

What You Should Know About Joining the National Children's Study Vanguard Study

- Your neighborhood is one of many communities across the country that is taking part in the National Children's Study.
- The National Children's Study has several stages. We are currently in the Vanguard Stage. Different stages of the Study will run at the same time and each stage will inform the others.
- The overall purpose of the Study is to improve the health and well-being of all children.
- We need both pregnant women and women who are not pregnant to join the Study.
- With your help, the National Children's Study will learn more about how our physical, social, and family environments affect the health, growth, and development of all our children.
- We hope you will join thousands of women from across the United States to help us learn information that will help improve our children's health. Although what we find out may not help you or your family right now, our plan is to help people in the future.
- Joining the Vanguard Study is your choice. You can decide to join or not to join. If you do join, you can leave at any time for any reason. You can refuse to answer any questions or decline any tests at any time for any reason.

Sponsors

The National Children's Study is led by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development in collaboration with a consortium of federal partners: the National Institute of Environmental Health Sciences of the National Institutes of Health and the Centers for Disease Control and Prevention, and the U.S. Environmental Protection Agency.

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What is the purpose of the National Children’s Study?

- The goal of the National Children’s Study is to improve the health of all children in the United States.
- The Study will help us learn more about how our community and our surroundings – that is, the physical environment (including air and dust), the social environment (our neighborhoods and communities), and the family environment:
 - ▶ Affect how children grow, and
 - ▶ Help children stay healthy.
- The Study will look at how a person’s genes act together with their surroundings to influence health, growth, and development.
- The National Children’s Study consists of several stages, beginning with the Vanguard Study and followed by the Main Study.
- The Vanguard Study is intended to guide the design of the Main Study.
- The questions that we ask and the procedures that we do during the Vanguard Study may differ from those in the Main Study.
- Only those questions and procedures that work best will be used in the Main Study.
- As the National Children’s Study goes forward, we will continue to use the information that we learn from earlier parts of the Study, including the Vanguard stage, to inform the later parts of the Study, including the Main Study. Therefore, Study activities will change over time.
- We need the combined information from the Vanguard Study and the Main Study to achieve the goal of the National Children’s Study.

Why is the National Children’s Study important?

- The National Children’s Study is important because it will help us to understand ways to improve children’s health.
- The National Children’s Study is the largest research study of children’s health and development in the history of the United States.
- With your help, the National Children’s Study will learn more about how our surroundings – that is, the physical environment (including factors such as air and water), the social environment (such as our neighborhoods and communities), and the family environment affect the health, growth, and development of all our children while they are young and when they develop into adults.
- In addition, the Study may help us to better understand why children develop conditions such as obesity, diabetes, autism, learning disabilities, and heart disease.

What kind of study is the National Children’s Study?

- The National Children’s Study is an observational study. That means we will

observe and follow children from birth to age twenty-one. To do that, we will:

- ▶ Visit with you and your child at home, and perhaps at other places where your child spends a lot of time, and at the Study Center.
 - ▶ Ask questions about you and where you live and work. If you are pregnant or become pregnant, we will also ask questions about your baby and your baby's experiences.
 - ▶ Collect samples from your home like dust and air and samples from you such as blood, urine, and saliva.
- As an observational study, we will not:
 - ▶ Ask you to change what you normally do.
 - ▶ Ask you or your child to take any medicines or drugs.

How many children will be in the National Children's Study?

- About 5,000 children will take part in the Vanguard Study.
- Overall, about 100,000 children from all over the United States will participate in all parts of the Study.
- We are also asking mothers and fathers to join.

How long will the National Children's Study last?

- The Study will interact with women before, during, and after pregnancy.
- The Study will continue to follow children until they are 21 years old.

What is involved in taking part in the National Children's Study?

- Generally, if you join the Study, we will sometimes visit you at home and sometimes invite you to come to a clinic or doctor's office for tests, exams, and measurements.
- Parts of the Study will change as the Study continues over the 21 years after children are born.
- Therefore, different families may be asked to participate in different combinations of parts of the Study.
- Whenever we contact you, we will explain what we are doing and ask for your permission.

How many visits should I expect?

- **If you are not pregnant:** We will visit one time and call, email, or send you a letter from time to time to ask you a few questions.
- **If you become pregnant:** We will visit you and your child regularly over 21 years.
 - **While you are pregnant:** We will visit you a few times.
 - **When your baby is born:** We will visit you and your baby in the hospital.
 - **As your child grows up:** We will plan regular visits, generally every one to three years.
- Each time that we visit, we will explain what we are doing and ask for your permission. We will give you a visit information sheet which describes all the activities that we would like to do during the visit.
- Between visits, we will call, email, or send you surveys from time to time to keep in touch and ask questions about you and your child.

What kinds of information and samples will the National Children's Study collect?

- The Study will visit your home to collect information about you, your health, and your physical, social, and family environment.
- We may get your body measurements like height, weight, and blood pressure.
- We may ask you to answer questions, fill out forms, and keep track of what you eat.
- If there are questions you do not want to answer, you can skip them and still be in the Study.
- The Study may ask for your permission to look at your health information and medical records, and those of your child, throughout the course of the Study.
 - If you change your mind after you give us permission, we will stop getting new information from your medical records, but we may keep using the information we have already gotten.
- If you are pregnant or become pregnant during the Study, we will ask questions about your pregnancy.
 - We may ask for a copy of your baby's ultrasound, if you have one.
 - We may also ask to schedule, and we will pay for, one or two ultrasounds during your pregnancy. We will give you a copy of these ultrasound pictures.
- During some visits, we may ask your permission to collect biological samples, such as your blood, hair, urine, and saliva.

- Before we ask for any samples, we will explain what type of samples we want, how much we will need, and how we will collect them.
- For example, during some visits, our trained Study Center staff will:
 - ▶ Use a needle to collect a small amount of your blood from a vein in your arm.
 - ▶ Cut a small sample of hair from the back of your head.
- We may also ask you to take some samples yourself by:
 - ▶ Collecting a small amount of your urine in a cup.
 - ▶ Collecting samples of the fluids from your vagina.
 - ▶ Using a straw to collect a small amount of your saliva 3 times a day for 2 days.
 - ▶ Giving us some of your toenail clippings.
- During some visits, we may also ask for your permission to collect samples from your home, such as air, dust, and water. For example, we may have our staff:
 - ▶ Collect dust samples using a vacuum cleaner and dust cloth.
 - ▶ Collect samples of the water you drink.
- In addition, we may also 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 will the Study do with all this information?

- The information and samples we get from you and your child may be used in several ways.
- We will store your information and samples along with those of other people in the Study indefinitely.
- Researchers may use this information to find out:
 - ▶ How the experiences during pregnancy or early life may affect our children's health.
 - ▶ How children's genes, surroundings and experiences interact to affect growth, development, and health.
 - ▶ How conditions that appear later in childhood and adulthood begin in early childhood.
- What we learn early in the Study may lead to more questions about our children's health. We may use the information we get from you to answer those questions as well.

- It is possible that scientists could develop new technologies or products in the future based on the information and samples that we collect from you and store for the Study. You will not receive any money that may result from such new technologies or products.
- We may also combine the information that we receive from you for this Study with information from other research studies. A committee of doctors, scientists, and community members (the Independent Safety Monitoring and Oversight Committee (iSMOC)) will make sure that your information and samples will only be used to help us better understand child health and growth and answer questions about why some children are more likely to get diseases.
- By agreeing to be in the Study, you are also agreeing to allow possible future use of your information and samples for future studies on child and maternal health and disease that are consistent with the goals of this Study.

What about genetic information?

- If you agree, we would like to get information about your genes and those of your child from the blood, saliva, and other samples you give us. We will also ask you questions about your family medical history.
- Genetic information is collected to learn how genes affect our children's health and how our physical environment and experiences affect the way our genes work.
- Some people worry about how their genetic information will be used. We will protect your genetic information the same way we protect all your other information.
- Some people are sensitive about genetic information for cultural or religious reasons. If you don't want us to conduct genetic tests, let us know. You can still be in the Study.
- The Study won't do the genetic testing right away. We will do the testing of your stored samples in the future using state-of-the-art technologies.
- To answer the Study's research questions, we may also combine the genetic information that we receive from you with information from other research studies and information sources.
- We will not routinely share the results of genetic tests with you.

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

- We will share with you what we learn from the Study as a whole. We will keep in touch through newsletters, on our website, and in other ways.
- We will share with you some of the information we learn about you and your child when it becomes available.
- If we know the results from tests we do during a visit, we will share them with you during the visit. For example, we will tell you information about your height, weight

and blood pressure.

- We plan to test most of your biological samples and samples from your home in the future.
 - ▶ At this time, we do not yet know exactly when these tests will be done, which tests will be done, and when information from the tests will become available.
 - ▶ Most of the tests that we will do on the samples we collect are to add to our knowledge of how the physical, social, and family environments, genes, and other factors affect health and disease and will not provide information about your personal health status.
 - ▶ A committee of doctors, scientists, and community members (the iSMOC) will advise the Study on which tests may provide information about participants' health.
 - ▶ When test results related to your health and your child's health become available, we may contact you to see if you are interested in learning about these results.

How will the Study protect my information?

- We will protect your privacy and keep your information safe by:
 - ▶ Using a unique number code to label your samples and other information.
 - ▶ Keeping your number code separate from your name and address and other personal information. We will look at the information you give us by using the number code and not your name and address and other personal information.
 - ▶ Keeping your test results and other information in a computer database that is protected by advanced security.
 - ▶ Storing biological and household samples, like blood and urine, and other information in a secure facility. Access to this facility will be restricted and monitored to make sure your samples are safe.
- Researchers who want to use your information must go through several steps:
 - ▶ Get certified by the National Children's Study and the Federal government.
 - ▶ Receive permission to use your information. A committee of doctors, scientists, and community members (the iSMOC) will make sure that your information and samples will only be used to help us better understand child health and growth and answer questions about why some children are more likely to get diseases.
 - ▶ Sign an affidavit of nondisclosure. This means promising to use your information for research purposes only. They must also agree not to share your information with anyone who has not made this same promise.
 - ▶ Protect your information by reporting it only as part of a group.

- We will monitor researchers to check if they are protecting your information.
- We will review all of the ways we keep your information and samples safe on a regular basis to keep improving how we protect your privacy.
- In addition, the U.S. Department of Health and Human Services (HHS) gave the National Children's Study a legal document, called a Certificate of Confidentiality. This means the Study cannot be forced by a court order or subpoena to disclose information that might identify you in any civil, criminal, or other type of court.

When might the Study have to give out my information?

- If we learn that you or someone else is harming you, your child, or others around you, we may be required by law to report this to the police or a social services agency in your community.
- If you give someone 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.

What are the possible benefits of being in the National Children's Study?

- Taking part in the National Children's Study may not help you or your family 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. But the Study cannot and will not pay for your health care or mental health services.

What are the possible risks or burdens to me and my child and to my community from being in the National Children's Study?

- The immediate risks from the Study are the same as those in routine health care.
- Some of the questions we ask and some of the ways in which we collect samples may be uncomfortable. But you can skip any part of the 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, and there is a very small risk of infection, bruising, bleeding, or fainting.
- A home visit is likely to take 2 to 3 hours. We will schedule home visits at a convenient time, but they may interrupt your daily routine. You can change the date or time of any scheduled visit whenever you wish.

- Information about adoption and parentage (biological fatherhood or motherhood) may be discovered in the course of this study. It is our policy not to give out any information about parentage to you or any other members of your family.
- While we are taking many steps to protect your information, there is always a chance that your information could be disclosed. We will continue to review and improve the ways we keep your information private. To protect your information, we will not keep your name and address with any study data files.
- We will collect information about your, physical, social, and family environment, your health, your community, as well as your race and ethnicity. In addition to any potential harm to an individual, there may be potential harms to racial and ethnic groups or communities. Study data files with information about racial and ethnic groups will be made available to researchers. The risks of providing information about racial or community groups are unknown. However, 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 National Children’s Study?

- We will give you about \$25 to \$100 each time you participate in a Study visit.
- From time to time, we may also give you small gifts like a tote bag, bathrobe, picture frame, or other small items to thank you.

What if I want to leave the National Children’s Study?

- You can leave the Study at any time. You also can leave the Study for a short time and come back.
- If you leave the Study, we will not ask you for any new information, but we will keep using the information and samples you have already given us.
- If you want us to get rid of any of your samples, you can ask us to destroy them.
- Leaving 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 hope that 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 using 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 you if you want to continue to be part of the

Study.

Will it cost me anything to be in the National Children's Study?

- No. There is no cost to you for being in the National Children's Study.
- All tests and procedures done as part of the Study will be paid for by the Study. Any future tests done on your samples or those of your child will also be paid for by the Study.

Does the National Children's Study pay for health care for my family or me?

- The 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 Study does not take the place of your usual doctor or clinic visits.

If I join the National Children's Study, will I have to join other studies?

- If you join the National Children's Study you do not have to join any other studies. We may invite you to be in other studies connected with the National Children's Study.
- If you are invited to be in other studies, you can always say no.

Will newspapers and media be interested in my participation and my child's participation in the National Children's Study?

- The National Children's Study will not share any information about the identities of people participating in the Study with the media.
- Because of the importance of the National Children's Study, it is possible that reporters and news media may go to communities where the National Children's Study is taking place to ask if people participating in the Study would like to talk about their experiences.
- If you are contacted by reporters, you can decide whether or not to talk with them. If you do decide to talk with them, you should be aware that any information that you provide will be publicly available and that the news media organization will have control over any information and material that they gather.

- Additionally, if you decide to talk with the media about your participation or your child's participation in the National Children's Study, you should be aware that your role and your child's role as Study participants will be public knowledge. This will decrease our ability to protect the confidentiality of your data and the data of other participants in your community.

Who can I contact if I have questions?

- If you have questions, you can ask the Study representative who gave you this booklet.
- If you have any other questions about your or your child's rights as a research participant, now or in the future, you may contact the persons listed on the form we will ask you to sign.

Important things to remember about joining the National Children's Study

- After reading this booklet, we hope you choose to join the National Children's Study.
- We will ask you to sign a form that says you have decided to join the Study.
- If you decide to join the Study now, you can quit at any time.
- You can decide what questions to answer. You can also decide what samples to give. Either way, you still can be in the Study.
- Before you sign the form, you may want to talk about joining the Study with your family, friends, or doctor.

Thank you for taking the time to learn about the National Children's Study.