

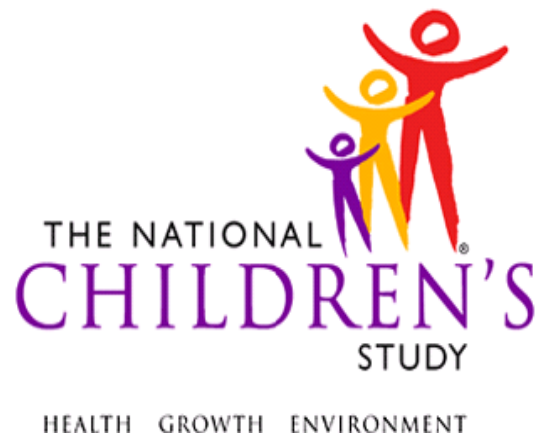
The National Children's Study Consent Documents

Table of Contents:

Consent Document:	Page Number
Pregnant Women Informed Consent	2-15
Father Informed Consent	16-29
New Adult Informed Consent	30-43
Parental Permission for Child's Participation	44-57
Parental Permission for Child's Participation with Samples	58-62
Multi-Mode Introductory Visit Information Script	63-65
Sample Collection Visit Information Sheet Scripts	66-74
Example: 6 Month Sample Collection Visit Information Sheet	75-76
Example: 12 Month Sample Collection Visit Information Sheet	77-78
Example: 24 Month Sample Collection Visit Information Sheet	79-80
Reconsideration Script	81-86

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

Informed Consent Form



- Your neighborhood is one of many communities across the country taking part in the National Children's Study.
- The goal of the Study is to improve the health and well-being of all children.
- We need pregnant women and women who are not pregnant to join the Study.
- With your help, the National Children's Study will help us learn more about how our physical, social, and family environments affect the health, growth, and development of our children.
- The National Children's Study has several stages. Different stages of the Study will run at the same time. We are currently in the first stage, called the Vanguard Study. The Vanguard Study will help us decide on the design of the next stage, called the Main Study.
- We hope you will join thousands of women from across the United States in helping us to learn information that will help improve our children's health. Although what we learn in the Vanguard Study may not help you or your family right now, the things we learn may 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 decide not to answer certain questions or 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. Study partners include the National Institute of Environmental Health Sciences of the NIH, the Centers for Disease Control and Prevention, and the Environmental Protection Agency.

What is the goal 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 physical environment (including air and dust), social environment (our neighborhoods and communities), and family environment:
 - Affect how children grow, and
 - Help children stay healthy.
- The Study will look at how our genes act together with our surroundings to influence health, growth, and development.
- The National Children’s Study has several stages. The first stage is called the Vanguard Study. The next stage is called the Main Study.
- What we do—the questions we ask and the procedures we use—during the Vanguard Study may be different from what we do in the Main Study.
- The Vanguard Study will help us decide what questions and procedures will work best in the Main Study.
- As we progress through the Vanguard Study, we will use what we learn to help us decide what will work best for the rest of the Vanguard Study. That is why what we do as part of the Vanguard Study will change over time.
- We will use what we learn in the Vanguard Study and in the Main Study to achieve our goal of improving the health of all children.

Why is the National Children’s Study important?

- The National Children’s Study is important because it will help us understand how we can improve our 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, we can learn more about how our physical environment, social environment, and family environment affects 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, or 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 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 will also ask you to visit us at a clinic or the local Study Center near you.
- ▶ Asking 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.
- ▶ Collecting samples from you like blood, urine, and saliva and from your home like dust and air.
- 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 be in the Vanguard Study.
- About 100,000 children from all over the United States will be in all parts of the Study.
- We are also asking mothers and fathers to join the Study.

How long will the National Children's Study last?

- The National Children's Study will get information from women before, during, and after pregnancy.
- The Study will follow children until they are 21 years old.

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

- If you join the National Children's Study, we will sometimes visit you at home and sometimes ask you to visit a clinic or doctor's office for tests, exams, and measurements.
- Because the Study will change over time, different families may be asked to take part in different Study activities.
- Each time we visit, we will explain what we are doing and ask your permission to do it. We will give you a visit information sheet that describes everything we want to do during the visit.

How many visits should I expect?

- 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 plan to visit you and your baby in the hospital.
 - ▶ **During your baby's first year:** We plan to visit twice.
 - ▶ **As your child grows up:** We plan to visit about every 1 to 3 years.
- Between visits, we will call, e-mail, or send you surveys from time to time to keep in touch and find out about you and your child.

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

- The National Children's Study will visit your home to collect information about you, your health, and your physical, social, and family environment.
- We may take 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.
- We may ask for your permission to look at your health information and medical records, and those of your child, during the time 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 ask to schedule, and we will pay for, one or two ultrasounds during your pregnancy. The National Children's Study will pay for these exams and give you a copy of these ultrasound pictures.
- During some visits, we may ask for your permission to collect samples like 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.
- During some visits, trained National Children's Study 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 get some samples by collecting:
 - ▶ A small amount of your urine in a cup.
 - ▶ Samples of the fluids from your vagina.
 - ▶ A small amount of your saliva 3 times a day for 2 days.
 - ▶ 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.
 - ▶ 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 about genetic information?

- If you agree, we will get information about your genes and those of your child. We will get this information from the blood, saliva, and other samples you give us. We will also ask questions about your family medical history.
- 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.
- Some people worry that research about genetic causes of disease may give information not only about themselves but about family members. There is always some chance that technology could be developed that would make it possible to reveal your identity or that of your family members. We will make every effort to prevent this. We will continue to review and improve the ways we keep your information private.
- Some people are sensitive about genetic information for cultural or religious reasons. If you do not want us to conduct genetic tests, let us know. You can tell us not to collect your genetic information and still be in the Study.
- The Study will not do the genetic testing right away. We will store and test those samples in the future.
- Future genetic testing of samples may sometimes be done together with other approved researchers who receive permission from the National Children's Study. We may share your information directly with researchers or we may share it through a secure national research database. The goals of these future studies will be similar to the goals of the National Children's Study.
- To answer the Study's research questions, we may also look at your genetic information together with information from other research studies and information

sources.

What will the National Children's Study do with all this information?

- The National Children's Study may use the information and samples we get from you and your child 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 experiences during pregnancy or early life may affect our children's health.
 - ▶ How children's genes, surroundings, and experiences work together 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, too.
- In the future, scientists could develop new technologies or products based on the information and samples 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 we receive from you for this Study with information from other research studies to answer our research questions.
- By agreeing to be in the Study, you are agreeing to allow possible use of your information and samples for future studies on child and maternal health and disease.
- These studies might be done by other approved researchers. The goals of these future studies will be similar to the goals of the National Children's Study.
- An independent group of doctors, scientists, and community members will make sure that your information and samples will only be used to meet the goals of the National Children's Study. The Independent Safety Monitoring and Oversight Committee, or iSMOC, will make sure that your information and samples will only be used to:
 - ▶ Help us better understand children's health and growth.
 - ▶ Answer questions about why some children are more likely to get certain diseases.

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

- We will share what we learn from the Study as a whole. We will keep in touch through newsletters, on our Web site, and in other ways.
- We will share some information we learn about you and your child with you when it is available.
- If we know the results from tests we do during a visit, we will share them with you then. For example, we will tell you information about your height, weight, and blood pressure.
- We plan to test most of your samples in the future.
 - ▶ At this time, we do not know when these tests will be done, which tests will be done, and when information from the tests will be available.
 - ▶ Most of the tests we will do on the samples will be to help us understand how the physical, social, and family environments, genes, and other factors affect health and disease. These tests will not provide information about your 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 are available, we may ask you if you want to learn about them.

How will the Study protect my information?

- We will protect your privacy and keep your information safe by:
 - ▶ Using a number code to label your samples and other information.
 - ▶ Keeping your number code separate from your name, address, and other personal information. We will look at your information using the number code and not your personal information.
 - ▶ Keeping your test results and other information in a secure computer database.
 - ▶ Storing samples and other information in a secure place. We will limit and keep track of access to your samples to make sure they are safe.
- Researchers who want to use your information must:
 - ▶ Get certified by the National Children's Study and the Federal government.
 - ▶ Get permission to use your information. A group of doctors, scientists, and community members (the iSMOC) will make sure that your information and samples will only be used to meet the goals of the Study. The goals are to better understand child health and growth and to learn why some children are more likely to get diseases.
 - ▶ Sign an affidavit of nondisclosure. This means promising to use your

information only for research. 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 track researchers to make sure they are keeping your information safe.
- We will regularly review all of the ways we keep your information and samples safe to keep improving how we protect your privacy.
- 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 give out information that might identify you in any 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 we get samples may be uncomfortable. If you are uncomfortable, 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 visit to your home will probably take 2 to 3 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 the biological parents of your child. We will not give out any information about parentage to you or any other members of your family.
- Although we are taking many steps to protect your information, there is always a chance that your information or identity could be disclosed. We will continue to review and improve the ways we keep your information private. To protect your information, we will keep your name and address separate from our information files.
- 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 National Children's 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, bathrobe, picture frame, or other small items to thank you for being in the Study.

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 for any new information, but we will keep using the information and samples you have already given us.
- If you want us to destroy or return any of your unused samples, you can ask us to do so and we will.
- 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 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 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.
- The Study will pay for all tests and procedures done as part of 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 the media be interested in my participation and my child's participation in the National Children's Study?

- The National Children's Study 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 if they want to talk about their experiences with the Study.
- If you are contacted by reporters, you can decide if you want to talk to them. If you do talk to a reporter, they can write about anything you tell them. What you say will be

public information. The organization that the reporter works for will have control over any information and material you give them.

- If you talk with the media about your or your child's experience with the Study, your role and your child's role as Study participants will be public knowledge. When this information becomes public, it will be harder for the Study to protect the privacy of your information and information about other participants from your community.

Who can I contact if I have questions about the National Children's Study?

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

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

- After reading this informed consent form, we hope you will decide to join the National Children's Study.
- We will ask you to sign a page that says you have decided to join the Study.
- If you join the Study now, you can quit at any time.
- 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.
- Before you decide, you may want to talk with your family, friends, or doctor about joining the Study.

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

**National Children's Study: Vanguard Study
Informed Consent for Pregnant Women's Study Participation**

- I have received the informed consent form, "What You Should Know About Joining the National Children's Study Vanguard Study," which explains the nature and purpose of the Study.
- I understand that I can leave the Study at any time and for any reason and then rejoin later.
- I understand that if there is a question I do not want to answer, a sample that I do not want to provide, or a part of the Study I do not want to do, I can skip it and still be in the Study.
- I understand that my biological samples and environmental samples from my home will be stored in a secure facility and that the Study will protect access to my samples.
- I understand that these samples may be used for a variety of tests in the future, including genetic tests.
- I understand that I will not routinely get results back from tests done on the samples I give to the Study.
- I have asked and received answers to all my questions about the Study. I understand that I can ask more questions at any time.

	Yes	No
I give my permission for the Study to collect environmental samples from my home.	<input type="checkbox"/>	<input type="checkbox"/>
I give my permission for the Study to collect biological samples from me.	<input type="checkbox"/>	<input type="checkbox"/>
I give my permission for the Study to use my biological samples to obtain my genetic information.	<input type="checkbox"/>	<input type="checkbox"/>

I choose to join the National Children's Study.

<p><u>Participant</u></p> <p>Printed Legal Name of Participant: _____</p> <p>Signature of Participant: _____ Date: ____/____/____ (mm/dd/yyyy)</p> <p>Date of Birth: ____/____/____ (mm/dd/yyyy)</p>

<p><u>Parent/Legal Guardian (if participant is a non-emancipated minor)</u></p> <p>I have received information about "What You Should Know About Joining the National Children's Study Vanguard Study," which explains the nature and purpose of the National Children's Study. I give my permission for _____ to take part in the Study if she agrees to be part of it. (Printed Name of Child)</p> <p>Printed Legal Name of Parent/Legal Guardian: _____</p> <p>Signature of Parent/Legal Guardian: _____ Date: ____/____/____ (mm/dd/yyyy)</p>
--

<p><u>Witness (if required)</u></p> <p>I observed the interviewer explain "What You Should Know About Joining the National Children's Study Vanguard Study" to the participant and she signed or marked this form.</p> <p>_____/_____/_____ Signature of Witness (mm/dd/yyyy)</p>
--

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____ Date: ____/____/____

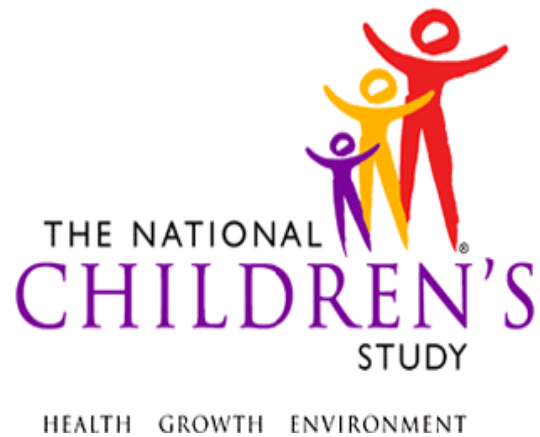
If you have questions about this study, you may call the local numbers listed on the label below.

For Office Use Only	<input type="checkbox"/>	Study Participant (Adult or Emancipated Minor Only)	<input type="checkbox"/>
		Parent/Legal Guardian (If Participant is Minor)	<input type="checkbox"/> Both

SO keep top copy Give participant bottom copy

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

Informed Consent Form



- The mother of your child has joined the National Children's Study, an important research study to improve the health and well-being of our nation's children.
- Because fathers play an important part in their children's lives, we are hoping you will agree to join the Study, too.
- The goal of the Study is to improve the health and well-being of all children.
- With your help, the National Children's Study will help us learn more about how our physical, social, and family environments affect the health, growth, and development of our children.
- The National Children's Study has several stages. Different stages of the Study will run at the same time. We are currently in the first stage, called the Vanguard Study. The Vanguard Study will help us decide on the design of the next stage, called the Main Study.
- We hope you will join thousands of fathers from across the United States in helping us to learn information that will help improve our children's health. Although what we learn in the Vanguard Study may not help you or your family right now, to the things we learn may 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 decide not to answer certain questions or 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. Study partners include the National Institute of Environmental Health Sciences of the NIH, and the Centers for Disease Control and Prevention, and the Environmental Protection Agency.

What is the goal 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 physical environment (including air and dust), social environment (our neighborhoods and communities), and family environment:
 - ▶ Affect how children grow, and
 - ▶ Help children stay healthy.
- The Study will look at how our genes act together with our surroundings to influence health, growth, and development.
- The National Children's Study has several stages. The first stage is called the Vanguard Study. The next stage is called the Main Study.
- What we do—the questions we ask and the procedures we use—during the Vanguard Study may be different from what we do in the Main Study.
- The Vanguard Study will help us decide what questions and procedures will work best in the Main Study.
- As we progress through the Vanguard Study, we will use what we learn to help us decide what will work best for the rest of the Vanguard Study. That is why what we do as part of the Vanguard Study will change over time.
- We will use what we learn in the Vanguard Study and in the Main Study to achieve our goal of improving the health of all children.

Why is the National Children's Study important?

- The National Children's Study is important because it will help us understand how we can improve our 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, we can learn more about how our physical environment, social environment, and family environment affects 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, or 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 follow children from birth to age 21 by:

- ▶ Visiting with you at home.
 - ▶ Asking questions about you and where you live and work.
 - ▶ Collecting samples from you like blood, urine, and saliva.
 - ▶ Involving you and your child's mother in the Study because we know that parents are important to the health of their children.
- As an observational study, we will not:
 - ▶ Ask you to change what you normally do.
 - ▶ Ask you to take any medicines or drugs.

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

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

How long will the National Children's Study last?

- The National Children's Study will get information from mothers and fathers before, during, and after pregnancy.
- The Study will follow children until they are 21 years old. Each time that we visit, we will explain what we are doing and ask your permission to do it. We will give you a visit information sheet that describes everything we want to do during the visit.

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

- If you join the National Children's Study, we will visit you at home to get information about you, your health, and where you live.
- Because the Study will change over time, different families may be asked to take part in different Study activities.
- Each time that we visit, we will explain what we are doing and ask your permission to do it. We will give you a visit information sheet that describes everything we want to do during the visit.

How many visits should I expect?

- We plan to visit you once at home during your partner's pregnancy. We also may ask to visit you at home again.

- Between visits, we will call, e-mail, or send you surveys from time to time to keep in touch and find out about you.

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

- The National Children's Study will visit your home to collect information about you, your health, and your physical, social, and family environment.
- We may take your body measurements like height, weight, and blood pressure.
- We may ask you to answer questions and fill out forms.
- If there are questions you do not want to answer, you can skip them and still be in the Study.
- We may ask for your permission to look at your health information and medical records during the time 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.
- During some visits, we may ask for your permission to collect samples, like 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.
- During some visits, trained National Children's Study staff will:
 - Use a needle to collect a small amount of 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 get some samples by collecting:
 - A small amount of your urine in a cup.
 - A small amount of your saliva 3 times a day for 2 days.
 - Some of your toenail clippings.
- 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?

- If you agree, we will get information about your genes. We will get this information from the blood, saliva, and other samples you give us. We will also ask questions about your family medical history.
- 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.

- Some people worry that research about genetic causes of disease may give information not only about themselves but about family members. There is always some chance that technology could be developed that would make it possible to reveal your identity or that of your family members. We will make every effort to prevent this. We will continue to review and improve the ways we keep your information private.
- Some people are sensitive about genetic information for cultural or religious reasons. If you do not want us to conduct genetic tests, let us know. You can tell us not to collect your genetic information and still be in the Study.
- The Study will not do the genetic testing right away. We will store and test those samples in the future.
- Future genetic testing of samples may sometimes be done together with other approved researchers who receive permission from the Study. We may share your information directly with researchers or we may share it through a secure national research database. The goals of these future studies will be similar to the goals of the National Children's Study.
- To answer the Study's research questions, we may also look at your genetic information together with information from other research studies and information sources.

What will the National Children's Study do with all this information?

- The National Children's Study may use the information and samples we get from you 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 experiences during early life may affect our children's health.
 - ▶ How genes, surroundings, and experiences work together 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, too.
- In the future, scientists could develop new technologies or products based on the information and samples 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 we receive from you for this Study with information from other research studies to answer our research questions.

- By agreeing to be in the Study, you are agreeing to allow possible use of your information and samples for future studies on child and maternal health and disease.
- These studies might be done by other approved researchers. The goals of these future studies will be similar to the goals of the National Children's Study.
- An independent group of doctors, scientists, and community members will make sure that your information and samples will only be used to meet the goals of the National Children's Study. The Independent Study Monitoring and Oversight Committee, or iSMOC, will make sure that your information and samples will only be used to:
 - ▶ Help us better understand children's health and growth.
 - ▶ Answer questions about why some children are likely to get certain diseases.

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

- We will share what we learn from the Study as a whole. We will keep in touch through newsletters, on our Web site, and in other ways.
- We will share some of the information we learn about you with you when it is available.
- If we know the results from tests we do during a visit, we will share them with you then. For example, we will tell you information about your height, weight, and blood pressure.
- We plan to test most of your samples in the future.
 - ▶ At this time, we do not know when these tests will be done, which tests will be done, and when information from the tests will be available.
 - ▶ Most of the tests we will do on the samples will be to help us understand how the physical, social, and family environments, genes, and other factors affect health and disease. These tests will not provide information about your 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 are available, we may ask you if you want to learn about them.

How will the Study protect my information?

- We will protect your privacy and keep your information safe by:
 - ▶ Using a number code to label your samples and other information.
 - ▶ Keeping your number code separate from your name, address, and other personal information. We will look at your information using the number code

- and not your personal information.
- ▶ Keeping your test results and other information in a secure computer database.
 - ▶ Storing samples and other information in a secure place. We will limit and keep track of access to your samples to make sure they are safe.
- Researchers who want to use your information must:
 - ▶ Get certified by the National Children’s Study and the Federal government.
 - ▶ Get permission to use your information. A group of doctors, scientists, and community members (the iSMOC) will make sure that your information and samples will only be used to meet the goals of the Study. The goals are to better understand child health and growth and to learn about why some children are more likely to get diseases.
 - ▶ Sign an affidavit of nondisclosure. This means promising to use your information only for research. 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 track researchers to make sure they are keeping your information safe.
 - We will regularly review all of the ways we keep your information and samples safe to keep improving how we protect your privacy.
 - 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 give out information that might identify you in any 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 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 we get samples may be uncomfortable. If you are uncomfortable, 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 visit to your home will probably take 2 to 3 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 the biological parents of your child. We will not give out any information about parentage to you or any other members of your family.
- Although we are taking many steps to protect your information, there is always a chance that your information or identity could be disclosed. We will continue to review and improve the ways we keep your information private. To protect your information, we will keep your name and address separate from our information files.
- 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 National Children's Study?

- We will give you about \$25 to \$100 in cash or gift certificates 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, picture frame, or other small items to thank you for being in the Study.

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 for any new information, but we will keep

using the information and samples you have already given us.

- If you want us to destroy or return of any of your unused samples, you can ask us to do so and we will.
- 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 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 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.
- The Study will pay for all tests and procedures done as part of the Study. Any future tests done on your samples 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 the media be interested in my participation in the National Children's Study?

- The National Children's Study 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 if they want to talk about their experiences with the Study.
- If you are contacted by reporters, you can decide if you want to talk to them. If you do talk to a reporter, they can write about anything you tell them. What you say will be public information. The organization that the reporter works for will have control over any information and material you give them.
- If you talk with the media about your or your child's experience with the Study, your role and your child's role as Study participants will be public knowledge. When this information becomes public, it will be harder for the Study to protect the privacy of your information and information about other participants from your community.

Who can I contact if I have questions about the National Children's Study?

- If you have questions now, you can ask the Study representative who gave you this informed consent form.
- If you have any other questions about your rights as a Study participant, now or in the future, you can contact the people listed on the page that we will ask you to sign.

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

- After reading this informed consent form, we hope you will decide to join the National Children's Study.
- We will ask you to sign a page that says you have decided to join the Study.
- If you join the Study now, you can quit at any time.
- 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.
- Before you decide, you may want to talk with your family, friends, or doctor about joining the Study.

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

**National Children’s Study: Vanguard Study
Informed Consent for Fathers Study Participation**

- I have received the informed consent form, “What You Should Know about Joining the National Children’s Study Vanguard Study,” which explains the nature and purpose of the Study.
- I understand that I can leave the Study at any time and for any reason and then rejoin later.
- I understand that if there is a question I do not want to answer, a sample that I do not want to provide, or a part of the Study I do not want to do, I can skip it and still be in the Study.
- I understand that my biological samples will be stored in a secure facility and that the Study will protect access to my samples.
- I understand that these samples may be used for a variety of tests in the future, including genetic tests.
- I understand that I will not routinely get results back from tests done on the samples I give to the Study.
- I have asked and received answers to all my questions about the Study. I understand that I can ask more questions at any time.

	Yes	No
I give my permission for the Study to collect biological samples from me.	<input type="checkbox"/>	<input type="checkbox"/>
I give my permission for the Study to use my biological samples to obtain my genetic information.	<input type="checkbox"/>	<input type="checkbox"/>

I choose to join the National Children’s Study.

Participant
 Printed Legal Name of Participant: _____
 Signature of Participant: _____ Date: ____/____/____
 (mm/dd/yyyy)
 Date of Birth: ____/____/____ (mm/dd/yyyy)

Parent/Legal Guardian (if participant is a non-emancipated minor)
 I have received the informed consent form, “What You Should Know About Joining the National Children’s Study Vanguard Study,” which explains the nature and purpose of the National Children’s Study. I give my permission for _____ to take part in the Study if he agrees to be part of it.
 (Printed Name of Child)
 Printed Legal Name of Parent/Legal Guardian: _____
 Signature of Parent/Legal Guardian: _____ Date: ____/____/____
 (mm/dd/yyyy)

Witness (if required)
 I observed the interviewer explain “What You Should Know about Joining the National Children’s Study Vanguard Study” to the participant and he signed or marked this form.

 Signature of Witness (mm/dd/yyyy)

Printed Name of Person Obtaining Consent: _____
 Signature of Person Obtaining Consent: _____ Date: ____/____/____

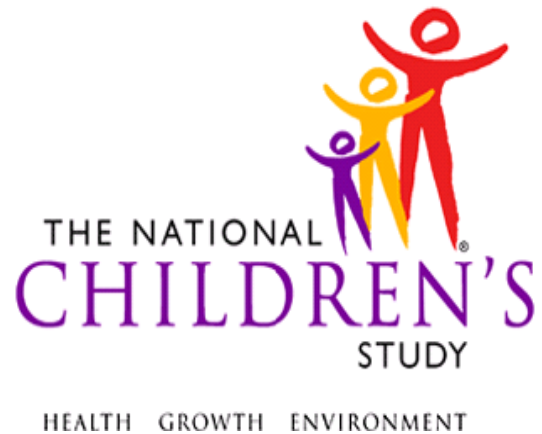
If you have questions about this study, you may call the local numbers listed on the label below.

For Office Use Only	<input type="checkbox"/>	Study Participant (Adult or Emancipated Minor Only)
<input type="checkbox"/>	Parent/Legal Guardian (If Participant is Minor)	<input type="checkbox"/> Both

SO keep top copy Give participant bottom copy

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

Informed Consent Form



- Because you are caring for a child who is part of the National Children’s Study, we are inviting you to join the Study, too.
- The goal of the Study is to improve the health and well-being of all children.
- With your help, the National Children’s Study will help us learn more about how our physical, social, and family environments affect the health, growth, and development of our children.
- The National Children’s Study has several stages. Different stages of the Study will run at the same time. We are currently in the first stage, called the Vanguard Study. The Vanguard Study will help us decide on the design of the next stage, called the Main Study.
- We hope you will join thousands of participants from across the United States in helping us to learn information that will help improve our children’s health. Although what we learn in the Vanguard Study may not help you or your family right now, the things we learn may 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 decide not to answer certain questions or 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. Study partners include the National Institute of Environmental Health Sciences of the NIH, the Centers for Disease Control and Prevention, and the Environmental Protection Agency.

What is the goal 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 physical environment (including air and dust), social environment (our neighborhoods and communities), and family environment:
 - Affect how children grow, and
 - Help children stay healthy.
- The Study will look at how our genes act together with our surroundings to influence health, growth, and development.
- The National Children’s Study has several stages. The first stage is called the Vanguard Study. The next stage is called the Main Study.
- The Vanguard Study will help guide the design of the Main Study.
- What we do—the questions we ask and the procedures we use—during the Vanguard Study may be different from what we do in the Main Study.
- The Vanguard Study will help us decide what questions and procedures will work best in the Main Study.
- As we progress through the Vanguard Study, we will use what we learn to help us decide what will work best for the rest of the Vanguard Study. That is why what we do as part of the Vanguard Study will change over time.
- We will use what we learn in the Vanguard Study and in the Main Study to achieve our goal of improving the health of all children.

Why is the National Children’s Study important?

- The National Children’s Study is important because it will help us understand how we can improve our 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, we can learn more about how our physical environment, our social environment, and family environment affects 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, or heart disease.

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

- The National Children's Study is an observational study. That means that we will follow children from birth to age 21 by:
 - Visiting with you at home and maybe at other places where your child/the child you take care of spends a lot of time. We will ask you to visit us at a clinic or the local Study Center near you.
 - Asking questions about you and where you live and work.
 - Collecting samples from you like blood, urine, and saliva and from your home like dust and air.
- As an observational study, we will not:
 - Ask you to change what you normally do.
 - Ask you or your child/the child you take care of to take any medicines or drugs.

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

- About 5,000 children will be in the Vanguard Study.
- About 100,000 children from all over the United States will be in all parts of the Study.
- We are also asking those caring for the children in the Study to join.

How long will the National Children's Study last?

- The Study will follow children until they are 21 years old.

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

- If you join the National Children's Study, we will sometimes visit you at home and sometimes ask you to visit a clinic or doctor's office for tests, exams, and measurements.
- Because the Study will change over time different families may be asked to take part in different Study activities.
- Each time we visit, we will explain what we are doing and ask your permission to do it. We will give you a visit information sheet that describes everything we want to do during the visit.

How many visits should I expect?

- We plan to visit you and your child/the child you take care of regularly over 21 years.
 - ▶ We plan to visit twice during the first year of your baby's life.
 - ▶ After that, we plan to visit about every 1 to 3 years.
 - ▶ At other times, we will call, e-mail, or send a letter to ask questions about your child's development and health.
 - ▶ We will ask you to answer questions about your child/the child you take care of for the first several years. Once your child/the child you take care of is 7 years old, we will ask him or her questions, too.

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

- The National Children's Study will visit your home to collect information about you, your health, and your physical, social, and family environment.
- We may take your body measurements like height, weight, and blood pressure.
- We may ask you to answer questions or fill out forms about your child, like keeping a diary for a week about the food your child eats.
- If there are questions you do not want to answer, you can skip them and still be in the Study.
- We may ask for your permission to look at your health information and medical records during the time 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.
- During some visits, we may ask for your permission to collect samples, like 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.
- During some visits, trained National Children's Study 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 get some samples by collecting:
 - ▶ A small amount of your urine in a cup.
 - ▶ A small amount of your saliva 3 times a day for 2 days.

- ▶ 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.
 - ▶ 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 about genetic information?

- If you agree, we will get information about your genes. We will get this information from the blood, saliva, and other samples you give us. We will also ask questions about your family medical history.
- 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.
- Some people worry that research about genetic causes of disease may give information not only about themselves, but about family members. There is always some chance that technology could be developed that would make it possible to reveal your identity or that of your family members. We will continue to review and improve the ways we keep your information private.
- Some people are sensitive about genetic information for cultural or religious reasons. If you do not want us to conduct genetic tests, let us know. You can tell us not to collect your genetic information and still be in the Study.
- The Study will not do the genetic testing right away. We will store and test those samples in the future.
- Future genetic testing of samples may sometimes be done together with other approved researchers who receive permission from the Study. We may share your information directly with researchers or we may share it through a secure national research database. The goals of these future studies will be similar to the goals of the National Children's Study.
- To answer the Study's research questions, we may also look at your genetic information together with information from other research studies and information sources.

What will the National Children's Study do with all this information?

- The National Children’s Study may use the information and samples we get from you 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 experiences during early life may affect children’s health.
 - ▶ How children’s genes, surroundings, and experiences work together 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, too.
- In the future, scientists could develop new technologies or products based on the information and samples 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 to answer our research questions.
- By agreeing to be in the Study, you are agreeing to allow possible use of your information and samples for future studies on child and maternal health and disease.
- These studies might be done by other approved researchers. The goals of these future studies will be similar to the goals of the National Children’s Study.
- An independent group of doctors, scientists, and community members will make sure that your information and samples will only be used to meet the goals of the Study. The Independent Safety Monitoring and Oversight Committee, or iSMOC, will make sure that your information and samples will only be used to:
 - ▶ Help us better understand children’s health and growth.
 - ▶ Answer questions about why some children are more likely to get certain diseases.

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

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

- We plan to test most of your samples in the future.
 - ▶ At this time, we do not know when these tests will be done, which tests will be done, and when information from the tests will be available.
 - ▶ Most of the tests we will do on the samples will be to help us understand how the physical, social, and family environments, genes, and other factors affect health and disease. These tests will not provide information about your 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 are available, we may ask if you want to learn about them.

How will the Study protect my information?

- We will protect your privacy and keep information about you safe by:
 - ▶ Using a number code to label all samples and other information.
 - ▶ Keeping your number code separate from your name, address, and other personal information. We will look at your information using the number code and not your personal information.
 - ▶ Keeping your test results and other information in a secure computer database.
 - ▶ Storing samples and other information in a secure place. We will limit and keep track of access to your samples to make sure they are safe.
- Researchers who want to use your information must:
 - ▶ Get certified by the National Children's Study and the Federal government.
 - ▶ Get permission to use your information. A group of doctors, scientists, and community members (the iSMOC) will make sure that your information and samples will only be used to meet the goals of the Study. The goals are to better understand child health and growth and to learn about why some children are more likely to get diseases.
 - ▶ Sign an affidavit of nondisclosure. This means promising to use your information only for research. 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 track researchers to make sure they are keeping your information safe.
- We will regularly review all of the ways we keep your information and samples safe to keep improving how we protect your privacy.

- 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 that the Study cannot be forced by a court order or subpoena to give out information that might identify you in any court.

When might the Study have to give out my information?

- If we learn that you or someone else is harming you, your child/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.
- 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.

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 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 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 we get samples may be uncomfortable. If you are uncomfortable, 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 visit to your home will probably take 2 to 3 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 biological parents of the child you take care of. We will not give out any information about parentage to you or any other

members of your family.

- Although we are taking many steps to protect your information, there is always a chance that your information or identity could be disclosed. We will continue to review and improve the ways we keep your information private. To protect your information, we will keep your name and address separate from our information files.
- 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 National Children's 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, bathrobe, picture frame, or other small items to thank you for being in the Study.

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

- You can leave the National Children's Study at any time. You also can leave the Study for a short time and, if you are still responsible for caring for the participating child, you can come back.
- 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 or return any of your unused samples, you can ask us to do so and we will.
- 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 would like to keep in touch with you as long as the 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 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.
- The Study will pay for all tests and procedures done as part of the Study. Any future tests done on your samples 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 the media be interested in my participation or the participation of my child/the child I take care of in the National Children's Study?

- The National Children's Study 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 if they want to talk about their experiences with the Study.

- If you are contacted by reporters, you can decide if you want to talk to them. If you do talk to a reporter, they can write about anything you tell them. What you say will be public information. The organization that the reporter works for will have control over any information and material you give them.
- If you talk with the media about your Study experience or the Study experience of your child/the child that you take care of, your role and the role of your child/the child you take care of as Study participants 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 National Children's Study?

- If you have questions now, you can ask the Study representative who gave you this informed consent form.
- If you have any other questions about your rights as a Study participant, now or in the future, you can contact the people listed on the page that we will ask you to sign.

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

- After reading this informed consent form, we hope you will decide to join the National Children's Study.
- We will ask you to sign a page that says you have decided to join the Study.
- If you join the Study now, you can quit at any time.
- 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.
- Before you decide, you may want to talk with your family, friends, or doctor about joining the Study.

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

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

- I have received the informed consent form, "What You Should Know About Joining the National Children's Study Vanguard Study," which explains the nature and purpose of the Study.
- I understand that I can leave the Study at any time and for any reason and then rejoin later.
- I understand that if there is a question I do not want to answer, a sample that I do not want to provide, or a part of the Study I do not want to do, I can skip it and still be in the Study.
- I understand that my biological samples and environmental samples from my home will be stored in a secure facility and that the Study will protect access to my samples.
- I understand that these samples may be used for a variety of tests in the future, including genetic tests.
- I understand that I will not routinely get results back from tests done on the samples I give to the Study.
- I have asked and received answers to all my questions about the Study. I understand that I can ask more questions at any time.

	<u>Yes</u>	<u>No</u>
I give my permission for the Study to collect environmental samples from my home.	<input type="checkbox"/>	<input type="checkbox"/>
I give my permission for the Study to collect biological samples from me.	<input type="checkbox"/>	<input type="checkbox"/>
I give my permission for the Study to use my biological samples to obtain my genetic information.	<input type="checkbox"/>	<input type="checkbox"/>

I choose to join the National Children's Study.

<p><u>Participant</u></p> <p>Printed Legal Name of Participant: _____</p> <p>Signature of Participant: _____ Date: ____/____/____ (mm/dd/yyyy)</p> <p>Date of Birth: ____/____/____ (mm/dd/yyyy)</p>

<p><u>Witness (if required)</u></p> <p>I observed the interviewer explain the informed consent form "What You Should Know About Joining the National Children's Study Vanguard Study," to the participant and he or she signed or marked this form.</p> <p>_____ Signature of Witness</p> <p>Date: ____/____/____ (mm/dd/yyyy)</p>

Printed Name of Person Obtaining Consent: _____
Signature of Person Obtaining Consent: _____ Date: ____/____/____ (mm/dd/yyyy)

If you have questions about this study, you may call the local numbers listed on the label below.

For Office Use Only: New Adult Signature

SO keep top copy.
Give participant
bottom copy.



What You Should Know About Your Child's Participation in the National Children's Study Vanguard Study

Parental Permission for Child's Participation

Thank you for supporting the National Children's Study!

- The goal of the Study is to improve the health and well-being of all children.
- We are inviting your child to be one of 100,000 children helping us learn more about how our physical, social, and family environments affect the health, growth, and development of our children.
- The National Children's Study has several stages. Different stages of the Study will run at the same time. We are currently in the first stage, called the Vanguard Study. The Vanguard Study will help us decide on the design of the next stage, called the Main Study.
- It is up to you whether or not your child participates in the National Children's Study. You can change your mind about having your child in the Study at any time and for any reason.
- If you decide not to give certain information about your child, he or she can still be in the Study.
- Your child can leave the Study for a period of time and rejoin later. You can decide not to answer certain questions or give certain samples 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 of the National Institutes of Health (NIH) in collaboration with a consortium of federal government partners. Study partners include the National Institute of Environmental Health Sciences of the NIH, the Centers for Disease Control and Prevention, and the Environmental Protection Agency.

What is the goal 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 physical environment (including air and dust), social environment (our neighborhoods and communities), and family environment:
 - ▶ Affect how children grow, and
 - ▶ Help children stay healthy.
- The Study will look at how our genes act together with our surroundings to influence health, growth, and development.
- The National Children’s Study has several stages. The first stage is called the Vanguard Study. The next stage is called the Main Study.
- What we do—the questions we ask and the procedures we use—during the Vanguard Study may be different from what we do in the Main Study.
- The Vanguard Study will help us decide what questions and procedures will work best in the Main Study.
- As we progress through the Vanguard Study, we will use what we learn to help us decide what will work best for the rest of the Vanguard Study. That is why what we do as part of the Vanguard Study will change over time.
- We will use what we learn in the Vanguard Study and in the Main Study to achieve our goal of improving the health of all children.

Why is the National Children’s Study important?

- The National Children’s Study is important because it will help us understand how we can improve our 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, we can learn more about how our physical environment, social environment, and family environment affects children’s health, growth, and development while they are young and when they become adults.
- The Study may also help us to better understand why some children develop obesity, diabetes, autism, learning disabilities, or 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 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 will ask you to visit us at a clinic or the local Study Center near you.

- ▶ Asking questions about you and your child, and where you live and work.
- Collecting samples from your child like blood, urine, and saliva.
- As an observational study, we will not:
 - ▶ Change how you treat your child from what you would normally do.
 - ▶ Ask your child to take any medicines or drugs.

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

- About 5,000 children will be in the Vanguard Study.
- About 100,000 children from all over the United States will be in all parts of the Study.

How long does the National Children’s Study last?

- We hope your child will be in the National Children’s Study until he or she is 21 years old.

What is involved in my child’s being in the National Children’s Study?

- If your child joins the National Children’s Study, we will sometimes visit you and your child at home and sometimes ask you and your child to visit a clinic or doctor’s office for tests, exams, and measurements.
- Because the Study will change over time, different families may be asked to take part in different Study activities.
- Each time we visit, we will explain what we are doing and ask your permission to do it. We will give you a visit information sheet that describes everything we want to do during the visit.

How many visits should I expect?

- We plan to visit you and your child regularly over 21 years of the National Children’s Study.
 - ▶ We plan to visit you and your child shortly after the birth of your child.
 - ▶ We plan to visit twice in your child’s first year.
 - ▶ After that, we plan to visit about every 1 – 3 years.
 - ▶ Between visits, we will call, e-mail, or send you surveys from time to time to keep in touch and find out about your child.
 - ▶ We will ask you to answer questions about your child for the first several years. Once your child is 7 years old, we will ask him or her questions, too.

What kinds of information and samples will the National

Children's Study collect?

- The National Children's Study will visit your home to collect information about your child, your child's health, and your child's physical, social, and family environment.
- We may take your child's body measurements like height, weight, and blood pressure.
- We may ask you to answer questions or fill out forms about your child, like keeping a diary for a week about the food your child eats.
- If there are questions you do not want to answer, you can skip them and still be in the Study.
- We may ask for your permission to look at your child's health information and medical records during the time of the Study.
 - ▶ If you change your mind after you give us permission, we will stop getting new information from your child's medical records, but we may keep using the information we have already gotten.
- During some visits, we may ask for your permission to collect samples from your child.
 - ▶ When your child is a newborn, we may ask to collect samples like a stool sample from your child's diaper, and a small amount of blood (up to 7 drops) from your child's heel on a paper blood spot card.
 - ▶ As your child grows older, we may ask to collect blood, hair, saliva, and toenail clippings.
- 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.
- We may also ask for your help to get some samples from your child, like urine.
- During some visits we may ask to collect samples from the home where your child lives, such as air, dust, and water. For example, we may have our staff collect:
 - ▶ Dust samples using a vacuum cleaner and dust cloth we provide.
 - ▶ Air samples using special equipment we bring with us.
 - ▶ Samples of the water your child drinks.
 - ▶ If we are collecting samples from rooms in your home, we will ask your permission first.
- We may take some dust, air, or water samples from other places where your child spends time like a day care center or school.
- Sometimes, we will ask you if we can videotape or take pictures of your child.
- Before we ask any questions or collect any samples, we will explain what we are doing to make sure it is okay with you.
- 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?

- If you agree, we will get information about your child's genes. We will get this information from the blood, saliva, and other samples we collect. We will also ask questions about your family medical history.

- 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.
- Some people worry that research about genetic causes of disease may give information not only about themselves but about family members. There is always some chance that technology could be developed that would make it possible to reveal you identity or that of your family members. We will make every effort to prevent this. We will continue to review and improve the ways we keep your information private.
- Some people are sensitive about genetic information for cultural or religious reasons. If you do not want us to conduct genetic tests, let us know. You can tell us not to collect your child’s genetic information and your child can still be in the Study.
- The Study will not do the genetic testing right away. We will store and test those samples in the future.
- Future genetic testing of samples may sometimes be done together with other approved researchers who receive permission from the Study. We may share your information directly with researchers or we may share it through a secure national research database. The goals of these future studies will be similar to the goals of the National Children’s Study.
- To answer the Study’s research questions, we may also look at your genetic information together with information from other research studies and information sources.

What will the National Children’s Study do with all of this information?

- The National Children’s Study may use the information and samples we get from your child in several ways.
- We will store your child’s information and samples along with information and samples from the other children and families in the National Children’s Study indefinitely.
- Researchers may use this information to find out:
 - ▶ How experiences during pregnancy or early life may affect our children’s health.
 - ▶ How children’s genes, surroundings, and experiences work together 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 your child to answer those questions, too.
- In the future scientists could develop new technologies or products based on the information and samples we collect from your child and store for the Study. Your child will not receive any money that may result from such new technologies or products.
- We may also combine the information we receive from your child for this Study with information from other research studies to answer our research questions.
- By letting your child be in the Study, you are agreeing to allow possible use of your child’s information and samples for future studies on child and maternal health and disease.
- These studies might be done by other approved researchers. The goals of these future studies will be similar to the goals of the National Children’s Study.

- An independent group of doctors, scientists, and community members will make sure that your information and samples will only be used to meet the goals of the Study. The Independent Safety and Monitoring Committee, or iSMOC, will make sure that your child's information and samples will only be used to:
 - ▶ Help us better understand children's health and growth.
 - ▶ Answer questions about why some children are more likely to get certain diseases.

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

- We will share what we learn from the Study as a whole. We will keep in touch through newsletters, on our Web site, and in other ways.
- We will share some of the information we learn about your child with you when it is available.
- If we know the results from tests we do during a visit, we will share them with you then. For example, we will tell you information about your child's height, weight, and blood pressure.
- We plan to test most of your child's samples in the future.
 - ▶ At this time, we do not know when these tests will be done, which tests will be done, and when information from the tests will be available.
 - ▶ Most of the tests we will do on the samples will be to help us understand how the physical, social, and family environments, genes, and other factors affect health and disease. These tests will not provide information about your child's 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 child's health are available, we may ask you if you want to learn about them.

How will the Study protect my child's information?

- We will protect your child's privacy and keep his or her information safe by:
 - ▶ Using a number code to label your child's samples and other information.
 - ▶ Keeping your child's number code separate from his or her name, address, and other personal information. We will look at your child's information using the number code and not your child's other personal information.
 - ▶ Keeping your child's test results and other information in a secure computer database.
 - ▶ Storing your child's samples and other information in a secure place. We will limit and keep track of access to your samples to make sure they are safe.
- Researchers who want to use your child's information must:
 - ▶ Get certified by the National Children's Study and the Federal government.
 - ▶ Get permission to use your information. A group of doctors, scientists, and community members (the iSMOC) will make sure that your child's information and samples will only be used to meet the goals of the Study. The goals are to better understand child health

and growth and to learn about why some children are more likely to get diseases.

- ▶ Sign an affidavit of nondisclosure. This means promising to use your child's information only for research. They also must agree not to share your child's information with anyone who has not made this same promise.
- ▶ Protect your child's information by reporting it only as part of a group.
- We will track researchers to make sure they are keeping your child's information safe.
- We will regularly review all of the ways we keep your child's information and samples safe to keep improving how we protect your privacy.
- 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 that the Study cannot be forced by a court order or subpoena to give out information that might identify your child in any court.

When might the Study have to give out my child's information?

- 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.
- If you give someone or an organization written permission to see the information your child gave the Study, we cannot use the Certificate of Confidentiality to protect your child's 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 your child or your family right now. But the Study may help us learn things about children's 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. But the Study cannot and will not pay for your child's 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 National Children's Study are the same as those in routine health care.
- Some of the ways we get measurements or samples may make your child uncomfortable. If you are uncomfortable, you can skip any part of the Study. You are in charge.
- Some materials, like the adhesive on the bag used to collect your child's urine sample, may

irritate your child's skin.

- Giving a blood sample may cause a small amount of pain. Your child may sometimes feel brief pain when blood is taken, and there is a very small risk of infection, bruising, bleeding, or fainting.
- A visit to your home may take 2 to 3 hours. We will schedule these visits at a convenient time, but it may interrupt your family's routine. You can change the date or time of any scheduled visit at any time.
- We may learn information about adoption or the biological parents of your child. We will not give out any information about parentage to you or any other members of your family.
- Although we are taking many steps to protect your child's information, there is always a chance that your child's information or identity could be disclosed. We will continue to review and improve the ways we keep your child's information private. To protect your child's information, we will keep your child's name and address separate from our information files.
- 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 my child be paid for being in the National Children's Study?

- From time to time, we may give your child small gifts like a toy, a t-shirt, a tote bag, or a music CD to thank him or her for being in the Study.
- As your child gets older, as a thank you for being in the Study we may give him or her gift certificates or small amounts of money.

What if I want my child to leave the National Children's Study?

- Your child can leave the Study at any time. Your child can also leave the Study for a short time and come back.
- If you decide to take your child out of the Study, we will not ask for any new information, but we will keep using the information and samples your child has already given us.
- If you want us to destroy or return any of your child's unused samples, you can ask us to do so and we will.
- Leaving the Study will not affect your child's access to health care or any other benefits he or she might be receiving, like those from Social Security, Medicaid, WIC, or the Supplemental Nutrition Assistance Program.

What if my child and I move?

- We hope you will tell us if you and your child are planning to move so your child can still be part of the Study in his or her new home.

- If you and your child 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 if you want your child to continue to be part of the Study.

When my child gets older, will he or she be able to make decisions about participating in the National Children's Study?

- We need your permission for your child to join the Study.
- Young children and adolescents will be asked their permission to stay in the Study and can choose not to be in the Study anymore.
- When your child becomes a legal adult (at about age 18, depending on your state law) he or she will be asked to sign a consent form, like this one, saying that he or she would like to continue to be part of the Study.

Will it cost me anything if my child joins the National Children's Study?

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

Does the National Children's Study pay for health care for my child?

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

If my child joins the National Children's Study, will he or she have to join other studies?

- If your child joins the National Children's 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 National Children's Study.
- If your child is invited to be in other studies, you can always say no.

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

- The National Children's Study 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 if they want to talk about their experiences with the Study.
- If you are contacted by reporters, you can decide if you want to talk to them. If you do talk to a reporter, they can write about anything you tell them. What you say will be public information. The organization that the reporter works for will have control over any information and material you give them.
- If you talk with the media about your child's experience with the Study, your child's role as Study participant 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 information about other participants from your community.

Who can I contact if I have questions about the National Children's Study?

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

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

- After reading this parental permission form, we hope you will decide to allow your child to join the National Children's Study.
- We will ask you to sign a page that says you allow your child to join the Study.
- If you allow your child to join the Study now, your child can leave at any time.
- You decide what questions to answer. You can also decide what samples your child will give. If you decide not to answer some questions or allow your child to give some samples, your child can still be in the Study.
- Before you decide, you may want to talk with your family, friends, or doctor about joining the Study.

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

**National Children's Study: Vanguard Study
Permission for Your Child's Study Participation**

- I have received the parental permission form "What You Should Know About Your Child's Participation in the National Children's Study Vanguard Study," which explains the nature and purpose of the Study.
- I understand that I can withdraw my child from the Study for any time and for any reason. My child can rejoin later.
- I give permission for the Study to collect information and samples about my child from birth through my child's age of majority.
- I understand and permit the Study to look at and handle my baby soon after birth to make assessments and record measurements during our stay at my chosen hospital, clinic, birthing center, or at my home (for home births).
- I understand that I am also giving my permission for the National Children's Study to get and use my child's medical records and health information.
- I understand that if there is a question about my child that I do not want to answer, a sample from my child that I do not want to provide, or a part of the Study that I do not want my child to do, my child can skip it and still be in the Study.
- I understand that my child's biological and environmental samples will be stored in a secure facility and that the Study will protect access to my child's samples.
- I understand that my child's samples may be used for a variety of tests in the future, including genetic tests.
- I understand that I will not routinely get results back from tests done on my child's samples.
- I have asked and received answers to all my questions about this Study. I understand that I can ask more questions at any time.

	Yes	No
I give my permission for the Study to collect environmental samples from places where my child spends time.	<input type="checkbox"/>	<input type="checkbox"/>
I give my permission for the Study to collect biological samples from my child.	<input type="checkbox"/>	<input type="checkbox"/>
I give my permission for the Study to use my child's biological samples to obtain my child's genetic information.	<input type="checkbox"/>	<input type="checkbox"/>

Child's Parent/Legal Guardian

By signing this form, I give permission for my child, _____, to join the National Children's Study.
(Name of Child)

Printed Legal Name of Parent/Legal Guardian: _____

Signature of Parent/Legal Guardian: _____ Date: ____/____/____
(mm/dd/yyyy)

Supporting Adult or Child Advocate (if required for non-emancipated parent)

I give permission for the child of _____ to join the National Children's Study.
(Name of Minor Parent)

Printed Legal Name of Supporting Adult/Advocate: _____

Signature of Supporting Adult/Advocate: _____ Date: ____/____/____
(mm/dd/yyyy)



The National Children's Study Parental Permission for Child's Participation

Birth Through 6-Months of Age

Thank you for participating in the National Children's Study. When you joined the Study, we explained how important you and your family are to its success. Now, we will tell you more about the kinds of information we would like to collect from you and your child and to ask for your permission to collect information about your child from birth through six months of age.

What will happen after the birth of my child?

- 1) Some hospitals routinely collect and store cord blood and the placenta when children are born at the hospital. If your hospital routinely collects these samples, we would like your permission to obtain them from the hospital for analysis in the National Children's Study. If you have decided to participate in a cord blood bank program to store your child's cord blood, we will not collect any umbilical cord blood for the Study.
- 2) We would also like to collect a blood sample from your child soon after birth. We would like to collect a small amount of blood (up to 7 drops) from the child's heel. We will work with hospital staff to collect the sample when they collect the baby's blood for routine tests.
 - All samples will be collected by trained medical professionals who know how to collect blood safely.
 - No additional heel sticks will be performed to collect this blood sample.
- 3) 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 10 minutes to complete. We will ask you about yourself, your child's birth, and your plans once your child is born.
 - You can decide what questions you want to answer. If you feel uncomfortable about any question, you can skip it.

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's visits when we talk to you on the phone or visit you in person.
- We will contact you to arrange a phone call with you when your child is about three months old and to schedule another visit with you and your child when your child is around six months old.

How may my child's umbilical cord blood sample, placenta, and blood from the heel stick be used?

- We may use your child's umbilical cord blood, placenta, and heel stick blood for analyses that include biological, genetic, and environmental testing based on the permission you give at the end of this informed consent process.
- The Study will not do the testing right away. We will store and test those samples in the future.
- 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.
- Some people are sensitive about sharing genetic information. If you do not want us to conduct genetic tests, let us know. You can tell us not to collect your child's genetic information and your child can still be in the Study.
- Future testing of samples may sometimes be done together with other approved researchers who receive permission from the Study. We may share your child's information directly with researchers or we may share it through a secure national research database. The goals of these future studies will be similar to the goals of the National Children's Study.

Are there any risks from the birth and follow-up visits?

- Some of the questions we ask and some of the ways we get samples may be uncomfortable. If you or your child are uncomfortable, you can skip any part of the visit. You are in charge.
- We may learn information about adoption or the biological parents of your child. We will not give out any information about parentage to you or any other members of your family.
- Some people worry that research about genetic causes of disease may give information not only about themselves but about family members. There is always some chance that technology could be developed that would make it possible to reveal your child's identity or that of your family members. We will make every effort to prevent such disclosure. 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.
- Although we are taking many steps to protect you and your child's information, there is always a chance that your information or identity could be disclosed. We will continue to review and improve the ways we keep your information private. To protect your information, we will keep your name and address and that of your child separate from our information files.

Are there any benefits from the birth and follow-up visits?

- Taking part in the National Children's Study may not help you, your child, 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.

Will I be paid for taking part in the birth and follow-up visits?

- To thank you for your time, we will give you \$25 for completing the interview. You will receive an additional \$25 dollars for providing any samples from you and your child.

What if I have questions about these visits?

- If you have any questions about this visit, you can ask the Study representative you are talking with today. If he or she cannot answer a question, we will give you the name and phone number of someone from our local office who can answer your questions.

Please remember:

- Whether or not you and your child stay in the National Children's Study is your choice. The alternative to taking part in the Study is not taking part in the Study.
- You can decide not to let us collect samples from you and your child and still be in the Study.
- If you leave the Study, you can rejoin it later.
- If you and your child leave the Study, we will not ask you for any new information, but we will keep using the information you have already given us. We will keep everything that you tell us confidential.
- 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.
- 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 proper authority or a social services agency in your community.
- This is a research study and we cannot give you medical advice. None of the Study visits take the place of regular doctor or clinic visits.
- We will ask you for ongoing permission for your child's participation in the remainder of the Study around the time that your child turns six months old.

National Children's Study
Permission for Your Child's Participation in the Study from Birth through Six Months of Age

- I have received the Parental Permission for Child's Participation for Birth through 6 Months of Age.
- I understand that my child can leave the Study at any time and for any reason and then rejoin later.
- I understand what activities the Study plans to do during my stay at my chosen hospital, clinic, or birthing center at the time of the birth of my expected child.
- I understand that if there is a question that I do not want to answer or a part of the Study that I do not want to do, I can skip it and still be in the Study.
- I give permission for the Study to collect information about my child from birth through six months of age.
- I understand that I will be asked for permission for my child's ongoing participation in the rest of the Study when my child is about six months old.

	Yes	No
I give my permission for the Study to collect my child's cord blood.	<input type="checkbox"/>	<input type="checkbox"/>
I give permission for the Study to collect my child's placenta.	<input type="checkbox"/>	<input type="checkbox"/>
I give permission for the Study to collect blood from my child's heel.	<input type="checkbox"/>	<input type="checkbox"/>
I give my permission for the Study to use my child's cord blood, placenta, and heel stick blood to obtain my child's genetic information.	<input type="checkbox"/>	<input type="checkbox"/>

Child's Parent/Legal Guardian

By signing this form, I give permission for my child, _____, to join the National Children's Study.
 (Name of Child. If known)

Printed Legal Name of Parent/Legal Guardian: _____

Signature of Parent/Legal Guardian: _____ Date: ____/____/____
 (mm/dd/yyyy)

Supporting Adult or Child Advocate (if required for non-emancipated parent)

I give permission for the child of _____ to join the National Children's Study.
 (Name of Minor Parent)

Printed Legal Name of Supporting Adult/Advocate: _____

Signature of Supporting Adult/Advocate: _____ Date: ____/____/____
 (mm/dd/yyyy)

Witness (if required)

I observed the interviewer explain "Parental Permission for Child's Participation for Birth through 6 Months of Age" to the participant and she signed or marked this form.

_____/_____/_____
 Signature of Witness Date (mm/dd/yyyy)

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____ Date: ____/____/____

If you have questions about this study, you may call the local number(s) listed below.

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 National Institute of Child Health & Human Development Institutional Review Board at 301-496-8370.



MULTI-MODE INTRODUCTORY SCRIPT FOR ALL STUDY CALLS AND VISITS

Event:	Pregnancy Loss (PBS only)*, Pregnancy Visit 1 (PBS only)*, Pregnancy Visit 2 (PBS only)*, Father, Birth, 3-Month, 6-Month, 9-Month, 12-Month, 18-Month, 24-Month, 30-Month
Participant:	Non-Pregnant Woman, Pregnant Woman, Father, Parent, Caregiver
Domain:	Consent
Type of Document:	Visit Information Sheet Script
Allowable Mode:	In-person (CAPI), Telephone (CATI)**
Allowable Method:	Interviewer-Administered
Recruitment Groups:	EH, PB, HI, LI, PBS
Version:	x.x
Release:	MDES 3.3

*The Multi-mode Introductory Script is only administered at the Pregnancy Loss, Pregnancy Visit 1, and Pregnancy Visit 2 events for the PBS recruitment strategy. For all other events, the Multi-mode Introductory Script is administered for all recruitment strategies (EH, PB, HI, LI, and PBS).

**In addition to the allowable modes listed above, this instrument is OMB-approved for Web but at this time there are no instruments available for this type of administration.

(TIME_STAMP_1) PROGRAMMER INSTRUCTION:

- INSERT DATE/TIME STAMP

Thank you for agreeing to participate in the National Children’s Study.

I’m {calling/here} today to ask you some questions about you {and your child}. {We appreciate your willingness to talk with us about the recent loss of your baby.} We realize that you are busy, and this {call/visit} should take only about {APPROXIMATE VISIT TIME} to complete. {I will ask you questions about you{, your child’s health and behavior,} and your household.} To thank you for your time, we will give you \$25 for answering these questions. {If we ask you for samples, you will receive an additional token of appreciation.}

PROGRAMMER INSTRUCTIONS:

- IF **EVENT_TYPE** = PREGNANCY LOSS, DISPLAY “We appreciate your willingness to talk with us about your loss”.
- IF **EVENT_TYPE** = BIRTH OR SUBSEQUENT EVENT, DISPLAY “and your child” AND “I will ask you questions about you, your child’s health and behavior, and your household.” OTHERWISE, IF **EVENT_TYPE** = PV1, PV2, OR FATHER, DISPLAY “I will ask you questions about you and your household.”
- IF **EVENT_TYPE** ≠ PREGNANCY LOSS, DISPLAY, “If we ask you for samples, you will receive an additional token of appreciation.”
- IF MODE = CATI OR PHONE PAPI, DISPLAY “calling” AND “call”.
- IF MODE = CAPI OR IN-PERSON PAPI, DISPLAY “here” AND “visit”. PRELOAD AND DISPLAY APPROXIMATE VISIT TIME FOR APPROPRIATE **EVENT_TYPE** AND **RECRUITMENT_STRATEGY** IN HOURS OR MINUTES USING THE APPROXIMATE VISIT TIME TABLE:

Approximate Visit Time Table

EVENT_TYPE	RECRUITMENT_STRATEGY	APPROXIMATE VISIT TIME (HRS, MIN)
PREGNANCY LOSS	PBS	15 MINUTES
PREGNANCY VISIT 1 & 2	PBS	1 HOUR
FATHER	EHPBHI	1 ¾ HOURS
BIRTH	EHPBHIPBS	45 MINUTES
BIRTH	LI	30 MINUTES
3 MONTH	EHPBHILIPBS	40 MINUTES
6 MONTH	EXPANDED EHPBHI	2 HOURS
6 MONTH	BASE EHPBHIPBS	1 ½ HOURS
9 MONTH	EHPBHILIPBS	35 MINUTES
12 MONTH	EXPANDED EHPBHI	2 HOURS
12 MONTH	BASE EHPBHIPBS	1 HOUR
18 MONTH	EHPBHILIPBS	45 MINUTES

24 MONTH	EHPBHI	1 ½ HOURS
24 MONTH	PBS & LI	45 MINUTES
30 MONTH	EHPBHILIPBS	1 ¾ HOURS

Your answers are very important to us. There are no right or wrong answers. You can skip over any question or stop the interview at any time. Participating in the Study is your choice.

We make every effort to keep what you tell us confidential. Please remember, that 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. Also, remember that this is a research study and we cannot give you medical advice. Finally, if you have any questions about this {call/visit} or the Study, you can ask me. If I can't answer your questions I will give you the name and phone number of someone from our local office who can.

PROGRAMMER INSTRUCTIONS:

- IF **EVENT_TYPE** ≠ PREGNANCY LOSS, DISPLAY “, or your child,”.
- IF **MODE** = CATI OR PHONE PAPI, DISPLAY “call”.
- OTHERWISE IF **MODE** = CAPI OR IN-PERSON PAPI, DISPLAY “visit”.

(TIME_STAMP_2) PROGRAMMER INSTRUCTION:

- INSERT DATE/TIME STAMP

INTERVIEWER INSTRUCTION:

- IF SAMPLE COLLECTIONS OR MEASUREMENTS ARE PART OF THE PROTOCOL FOR THIS VISIT, USE THE APPROPRIATE SAMPLE COLLECTION VISIT INFORMATION SHEET.



SAMPLE COLLECTION VISIT INFORMATION SHEET SCRIPTS

Event:	Birth, 6-, 12-, 24-Months
Participant:	Mother, Child
Respondent:	Mother, Parent, Caregiver
Domain:	Consent
Type of Document:	Visit Information Sheet Scripts
Recruitment Groups:	EH, PB, HI, PBS*
Version:	2.0
Release:	MDES 3.3

*The Sample Collection Visit Information Sheet Script is only approved for administration at the 6-month, 12-month, and 24-month events for the EH, PB, and HI recruitment strategies and at the Birth event for the EH, PB, HI, and PBS Birth Cohort recruitment strategies.

Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

This page intentionally left blank.

SAMPLE COLLECTION VISIT INFORMATION SHEET SCRIPTS

DATA COLLECTOR INSTRUCTIONS:

- THERE ARE 3 DOCUMENTS THAT ARE USED FOR CREATING THE VISIT-SPECIFIC SAMPLE COLLECTION VISIT INFORMATION SHEET (VIS).
 - SAMPLE COLLECTION VIS SCRIPTS (THIS DOCUMENT)
 - CONTAINS THE VISIT-SPECIFIC SCRIPTS NEEDED FOR EACH VISIT
 - SAMPLE COLLECTION VIS FIELD DOCUMENT
 - PROVIDES A LIST OF VISIT-SPECIFIC SAMPLE/SPECIMEN COLLECTIONS OR ASSESSMENTS
 - SAMPLE COLLECTION VIS TEMPLATE
 - PROVIDES A NCS STANDARD TEMPLATE THAT IS USED FOR DISPLAYING THE VISIT-SPECIFIC SCRIPTS THAT WILL BE PRESENTED TO THE PARTICIPANT/PARENT/CAREGIVER
- GO TO THE SAMPLE COLLECTION VIS FIELD DOCUMENT TO DETERMINE THE APPROPRIATE SAMPLE COLLECTIONS/ASSESSMENTS FOR THIS VISIT.
- TAKE THE ASSOCIATED SCRIPT FOR EACH OF THE SAMPLE COLLECTIONS/ASSESSMENTS FOR THIS VISIT AND INSERT THE SCRIPTS INTO THE SAMPLE COLLECTION VIS TEMPLATE.
- PRINT TWO (2) COPIES OF THE SAMPLE COLLECTION VIS SCRIPT:
 - ONE COPY WILL BE GIVEN TO THE PARTICIPANT/PARENT/CAREGIVER
 - ONE COPY WILL BE USED BY THE DATA COLLECTOR TO PRESENT THE VIS.

SAMPLE COLLECTION VISIT INFORMATION SHEET

1. THE LANGUAGE BELOW SHOULD BE USED FOR THE EH, PB, AND HI BIRTH EVENT.

In addition to asking you questions, we would also like to ask you to collect some samples.

What sample collections am I being asked to participate in?

2. THE LANGUAGE BELOW SHOULD BE USED FOR THE PBS BIRTH COHORT BIRTH EVENT.

In addition to asking you questions, we would also like to collect some samples from you today.

What sample collections am I being asked to participate in today?

3. THE LANGUAGE BELOW SHOULD BE USED FOR ALL EVENTS, BEGINNING WITH THE 6-MONTH EVENT, WHERE A SAMPLE COLLECTION VISIT INFORMATION SHEET IS USED.

In addition to asking you questions, we would also like to collect some samples and measurements from your child today.

What sample collection(s) is my child being asked to participate in today?

4. THE LANGUAGE BELOW SHOULD BE USED FOR THE ADULT BREAST MILK COLLECTION FOR THE EH, PB, HI BIRTH EVENT.

We would like to collect some **breast milk samples** from you when your child is 1 month old and again when your child is 3 months old. To do this we will:

- Either give you the breast milk collection kit when your child is born or we may mail it to you closer to the time that your child will be 1 month old.
- For the 3 month breast milk sample collection, we will mail you the kit.
- You can use these kits to collect a small amount of your breast milk.
- We ask that you freeze each sample until we can come back to pick it up.
- We may test your breast milk to see if the samples contain certain chemicals or hormones.

5. THE LANGUAGE BELOW SHOULD BE USED FOR ADULT URINE COLLECTION FOR THE PBS BIRTH COHORT BIRTH EVENT.

We would like to collect a **urine sample** from you.

- If a sample that the hospital collected from you before your baby's birth is available, with your permission and that of the hospital, we will use that.
- If there is no sample readily available, we will work with hospital staff to provide you with a collection cup for a fresh sample.
- You will collect a small amount of your urine (about 5 tablespoons) in the cup provided.

6. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD URINE COLLECTION FOR APPLICABLE EVENTS

We would like to collect a **urine sample** from your child. To do this we will:

- Use a urine collection bag to collect a urine sample from your child.
- The amount of time that this collection takes varies by child, but we will not leave the collection bag on your child for more than 75 minutes.
- We may test his/her urine for chemicals that may be present in the environment.

Are there any risks from this collection?

- As with any adhesive device, the adhesive component of this product may cause mild irritation upon removal.

7. THE LANGUAGE BELOW SHOULD BE USED FOR THE ADULT BLOOD SAMPLE COLLECTION FOR THE PBS BIRTH COHORT BIRTH EVENT.

We would like to collect a **blood sample** from you.

- If a sample that the hospital collected from you before your baby's birth is available, with your permission and that of the hospital, we will use that.
- If there is no sample readily available, we will work with hospital staff to collect a small amount (about 2 tablespoons) of your blood using a small needle.
- We may test your blood for hormones, nutrients, infections and inflammation, and for the presence of metals and other chemicals in the environment.

Are there any risks from this collection?

- Your blood will be drawn by trained medical professionals who know how to take blood safely. People sometimes feel brief pain when blood is taken, and there is a very small risk of infection, bruising, bleeding, or fainting.

8. THE LANGUAGE BELOW SHOULD BE USED FOR BLOOD SAMPLE COLLECTION FOR APPLICABLE EVENTS, BEGINNING WITH THE 12-MONTH EVENT.

We would like to collect a **blood sample** from your child. To do this we will:

- Collect a small amount (about 2 and a half teaspoons) of your child's blood by using a small needle.
- This will take about 15 minutes.
- We may test your child's blood for hormones, nutrients, infections and inflammation, and for the presence of metals and other chemicals in the environment.

Are there any risks from this collection?

- We are trained medical professionals who know how to take blood safely. People sometimes feel brief pain when blood is taken, and there is a very small risk of infection, bruising, bleeding, or fainting.

9. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD SALIVA COLLECTION FOR APPLICABLE EVENTS.

We would like to collect a sample of your child's **saliva**. This sample collection will either be completed by you or by a data collector.

- This will take about 15 minutes.
- We may measure your child's saliva sample for biological substances and environmental chemicals. We may use the sample for genetic testing with your permission.

Are there any risks from this collection?

- This procedure may be a little uncomfortable for your child.

10. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD PHYSICAL MEASURES COLLECTION FOR THE 6-MONTH EVENT.

We would like to collect some measurements from your child. We will share these measurements with you.

- We will measure his/her:
 - Weight
 - Length/Height when lying down
 - Length of their arm and upper leg
 - Skinfolds of the back or their upper arm and upper back
 - Distance around their head, waist, upper leg, and upper arm
- This will take about 20 minutes

Are there any risks from this collection?

- These procedures may be a little uncomfortable for your child.

11. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD PHYSICAL MEASURES COLLECTION FOR THE 12- AND 24-MONTH EVENTS.

We would like to collect some measurements from your child. We will share these measurements with you.

- We will measure his/her:
 - Weight
 - Length/Height when lying down
 - Length of their arm and upper leg
 - Skinfolds of the back or their upper arm and upper back
 - Distance around their head, waist, upper leg, and upper arm
 - Blood pressure and pulse/heart rate
- This will take about 30 minutes

Are there any risks from this collection?

- These procedures may be a little uncomfortable for your child.

12. THE LANGUAGE BELOW SHOULD BE USED FOR THE EH, PB, AND HI BIRTH EVENT.

Are there any benefits from the sample collection(s)?

- 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.

Will I be paid for taking part in sample collection?

- To thank you, we will give you \$25.

Please remember:

- Whether or not you stay in the National Children’s Study is your choice. The alternative to taking part in the Study is not taking part in the Study.
- Some of the ways we get samples may be uncomfortable. If you feel uncomfortable, you can skip any part of the Study. You are in charge.
- If you leave the Study, you can rejoin it later.
- If you leave the Study, we will not ask you for any new information, but we will keep using the information you have already given us. We will make every effort to protect the privacy of your information.

- This is a research study and we cannot give you medical advice. None of the Study visits take the place of your regular doctor or clinic visits. The Study's environmental measurements do not take the place of any other environmental testing of your home.
- We will not routinely report the results of tests done on any samples that we collect from you or your home.

13. THE LANGUAGE BELOW SHOULD BE USED FOR THE PBS BIRTH COHORT BIRTH EVENT.

Are there any benefits from the sample collection(s)?

- 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.

Will I be paid for taking part in sample collection?

- To thank you, we will give you \$25 for providing samples from you and your child.

Please remember:

- Whether or not you stay in the National Children's Study is your choice. The alternative to taking part in the Study is not taking part in the Study.
- Some of the ways we get samples may be uncomfortable. If you feel uncomfortable, you can skip any part of the Study. You are in charge.
- If you leave the Study, you can rejoin it later.
- If you leave the Study, we will not ask you for any new information, but we will keep using the information you have already given us. We will make every effort to protect the privacy of your information.
- This is a research study and we cannot give you medical advice. None of the Study visits take the place of your regular doctor or clinic visits. The Study's environmental measurements do not take the place of any other environmental testing of your home.
- We will not report the results of tests done on any samples that we collect from you.

14. THE LANGUAGE BELOW SHOULD BE USED FOR ALL EVENTS WHERE A SAMPLE COLLECTION VISIT INFORMATION SHEET IS USED, BEGINNING WITH THE 6-MONTH EVENT.

Are there any benefits from the sample collection(s)?

- 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.

Will I be paid for taking part in sample collection?

- To thank you, we will give you \$25.

Please remember:

- Whether or not you stay in the National Children's Study is your choice. The alternative to taking part in the Study is not taking part in the Study.
- Some of the ways we get samples may be uncomfortable. If you or your child feel uncomfortable, you can skip any part of the Study. You are in charge.
- If you leave the Study, you can rejoin it later.
- If you leave the Study, we will not ask you for any new information, but we will keep using the information you have already given us. We will make every effort to protect the privacy of your information.
- This is a research study and we cannot give you medical advice. None of the Study visits take the place of your regular doctor or clinic visits. The Study's environmental measurements do not take the place of any other environmental testing of your home.
- We will not routinely report the results of tests done on any samples that we collect from you or your home.

6 Month Visit

In addition to asking you questions we would also like to collect some samples and measurements from your child today.

What sample collection(s) is my child being asked to participate in today?

1. We would like to collect a **urine sample** from your child. To do this we will:
 - Use a urine collection bag to collect a urine sample from your child.
 - This may take up to 75 minutes.
 - We may test his/her urine for chemicals that may be present in the environment.

Are there any risks from this collection?

As with any adhesive device, the adhesive component of this product may cause mild irritation to his/her skin upon removal.

2. We would also like to collect some **measurements** from your child. We will share some of these measurements with you. We will measure his/her:
 - Weight
 - Length/Height when lying down
 - Length of their arm and upper thigh
 - Skinfolds of the back of their upper arm and upper back
 - Distance around their head, waist, upper thigh, and arm.
 - This will take about 20 minutes.

Are there any risks from this collection?

These procedures may be a little uncomfortable for your child

Are there any benefits from the sample collection(s)?

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.

Will I be paid for taking part in sample collection?

To thank you, we will give you \$25.

Please remember:

- Whether or not you stay in the National Children’s Study is your choice. The alternative to taking part in the Study is not taking part in the Study.
- Some of the ways we get samples may be uncomfortable. If you or your child feel uncomfortable, you can skip any part of the Study. You are in charge.
- If you leave the Study, you can rejoin it later.
- If you leave the Study, we will not ask you for any new information, but we will keep using the information you have already given us. We will make every effort to protect the privacy of your information.
- This is a research study and we cannot give you medical advice. None of the Study visits take the place of your regular doctor or clinic visits. The Study’s environmental measurements do not take the place of any other environmental testing of your home.
- We will not routinely report the results of tests done on any samples that we collect from you or your home.

Insert local contact information here.

12 Month Visit

In addition to asking you questions we would also like to collect some samples and measurements from your child today.

What sample collection(s) is my child being asked to participate in today?

1. We would like to collect a **urine sample** from your child. To do this we will:
 - Use a urine collection bag to collect a urine sample from your child.
 - This may take up to 75 minutes.
 - We may test his/her urine for chemicals that may be present in the environment.

Are there any risks from this collection?

As with any adhesive device, the adhesive component of this product may cause mild irritation to his/her skin upon removal.

2. We would like to collect a **blood sample** from your child. To do this we will:
 - Collect a small amount (about 2 and a half teaspoons) of your child's blood by using a small needle.
 - This will take about 15 minutes.
 - We may test your child's blood for hormones, nutrients, infections and inflammation, and for the presence of metals and other chemicals in the environment.

Are there any risks from this collection?

We are trained medical professionals who know how to take blood safely. People sometimes feel brief pain when blood is taken, and there is a very small risk of infection, bruising, bleeding, or fainting.

We would like to collect a sample of your child's **saliva**. This sample collection will either be completed by you or the data collector.

- This will take about 15 minutes.
- We may measure your child's saliva sample for cortisol, a chemical the body produces.

Are there any risks from this collection?

This procedure may be a little uncomfortable for your child.

2. We would also like to collect some **measurements** from your child. We will share some of these measurements with you. We will measure his/her:

- Weight
- Length/Height when lying down
- Length of their arm and upper thigh
- Skinfolds of the back of their upper arm and upper back
- Distance around their head, waist, upper thigh, and arm.
- Blood Pressure and Pulse/Heart Rate
- This will take about 30 minutes.

Are there any risks from this collection?

These procedures may be a little uncomfortable for your child

Are there any benefits from the sample collection(s)?

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.

Will I be paid for taking part in sample collection?

To thank you, we will give you \$25.

Please remember:

- Whether or not you stay in the National Children’s Study is your choice. The alternative to taking part in the Study is not taking part in the Study.
- Some of the ways we get samples may be uncomfortable. If you or your child feel uncomfortable, you can skip any part of the Study. You are in charge.
- If you leave the Study, you can rejoin it later.
- If you leave the Study, we will not ask you for any new information, but we will keep using the information you have already given us. We will make every effort to protect the privacy of your information.
- This is a research study and we cannot give you medical advice. None of the Study visits take the place of your regular doctor or clinic visits. The Study’s environmental measurements do not take the place of any other environmental testing of your home.
- We will not routinely report the results of tests done on any samples that we collect from you or your home.

Insert local contact information here

24 Month Visit

In addition to asking you questions we would also like to collect some samples and measurements from your child today.

What sample collection(s) is my child being asked to participate in today?

1. We would also like to collect some **measurements** from your child. We will share some of these measurements with you. We will measure his/her:
 - Weight
 - Length/Height when lying down
 - Length of their arm and upper thigh
 - Skinfolds of the back of their upper arm and upper back
 - Distance around their head, waist, upper thigh, and arm.
 - Blood Pressure and Pulse/Heart Rate
 - This will take about 30 minutes.

Are there any risks from this collection?

These procedures may be a little uncomfortable for your child

Are there any benefits from the sample collection(s)?

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.

Will I be paid for taking part in sample collection?

To thank you, we will give you \$25.

Please remember:

- Whether or not you stay in the National Children’s Study is your choice. The alternative to taking part in the Study is not taking part in the Study.
- Some of the ways we get samples may be uncomfortable. If you or your child feel uncomfortable, you can skip any part of the Study. You are in charge.
- If you leave the Study, you can rejoin it later.
- If you leave the Study, we will not ask you for any new information, but we will keep using the information you have already given us. We will make every effort to protect the privacy of your information.
- This is a research study and we cannot give you medical advice. None of the Study visits take the place of your regular doctor or clinic visits. The Study’s environmental measurements do not take the place of any other environmental testing of your home.
- We will not routinely report the results of tests done on any samples that we collect from you or your home.

Insert local contact information here.



Reconsideration Script

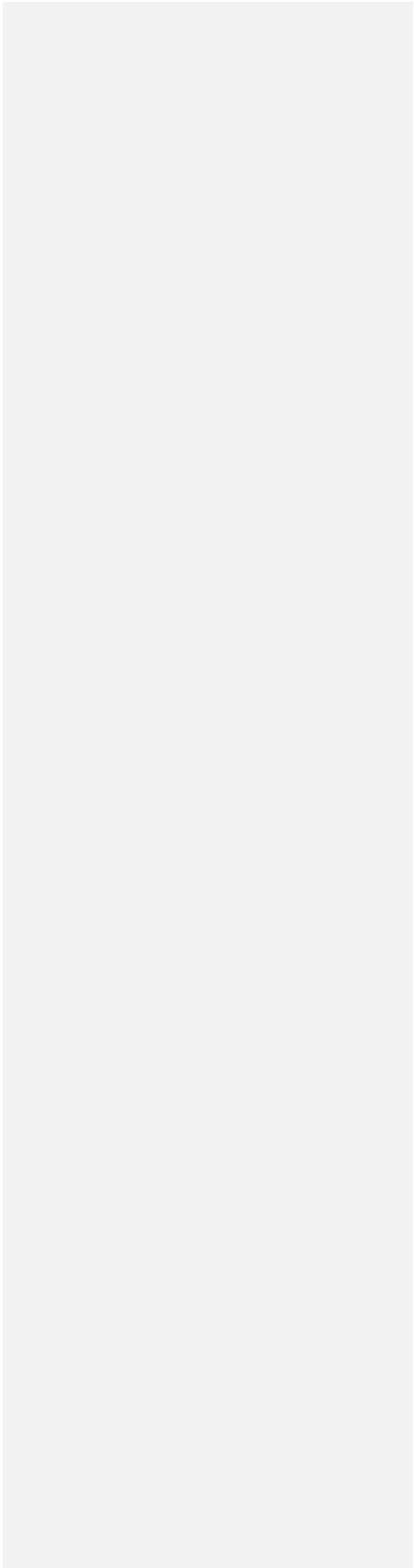
Event:	All Events
Participant:	Child
Respondent:	Parent/Caregiver
Domain:	Questionnaire
Type of Document:	Interview
Allowable Mode:	In person, Telephone
Allowable Method:	Interviewer-Administered, CATI/CAPI
Recruitment Groups:	EH, PB, HI, LI, PBS
Version:	1.0
Release:	MDES 3.0

This page intentionally left blank.

Reconsideration Script

TABLE OF CONTENTS

RE-CONSIDERATION SCRIPT 1



RE-CONSIDERATION SCRIPT

(TIME_STAMP_RCS_ST) PROGRAMMER INSTRUCTION:

- INSERT DATE/TIME STAMP

RCS001/(PREV_SAMPLE_REFUSE). DID THE {PARTICIPANT/PARENT/CAREGIVER} PREVIOUSLY REFUSE ANY SAMPLE COLLECTION?

YES 1
NO 2 (TIME_STAMP_RSC_ET)

Comment [A1]:
Source: New

PROGRAMMER INSTRUCTIONS:

- IF EVENT_TYPE = PV1 OR PV2, DISPLAY "PARTICIPANT".
- IF EVENT_TYPE = 12-MONTH OR 24-MONTH, DISPLAY "PARENT/CAREGIVER".

RCS010/(SAMPLE_REFUSE_TYPE). WHICH TYPES OF SAMPLE COLLECTIONS DID THE {PARTICIPANT/PARENT/CAREGIVER} REFUSE?

Comment [A2]:
Source: New

INTERVIEWER INSTRUCTION:

- SELECT ALL THAT APPLY.

BIOSPECIMEN 1
ENVIRONMENTAL 2

PROGRAMMER INSTRUCTIONS:

- IF EVENT_TYPE = PV1 OR PV2, DISPLAY "PARTICIPANT".
- IF EVENT_TYPE = 12-MONTH OR 24-MONTH, DISPLAY "PARENT/CAREGIVER".

RCS010/(RECON_INTRO). We understand that you did not give us your permission to collect some samples {from you when you consented to join the Study/from {C_FNAME/the child} when you consented for {him/her} to participate in the Study}. Once again, you do not have to agree to provide any samples that you do not want to give, but we would like to offer you the opportunity to provide samples during this visit to help us reach the goals of the Study.

Comment [A3]:
Source: New

PROGRAMMER INSTRUCTIONS:

- PRELOAD CHILD'S GENDER FROM MOST RECENT INTERVIEW:
 - IF CHILD_SEX = 1, DISPLAY "his" AND "he" IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.
 - IF CHILD_SEX = 2, DISPLAY "her" AND "she" IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.
- IF EVENT_TYPE = PV1 OR PV2, DISPLAY "from you when you consented to join the Study."
- IF EVENT_TYPE = 12-MONTH OR 24-MONTH, DISPLAY "from {C_FNAME/the child} when you consented for {him/her} to participant in the Study."
- IF SAMPLE_REFSUE_TYPE INCLUDES 1, GO TO RECON_BIO.
- OTHERWISE, IF SAMPLE_REFUSE_TYPE = 2, GO TO RECON_ENV.

RSC030/(RECON_BIO). Would you like to allow us to collect biological specimens from {you/{C_FNAME/the child}}?

Comment [A4]:
Source: New

INTERVIEWER INSTRUCTION:

- {PARTICIPANT/PARENT/CAREGIVERS} WHO AGREE TO ANY SAMPLE COLLECTION SHOULD BE RE-ADMINISTERED CONSENT USING THE INFORMED CONSENT FORM {INFORMED CONSENT FOR PREGNANT WOMEN'S STUDY PARTICIPATION/WHAT YOU SHOULD KNOW ABOUT YOUR CHILD'S PARTICIPATION IN THE NATIONAL CHILDREN'S STUDY VANGUARD STUDY} AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

YES 1
NO 2
REFUSED -1
DON'T KNOW -2

PROGRAMMER INSTRUCTIONS:

- IF **EVENT_TYPE** = PV1 OR PV2, DISPLAY "you" IN ITEM AND "PARTICIPANTS" AND "INFORMED CONSENT FOR PREGNANT WOMEN'S STUDY PARTICIPATION" IN INTERVIEWER INSTRUCTIONS.
- IF **EVENT_TYPE** = 12-MONTH OR 24-MONTH, DISPLAY "{C_FNAME/the child}" IN THE ITEM AND "PARENT/CAREGIVERS" AND "WHAT YOU SHOULD KNOW ABOUT YOUR CHILD'S PARTICIPATION IN THE NATIONAL CHILDREN'S STUDY VANGUARD STUDY" IN INTERVIEWER INSTRUCTIONS.
- IF **SAMPLE_REFUSE_TYPE** = 1 AND 2, GO TO **RECON_ENV**.
- IF **SAMPLE_REFUSE_TYPE** = 1:
 - AND **RECON_BIO**= 1, GO TO **READM_CON**.
 - AND **RECON_BIO** = 2, -1, OR -2, GO TO **TIME_STAMP_RCS_ET**.

RSC040/(RECON_ENV). Would you like to allow us to collect environmental samples?"

Comment [A5]:
Source: New

INTERVIEWER INSTRUCTION:

- {PARTICIPANTS/PARENT/CAREGIVERS} WHO AGREE TO ANY SAMPLE COLLECTION SHOULD BE RE-ADMINISTERED CONSENT USING THE INFORMED CONSENT FORM {INFORMED CONSENT FOR PREGNANT WOMEN'S STUDY PARTICIPATION/WHAT YOU SHOULD KNOW ABOUT YOUR CHILD'S PARTICIPATION IN THE NATIONAL CHILDREN'S STUDY VANGUARD STUDY} AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

YES 1
NO 2
REFUSED -1 (**TIME_STAMP_RCS_ET**)
DON'T KNOW -2 (**TIME_STAMP_RCS_ET**)

PROGRAMMER INSTRUCTIONS:

- IF **EVENT_TYPE** = PV1 OR PV2, DISPLAY "PARTICIPANTS" AND "INFORMED CONSENT FOR PREGNANT WOMEN'S STUDY PARTICIPATION" IN INTERVIEWER INSTRUCTIONS.

- IF **EVENT_TYPE** = 12-MONTH OR 24-MONTH, DISPLAY “PARENT/CAREGIVERS” AND “WHAT YOU SHOULD KNOW ABOUT YOUR CHILD’S PARTICIPATION IN THE NATIONAL CHILDREN’S STUDY VANGUARD STUDY” IN INTERVIEWER INSTRUCTIONS.
- IF **RECON_BIO** =1 BUT **RECON_ENV** = 2, GO TO **READM_CON**.
- OTHERWISE, IF:
 - **RECON_ENV** = 2 AND **SAMPLE_REFUSE_TYPE** = 2 GO TO **TIME_STAMP_RCS_ET**.
 - **RECON_ENV** = 2 AND **RECON_BIO** = 2, GO TO **TIME_STAMP_RCS_ET**.

RSC050/(READM_CON). Thank you for agreeing to provide {biospecimen samples {from {C_FNAME/the child}}/ {and} environmental samples}. We will now review the consent form to record that you have agreed to provide these samples.

Comment [A6]:
Source: New

INTERVIEWER INSTRUCTION:

- RE-ADMINISTER CONSENT USING THE INFORMED CONSENT FORM {INFORMED CONSENT FOR PREGNANT WOMEN’S STUDY PARTICIPATION/WHAT YOU SHOULD KNOW ABOUT YOUR CHILD’S PARTICIPATION IN THE NATIONAL CHILDREN’S STUDY VANGUARD STUDY} AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

CONTINUE 1
REFUSED 2 (**TIME_STAMP_RCS_ET**)

PROGRAMMER INSTRUCTIONS:

- IF **EVENT_TYPE** = PV1 OR PV2 AND:
 - **RECON_BIO** =1, DISPLAY “biospecimen samples”.
 - **RECON_BIO** =1 AND **RECON_ENV** = 1, DISPLAY “biospecimen samples and environmental samples”.
 - **RECON_ENV** = 1, DISPLAY “environmental samples”.
- IF **EVENT_TYPE** = 12-MONTH OR 24-MONTH AND:
 - **RECON_BIO** =1, DISPLAY “biospecimen samples from {C_FNAME/the child}”.
 - **RECON_BIO** =1 AND **RECON_ENV** = 1, DISPLAY “biospecimen samples from {C_FNAME/the child} and environmental samples”.
 - **RECON_ENV** = 1, DISPLAY “environmental samples”.
- IF **EVENT_TYPE** = PV1 OR PV2, DISPLAY “INFORMED CONSENT FOR PREGNANT WOMEN’S STUDY PARTICIPATION” IN INTERVIEWER INSTRUCTIONS.
- IF **EVENT_TYPE** = 12-MONTH OR 24-MONTH, DISPLAY “WHAT YOU SHOULD KNOW ABOUT YOUR CHILD’S PARTICIPATION IN THE NATIONAL CHILDREN’S STUDY VANGUARD STUDY” IN INTERVIEWER INSTRUCTIONS.

(TIME_STAMP_RCS_ET) PROGRAMMER INSTRUCTION:

- INSERT DATE/TIME STAMP