



Joining the National Children's Study Biological and Environmental Sample Collection

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Centers for Disease Control and Prevention
U.S. ENVIRONMENTAL PROTECTION AGENCY



HEALTH GROWTH ENVIRONMENT

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Thank you for joining the National Children's Study!

- With the help of you and thousands of other women across the United States, the National Children's Study will learn more about how our environment—our neighborhoods, the air we breathe, and the water we drink—affects the health and development of all our children.
- Now that you've joined the Study, we hope you'll let us take samples from you and your home.
- We'll take samples of things like your hair, saliva, blood, toenail clippings, and the dust, air, and water in your home.
- These samples are very important. The Study uses the samples to learn about how the environment affects our children's health.
- Before we ask for a sample, we'll tell you what we need and how we'll collect, store, and protect it. We'll also tell you if there are any risks from giving the sample.
- Joining the sample collection part of the Study is your choice.
- You can decide to give some samples but not others, and you can decide if your samples can be used for genetic research.
- If you decide not to give us samples, you can still be in the rest of the Study.
- If you do join this part of the Study, you can leave at any time for any reason.

Sponsors

The National Children's Study is led by a consortium of federal partners: the U.S. Department of Health and Human Services (including the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and 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.

What's the purpose of the National Children's Study?

- The goal of the 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 things in our environment such as air and water
 - ◆ Affect how children grow, and
 - ◆ Help children stay healthy.
- The Study will look at how things like our genes act together with the environment to keep us from getting diseases.



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

- The National Children's Study is an "observational" study. That means we will
 - ◆ Visit with you and your child at home, at other places where your child spends a lot of time, and at the Study Center.
 - ◆ Ask questions about you and your environment. If you are pregnant or become pregnant, we'll also ask questions about your baby and your baby's environment.
 - ◆ Collect samples of things from your environment like dust and air and things from you like blood and urine.
- As an observational study, we won't
 - ◆ Ask you to change what you normally do.
 - ◆ Ask you or your child to take any medicines or drugs.

Why is the National Children's Study important?

- The National Children's Study is the largest research study of children's health and development in the history of the United States.
- Thirty or 40 years ago, not as many children were overweight or had diabetes, autism, learning disabilities, or heart disease. The Study will help us understand why more children have these problems today.
- The Study will look at how our community and our environment affect children both while they're young and when they become adults.



How will the National Children's Study collect information?

- The Study will get information from you in many ways. We'll explain what we're doing to make sure it's okay with you.
 - ◆ We'll ask you to answer questions and fill out forms.
 - ◆ We'll do a brief physical exam.
 - ◆ We'll take some biological samples, like blood.
 - ◆ We'll also ask you to collect some of the samples yourself, like urine.
 - ◆ We'll take samples of the air, dust, and maybe water in your home.

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 environment.
- We'll get your body measurements like height, weight, and blood pressure.

- During some visits, we'll ask your permission to collect other types of samples like your blood and hair.
- Before we ask for any samples, we'll explain what type of samples we want, how much we'll need, and how we'll collect them.
- For example, during some visits, our Study Center staff trained to get samples might
 - ◆ Use a needle on a vein in your arm and collect a small amount of your blood.
 - ◆ 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'll also ask your permission to collect samples from your home like air, dust, and water. For example, we may
 - ◆ Collect dust samples using a vacuum cleaner and dust cloth.
 - ◆ Collect samples of the water you drink.
 - ◆ Ask you to collect dust samples using a kit we provide.
 - ◆ Ask you to keep a diary for a week about things like the foods you eat.
- When we do test your samples, we'll look for certain types of hormones, nutrients, chemicals like pesticides, metals, and genetic information.



- We'll test the samples from your home for metals, chemicals like pesticides, and other things that might cause allergies.
- If you join the Study and agree to give us samples, we will store those samples.
- We'll do tests on some of those samples at some time in the future.
- If you are pregnant or get pregnant during the Study, we'll 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 pay for one or two ultrasounds during your pregnancy. We'll give you a copy of these ultrasound pictures.

- If you give us permission to visit your home, we'll explain everything we're going to do to make sure it's okay with you.
- If there are samples you don't want to give us, you can skip them and still be in the Study.
- You can leave the Study at any time.

What will the Study do with all this information?

- We'll store your information along with information from the other women in the Study.
- We plan to store your information and samples indefinitely.
- If you decide to give us samples, you will be allowing us to test samples both now and in the years ahead.
- Doctors and scientists will use this information to find out how things in the environment might affect our children's health. This will help them understand more about what causes certain diseases like diabetes, autism, and asthma.
- If you join the Study and agree to give us samples, we'll do tests on those samples.
 - ◆ We'll test most of your samples sometime in the future using state-of-the-art technologies.
 - ◆ At each visit, we'll tell you which results we can or can't give you.

“Doctors and scientists will use this information to find out how things in the environment might affect our children's health.”

- A committee of doctors, scientists, and community members will make sure that all future tests will help us better understand child health and growth and why some children are more likely to get diseases.

How will the Study protect my information?

- We'll 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. We'll look at the information you give us by using the number code and not your name and address.
 - ◆ Keeping your test results and other information in a computer database that's protected by advanced security.
 - ◆ Storing biological and environmental 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.
 - ◆ Sign an affidavit of nondisclosure. This means promising to use your information for scientific purposes only. They must also agree not to share your information with anyone who hasn't made this same promise.
 - ◆ Protect your information by reporting it only as part of a group.



- We'll monitor researchers to make sure they're protecting your information. We'll also review all these steps on a regular basis to improve how we protect your information.
- There's another way we protect your information. The U.S. Department of Health and Human Services (HHS) gave the National Children's Study a very important legal document called a Certificate of Confidentiality. This means the Study can't be forced by a court order or subpoena to disclose information that might identify you in any civil, criminal, or other type of court.
- If you give someone or an organization written permission to see the information you gave the Study, we can't use the Certificate of Confidentiality to protect your information from that person or organization.
- 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.

“The Study will then look at how genes affect our children’s health and how the environment affects the way our genes work.”

What about genetic information?

- If it’s okay with you, we’d like to get information about your genes and those of your child from the blood, saliva, and other samples you give us. We’ll also ask you questions about your family medical history.
- The Study will then look at how genes affect our children’s health and how the environment affects the way our genes work.
- Some people worry about how their genetic information will be used. We’ll 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 to be in the genetics part of the Study, let us know. You can still be in the Study.
- The Study won’t do the genetic testing right away. We’ll test some of the stored samples in the future using state-of-the-art technologies.

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

- Taking part in the Study will help us learn things about health that could benefit all of us in the years to come, maybe even your children and grandchildren. But the Study may not help you or your family right now.
- We’ll share with you what we learn from the Study. We’ll keep in touch through a newsletter, on our Web site, and in other ways. We’ll also put what we learn in books and magazines. Some of the things we might learn about are
 - ◆ Why some children are more likely to get certain diseases.
 - ◆ What helps children do well in school.
 - ◆ What causes asthma.
 - ◆ What makes a healthy pregnancy.
 - ◆ How to reduce the number of miscarriages and premature births.





- We'll also share with you some of the things we learn about you and your child. We'll give you reports on things like height, weight, and blood pressure.
- If you need medical or social services, we'll give you names and contact information for people and agencies that can help. But the Study can't pay for your health care or any mental health services.

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

- The risks from the Study are very low.
- Some of the questions we ask or samples we take may be uncomfortable. But you can skip any part of the Study. You're in charge.

- We're taking many steps to protect your information. But just taking part in the Study means there's a chance that someone outside the Study could see your private information. We'll always do everything we can to protect your information and make sure that doesn't happen.
- There may be a small risk when you give a blood sample. People sometimes feel brief pain when blood is taken, and there is a very small risk of infection, bruising, or bleeding. The professionals who will take your blood are trained to make you feel comfortable.
- A home visit is likely to take 2 to 3 hours. We'll schedule it at a convenient time, but it may interrupt your daily routine. You can change the date or time of any scheduled visit at any time.

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 won't ask you for any new information, but we'll keep using the information and samples you've already given us.
- If you want us to get rid of any of your samples, you can ask us to destroy them.
- Leaving 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.

“We'll give you reports on things like height, weight, and blood pressure.”



Will my information and samples be used in other ways?

- The information we get from you or your child may be used in other ways.
- What we learn early in the Study may lead to more questions about children's health. We may use the information we get from you to answer those questions as well.
- It's possible that scientists could create new medicines or health products in the future based on biological samples we collect from you and store for the Study.
- By agreeing to be in the Study, you also are agreeing to allow possible future use of your information and biological materials for these purposes.

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.



<http://www.nationalchildrensstudy.gov>

