

What You Should Know About Joining the National Children's Study General Consent Booklet

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

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



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

- Your neighborhood is one of many communities across the country that is taking part in the National Children's Study.
- The Study's goal 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.
- We'll look at how things like the air we breathe and the water we drink might affect the health and growth of our children.
- We hope you'll join thousands of women from across the United States to help us learn things that may 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 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 also refuse to answer any question.

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.



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.

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.

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

- About 100,000 children from all over the United States will take part in the Study.
- We'll also ask mothers and fathers to join.

How long will the National Children's Study last?

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

What's involved in being in the National Children's Study?

- If you join the Study, we'll visit you at home to get information about you, your health, and where you live.
- We'll also call, e-mail, or send a letter from time to time to ask a few questions.
- We may also ask you and your child to come to the Study Center from time to time.
- If it is okay with you, we'll ask the child's father to join the Study, too.



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 take biological samples like blood, urine, saliva, and vaginal fluid.
 - ◆ We'll take samples of the air, dust, and water in your home.
 - ◆ We'll also ask you to collect some samples yourself.
 - ◆ We'll measure things like your blood pressure, height, and weight.
 - ◆ We may ask you to keep track of things like what you eat.

How many visits should I expect?

- How often we visit depends on your situation.
- **If you're not pregnant:** We'll visit one time and call, e-mail, or send you a letter from time to time to ask you a few questions.
- **If you become pregnant:** We'll visit up to 15 times over 21 years.
 - ◆ **While you are pregnant:** We'll visit you a few times.
 - ◆ **When your baby is born:** We'll visit you and your baby in the hospital.
 - ◆ **While your baby is small:** We'll visit a few more times.
 - ◆ **As your child grows up:** We'll visit about once every 2 years.



Will the Study need access to medical records?

- The Study will ask your permission to look at medical records.
- If you give us permission, we'll look at medical records about the birth of your baby.
- If you change your mind and want to take back your permission, we won't get any new information from those medical records. We may keep using the information we've already gotten. We'll keep all information collected private.

What will the Study do with all this information?

- We'll store your information along with information from the other women in the Study.

- 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 do tests on some of your samples right away. If we know the results from tests we do during a visit, we'll share them with you during the visit.
 - ◆ 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.
- 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.

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

- ◆ 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

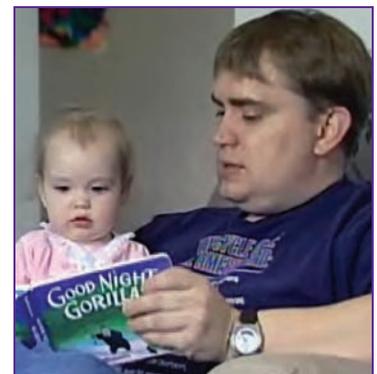
protect your information from that person or organization.

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.

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.



“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.”



- 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 do the testing of your stored samples in the future using state-of-the-art technologies. Since the results of your genetic tests won't be immediately available we won't give you the results of those tests.

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 your information could be disclosed. We'll always make sure we're doing everything we can to protect your information.
- 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.

Will I be paid for being in the National Children's Study?

- Yes. We'll give you about \$25 to \$100 each time you take part in a Study visit.
- The amount you get depends on what we ask you to do.
- From time to time, we may also give you small gifts like a t-shirt, tote bag, or music CD 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 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.

What if I move?

- We hope you'll 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'll look for you using the information you've given us about family members and friends, as well as publicly available information.
- If we find you, we'll 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 baby will also be paid for by the Study.





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

- If you join the National Children's Study you don't have to join other studies. We may invite you to be in other studies connected with the National Children's Study.
- If you're invited to be in other studies, we'll ask you if it's okay. You can always say no.

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

- The Study can't pay for health care for you or your family.
- The information we collect is for research purposes only. Being part of the Study does not take the place of your usual doctor visits.

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 samples for these purposes.

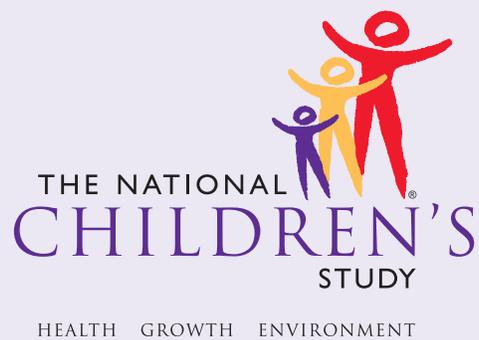
Who can I contact if I have questions?

- 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.

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'll 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.





<http://www.nationalchildrensstudy.gov>

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