complete the following check boxes, as indicated, and sign in the Participant box. You can answer "no" to any item and still be in the NCS Vanguard Study.

Yes No

I give my permission for the Study to collect environmental samples from my home.

I give my permission for the Study to collect biological samples from me.

(If yes, complete the line below.)

If I agree to collection of biological samples, I give my permission for the Study to use them for genetic analyses.

I choose to participate in the NCS Vanguard Study.

Participant

Printed Legal Name of Participant: _____

Signature of Participant: _____ Today's Date: ____/____/____
(mm/dd/yyyy)

Witness (if required)

I observed the interviewer administer the informed consent form "What You Should Know about Being in the National Children's Study (NCS) Vanguard Study," to the participant and the participant signed or marked this form.

Printed Legal Name of Witness: _____

Signature of Witness _____ Today's Date: ____/____/____
(mm/dd/yyyy)

- Printed Legal Name of Person Obtaining Consent: _____

- Signature of Person Obtaining Consent: _____ Today's Date: ____/____/____

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Data Collector: Keep top copy. Give participant bottom copy.