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

THE NATIONAL CHILDREN'S STUDY
HEALTH GROWTH ENVIRONMENT

The National Children's Study Consent Documents

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

Informed Consent Form for Pregnant Woman

- Your community is one of many across the country taking part in the National Children's Study (NCS) Vanguard Study. We are asking pregnant women to join the Study. We hope you will be one of thousands of women from across the United States helping us learn what will improve our children's health.
- Your experience is unique and critical to the success of this research study. With your help, the NCS 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 is a research program with several stages. Different stages of the Study will run at the same time. We are currently in the first stage, called the NCS Vanguard Study. The NCS Vanguard Study will help us decide on the design of the next stage, called the NCS Main Study.
- Although what we learn in the NCS Vanguard Study may not help you or your family right now, the things we learn may help people in the future.
- Participating in the NCS Vanguard Study is your choice. You can decide to take part or not take part. You can leave the Study at any time, decide not to answer certain questions, or not to give certain samples.

Sponsors

The National Children's Study is led by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development of the National Institutes of Health (NIH) in collaboration with a consortium of federal government partners.

What is the goal of the National Children's Study (NCS)?

- The goal of the NCS is to improve the health of all children in the United States.
- The NCS will help us learn more about how our physical environment (including air and dust), social surroundings (our neighborhoods and communities), and family life:
  - Affect how children grow, and
  - Help children stay healthy.
- The NCS has several stages. The first stage is called the NCS Vanguard Study.
  - The purpose of the NCS Vanguard Study is to help guide the design of the NCS Main Study.
- The next stage is called the NCS Main Study.
  - This phase of the NCS will look at how our genes act together with our environment to influence health, growth, and development.
- About 100,000 children from all over the United States will be in the NCS Main Study.
- You are being asked to participate in the NCS Vanguard Study.

Why is the NCS important?

- The NCS is important because it will help us understand how we can improve our children's health.
- It is one of the largest ever research studies of children's health and development.
- With your help, we can learn more about how our physical, social, and family environments affect children's health, growth, and development while they are young and when they become adults.
- The Study may also help us better understand why some children develop obesity, diabetes, autism, learning disabilities, asthma, or other problems.

What kind of study is the NCS Vanguard Study?

- The NCS Vanguard Study is an observational study.
- This means that we will not:
  - Ask you to change what you normally do.
  - Ask you or your child to take any medicines or drugs.

- We will follow children from birth to age 21 by.
    - Asking questions about you, your pregnancy, and where you live and work.
    - Visiting with you at home and maybe at other places where you or your future child will spend a lot of time. We may also ask you to visit us at a clinic or another location near you. Collecting samples from you (like blood, urine, and saliva) and from your home (like dust and air).
    - Closer to the birth of your baby, we will ask for your permission to collect samples from your baby once he or she is born.

How many children will be in the NCS Vanguard Study?

- About 5,000 children will be in the NCS Vanguard Study.
- We are also asking those caring for the children in the Study to participate.

How long will the NCS Vanguard Study last?

- The NCS Vanguard Study will get information from women during and after pregnancy.
- The Study will follow children until they are 21 years old.

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

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

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

- We plan to visit you and your child regularly over 21 years.

- We will visit you once or twice during your pregnancy.
- We plan to visit you and your baby in the hospital or birthing center.
- We plan to visit twice during the first year of your child's life.
- After that, we plan to visit about every 1 to 3 years.

- Between visits, we may call, e-mail, text or send a letter to:
  - Ask questions about the child's development and health; and
  - Confirm information like your address or phone number.

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

- We will visit your home to collect information about you, your child, your health, your family medical history and your physical, social, and family environments.
- We may ask to take your body measurements like height, weight, and blood pressure.
- We may ask you to answer questions or fill out forms about your child. For example, we may ask you to keep a diary about the food your child eats for several days.
- 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 will keep using the information we have already gotten.
- We will ask questions about your pregnancy.
  - We may ask for a copy of your baby's ultrasound, if you have one.
- During some visits, we may ask for your permission to collect samples, like your blood, urine, and saliva.
- Before we ask for any samples during a visit, we will:
  - Explain what type of samples we want and how much we will need.
  - Explain how we will collect the samples and any known risks of the collection.
  - Ask for your verbal permission to collect the samples.
- During some visits, trained staff will:
  - Use a needle to collect a small amount of your blood from a vein in your arm.
- We may also ask you to get some samples yourself. For example, by collecting:
  - A small amount of your urine in a cup.
  - A small amount of your saliva.

- We will try to minimize the number of samples that we ask to collect from you. If a Study visit is conducted at a hospital or birthing center (for example, the birth visit), we may ask for your permission to use leftover samples (such as blood or urine) that hospitals routinely collect from patients.
- During some visits, we may also ask for your permission to collect samples from your home, such as air, dust, noise level measurements, and water. For example, we may have our staff collect:
    - Dust samples from your vacuum cleaner or a dust cloth.
    - Samples of the water you drink.
- In addition, we may ask you to collect some dust samples yourself using a kit we provide.
- If there are samples you do not want to give us, you can skip them and still be in the Study.

What about genetic information?

- Genetic information is collected to help us learn how genes affect our children's health and how our physical environment and experiences affect the way our genes work.
- If you agree, we will get information about your genes. We will get this information from the blood, saliva, and other samples you give us. We will store your samples and analyze them in the future.
- The risks associated with genetic analyses are unknown. In some cases, the results of these genetic analyses may identify the risk of getting an illness or being a carrier of an illness. We will do our best to keep all results confidential.
    - There is a law that helps protect people from most kinds of health insurance and employment discrimination on the basis of genetics. This law is called the Genetic Information Nondiscrimination Act (GINA). GINA does not protect people against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.
- Some people have concerns about genetic information for cultural or religious reasons. If you do not want us to conduct genetic analyses, let us know. You can tell us not to do genetic analyses and still be in the Study.

What will the NCS Vanguard Study do with all this information?

- We will use what we learn in the NCS Vanguard Study to inform the NCS Main Study and to achieve the goal of the NCS to improve the health of all children.
- The NCS Vanguard Study may use the information and samples we get from you

and your child during the NCS Vanguard Study in several ways. Researchers may use this information to find out:

- What questions and procedures will work best in the NCS Main Study.
- How children's genes, surroundings, and experiences work together to affect growth, development, and health.
- How experiences during pregnancy or early life may affect our children's health. How some conditions that appear later in childhood and adulthood begin in early childhood.

- By agreeing to be in the NCS Vanguard Study, you are agreeing to allow the use of your information and samples for:
  - The NCS Main Study.
  - Future studies on children's health and human development. Future studies might be done by other approved researchers.
- We will store the information and samples that participants provide indefinitely.
  - We may combine your data and genetic information with data from other research studies or information sources to answer important research questions. To do this, we may share genetic information through a secure national research database.
- In the future, scientists could develop new technologies or products based on the information and samples we collect from you for the Study. You will not receive any money that may result from the development of such new technologies or products.

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

- We will share what we learn overall from the NCS Vanguard Study. We will keep in touch with you through newsletters, on our website, and in other ways.
- If tests we do during a visit show results important for your health care, we will share them with you at that time. For example, we will give you information about your height, weight, and blood pressure when we measure them.
- We plan to analyze your biological and environmental samples in the future.
  - At this time, we do not know when analyses will be done, which analyses will be done and when information from the analyses will be available.
- The analyses we will do on the samples will help us understand how the physical, social, family environments, genes, and other factors affect health and disease.
- These analyses are not intended to help guide your health care.

- In case any results of these analyses do turn out to be vital to your health care, we have a process in place for deciding this and telling you. We work with a group of doctors, scientists, and community members who advise us about analyses that could provide information vital to your health care.
    - If we do identify results that provide vital information directly related to your health care, we will discuss options for sharing this information with you.

How will the NCS Vanguard Study protect my information?

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

When might the NCS Vanguard Study share my information?

- The NCS needs to share your information to do the research described by this informed consent form.

- The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development runs the National Children's Study.
- We hire groups and organizations to do work for the Study such as collecting, storing and analyzing data. These groups must be authorized by the Study to protect your information in ways described by Federal Privacy Regulations.

- The NCS may need to share your information to protect public health and safety.
  - If we learn that you or someone else is harming you, your child, or others around you, we may be required by law to report this to the police or a social services agency in your community.

What are the possible benefits of being in the NCS Vanguard Study?

- Taking part in the NCS Vanguard Study will not improve your health or your baby's health right now. But the Study may help us learn things about health that could benefit all of us—including your children and grandchildren—in the years to come.
- If you need medical or social services, we will give you names and contact information for people and agencies that can try to help.

What are the possible risks or burdens to me, my future child, and my community from being in the NCS Vanguard Study?

- The immediate risks from the NCS Vanguard Study are the same as those in routine health care.
- Some of the questions we ask and some of the ways we get samples may make you feel uncomfortable. If you are uncomfortable, you can skip any part of the NCS Vanguard Study. You are in charge.
- Giving a blood sample may cause a small amount of pain. People sometimes feel brief pain when blood is taken, 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 parentage (biological fatherhood or motherhood) of your child. We will not give out any information about parentage to

you, your child, or anyone else.

- Although we are taking many steps to protect your information, there is always a chance that your information or identity or that of your family members could be disclosed. Such disclosures may also occur if you share information yourself or agree to have your research records released.
- We will continue to review and improve the ways we keep your information private.
- We will get information about your health, your community, and your race and ethnicity. We will make files with this information available to approved researchers. In addition to the risks to individuals, the risks of providing information about racial or community groups are unknown. There is a possibility that specific Study findings will be associated with particular racial and ethnic groups.

Will I be paid for being in the NCS Vanguard Study?

- We will give you about $25 to $100 in cash or gift cards to thank you each time you participate in a Study visit.
- From time to time, we may also give you small gifts like a tote bag, water bottle, picture frame, or other small items to thank you for being in the Study.

What is the alternative to taking part in the NCS Vanguard Study?

- The alternative to taking part in the NCS Vanguard Study is not taking part in the Study.

What if I want to leave the NCS Vanguard Study?

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

What if I move?

- We would like to keep in touch with you as long as the NCS Vanguard Study is collecting information and your child is still participating.
- We hope you will tell us if you are planning to move so you can still be part of the Study in your new home.
- If you move and forget to tell us, we will try to get in touch with you. We will use the information you have given us about family members and friends, as well as publicly available information.
- If we get in touch with you, we will ask whether you want to continue to be part of the Study.

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

- No. There is no cost to you for being in the NCS Vanguard Study.
- The Study will pay for all procedures done as part of the NCS Vanguard Study. Any future analyses done on your samples or those of your child as part of the NCS Vanguard Study will also be paid for by the NCS.

Does the NCS Vanguard Study pay for health care for my family or me?

- The NCS Vanguard Study cannot and will not pay for health care or mental health services for you or your family. If you need medical or social services, we will give you names and contact information for people and agencies that can try to help.
- The information we collect is for research purposes only. Being part of the NCS Vanguard Study does not take the place of your usual doctor or clinic visits.

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

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

What if the media wants to talk with me about my participation or my baby's participation in the NCS Vanguard Study?

- The NCS will not tell the media anything about the identities of Study participants.
- Because of the importance of the Study, reporters may go to communities where the Study is being done. They may ask participants whether they want to talk about their experiences with the Study.
- If you are contacted by reporters, you can decide whether you want to talk to them. If you do talk to a reporter, he or she can write about anything you say. What you say will be public information. The organization that the reporter works for will have control over any information and material you give it.
- If you talk with the media or post on social media websites about your Study experience your participation in the Study will be public knowledge. When this information becomes public, it will be harder for the Study to protect the privacy of your information and the information of other participants from your community.

Who can I contact if I have questions about the NCS Vanguard Study?

- If you have questions now, you can ask the Study representative who gave you this informed consent form.
- You may call the NCS toll free at 1-877-865-2619 at any time if you have questions. Ask to speak with a member of the Study staff or to the principal investigator, Dr. Steven Hirschfeld. If you have questions about your rights as a research participant, you may call the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Institutional Review Board at 301-496-8370.

Important things to remember about joining the NCS Vanguard Study.

- After reading this informed consent form, we hope you will decide to join the NCS Vanguard Study.
- We will ask you to sign a page that says you have decided to join the Study.
- You decide what questions to answer. You can also decide what samples to give. If you decide not to answer some questions or give some samples, you still can be in the Study.
- No matter what you decide now, you can quit at any time

- Before you decide, you may want to talk with your family, friends, or doctor about joining the Study.
- You will receive a copy of this informed consent form.

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

For office use: PID

NICHD IRB Expiration Date: /__/____

National Children's Study: Vanguard Study

Informed Consent Signature Page for Pregnant Woman's Study Participation

- The Study staff has explained the purpose of the NCS Vanguard Study, the procedures involved and the risks and benefits.
- I have asked all the questions I have now and I know who to contact if I have more questions.
- I understand that participation is voluntary and I can leave the NCS Vanguard Study at any time.
- 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 NCS Vanguard Study I do not want to do, I can skip it and still be in the NCS Vanguard Study.
- I understand that any biological samples and environmental samples that I provide will be stored in a secure facility and that the NCS Vanguard Study will control access to my samples.
- I understand that my data and samples will be used in the future to help researchers learn about children's health and human development.
- I understand that I will not routinely get results back from analyses done on the samples I give to the NCS Vanguard Study.

Please complete the following check boxes, as indicated, and sign in the Participant box. You can answer "no" to any item and still be in the NCS Vanguard Study.	**Yes**	**No**
I give my permission for the Study to collect environmental samples from my home.	☐	☐
I give my permission for the Study to collect biological samples from me.	☐	☐
(If yes complete the line below.)		
If I agree to collection of biological samples, I give my permission for the Study to use them for genetic analyses.	☐	☐

I choose to participate in the NCS Vanguard Study.

Participant

Printed Legal Name of Participant: _____

Signature of Participant: _____ Today's Date: /_ /_

(mm/dd/yyyy)

Witness (if required)

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

Printed Legal Name of Witness: _____

Signature of Witness _____ Today's Date: /_ /_

(mm/dd/yyyy)

Printed Legal Name of Person Obtaining Consent: _____

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

(mm/dd/yyyy)

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

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

Vanguard Study

Informed Consent Form for Father or Parental Partner

- The mother of your child has joined the National Children's Study (NCS) Vanguard Study. Fathers and parental partners play an important part in their children's lives, and we would like you to be a part of it too. With your help, the NCS will help us learn more about how our physical, social, and family environments affect the health, growth, and development of our children.
- The NCS is a research program with several stages. Different stages of the Study will run at the same time. We are currently in the first stage, called the NCS Vanguard Study. The NCS Vanguard Study will help us decide on the design of the next stage, called the NCS Main Study.
- We hope you will be one of thousands of fathers and parental partners from across the United States helping us learn what will improve our children's health. Although what we learn in the NCS Vanguard Study may not help you or your family right now, the things we learn may help people in the future.
- Participating in the NCS Vanguard Study is your choice. You can decide to take part or not take part. You can leave the Study at any time, decide not to answer certain questions, or not to give certain samples.

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What is the goal of the National Children's Study (NCS)?

- The goal of the NCS is to improve the health of all children in the United States.
- The NCS will help us learn more about how our physical environment (including air and dust), social surroundings (our neighborhoods and communities), and family life:
  - Affect how children grow, and
  - Help children stay healthy.
- The NCS has several stages. The first stage is called the NCS Vanguard Study.
  - The purpose of the NCS Vanguard Study is to help guide the design of the NCS Main Study.
- The next stage is called the NCS Main Study.
  - This phase of the NCS will look at how our genes act together with our environment to influence health, growth, and development.
- About 100,000 children from all over the United States will be in the NCS Main Study.
- You are being asked to participate in the NCS Vanguard Study.

Why is the NCS important?

- The NCS is important because it will help us understand how we can improve our children's health.
- It is one of the largest ever research studies of children's health and development.
- With your help, we can learn more about how our physical, social and family environments affect children's health, growth, and development while they are young and when they become adults.
- The Study may also help us better understand why some children develop obesity, diabetes, autism, learning disabilities, asthma, or other problems.

What kind of study is the NCS Vanguard Study?

- The NCS is an observational study.
- This means that we will not:
  - Ask you to change what you normally do.
  - Ask you to take any medicines or drugs.
- We will follow children from birth to age 21 by:
  - Once your child is born, visiting with you at home and maybe at other places where the child you take care of spends a lot of time. We may ask you to visit us at a clinic or another location near you.

- Asking questions about you and where you live and work.
- Collecting samples from you (like blood, urine, a swab from your rectum, and saliva) and from your home (like dust and air).

How many children will be in the NCS Vanguard Study?

- About 5,000 children will be in the NCS Vanguard Study.
- We are also asking mothers, fathers, and parental partners of children in the Study to participate.

How long will the NCS Vanguard Study last?

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

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

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

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

- We plan to visit you and your child regularly over 21 years.
  - We may visit you at home once or twice during your partner's pregnancy.
  - We plan to visit twice during the first year of your child's life.
  - After that, we plan to visit about every 1 to 3 years.
- Between visits we may call, e-mail, text or send a letter to:
  - Ask questions about the child's development and health; and
  - Confirm information like your address or phone number.

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

- We will visit your home to collect information about you, your child, your health, your family medical history, and your physical, social, and family environments.
- We may ask to take your body measurements like height, weight, and blood pressure.
- We may ask you to answer questions or fill out forms about your child. For example, we may ask you to keep a diary about the food your child eats for several days.
- We may ask for your permission to look at your health information and medical records.
    - If you change your mind after you give us permission, we will stop getting new information from your medical records, but we will keep using the information we have already gotten.
- During some visits, we may ask for your permission to collect samples, like your blood, hair, urine, a swab from your rectum, and saliva.
- Before we ask for any samples during a visit, we will:
    - Explain what type of samples we want and how much we will need.
    - Explain how we will collect the samples and any known risks of the collection.
    - Ask for your verbal permission to collect the samples.
- During some visits, trained staff will:
    - Use a needle to collect a small amount of your blood from a vein in your arm.
- We may also ask you to get some samples yourself. For example, by collecting:
    - A small amount of your urine in a cup.
    - A small amount of your saliva.
    - A swab from your rectum.
- During some visits, we may also ask for your permission to collect samples from your home, such as air, dust, noise level measurements and water. For example, we may have our staff collect:
    - Dust samples from your vacuum cleaner or a dust cloth.
    - Samples of the water you drink.
- In addition, we may ask you to collect some dust samples yourself using a kit we provide.
- If there are samples you do not want to give us, you can skip them and still be in the Study.

What about genetic information?

- Genetic information is collected to help us learn how genes affect our children's health and how our physical environment and experiences affect the way our genes work.
- If you agree, we will get information about your genes. We will get this information from blood, saliva, and other samples you give us. We will store your samples and analyze them

in the future.

- The risks associated with genetic analyses are unknown. In some cases, the results of these genetic analyses may identify the risk of getting an illness or being a carrier of an illness. We will do our best to keep all results confidential.
    - There is a law that helps protect people from most kinds of health insurance and employment discrimination on the basis of genetics. This law is called the Genetic Information Nondiscrimination Act (GINA). GINA does not protect people against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.
- Some people have concerns about genetic information for cultural or religious reasons. If you do not want us to conduct genetic analyses, let us know. You can tell us not to do genetic analyses and still be in the Study.

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    - How children's genes, surroundings, and experiences work together to affect growth, development, and health.
    - How some conditions that appear later in childhood and adulthood begin in early childhood.
- By agreeing to be in the NCS Vanguard Study, you are agreeing to allow the use of your information and samples for:
    - The NCS Main Study.
    - Future studies on children's health and human development. Future studies might be done by other approved researchers.
- We will store the information and samples that participants provide indefinitely.
    - We may combine your data and genetic information with data from other research studies or information sources to answer important research questions. To do this, we may share genetic information through a secure national research database.
- In the future, scientists could develop new technologies or products based on the information and samples we collect from you for the Study. You will not receive any money that may result from the development of such technologies or products.

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

- We will share what we learn overall from the NCS Vanguard Study. We will keep in touch with you through newsletters, on our website, and in other ways.
- If tests we do during a visit show results important for your health care, we will share them with you at that time. For example, we will give you information about your height, weight, and blood pressure when we measure them.
- We plan to analyze your biological and environmental samples in the future.
    - At this time, we do not know when analyses will be done, which analyses will be done and when information from the analyses will be available.
- The analyses we will do on the samples will help us understand how the physical, social, family environments, genes, and other factors affect health and disease.
- These analyses are not intended to help guide your health care.
- In case any results of these analyses do turn out to be vital to your health care, we have a process in place for deciding this and telling you. We work with a group of doctors, scientists, and community members who advise us about analyses that could provide information vital to your health care.
    - If we do identify results that provide vital information directly related to your health care, we will discuss options for sharing this information with you.

How will the NCS Vanguard Study protect my information?

- Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access.
- We will make our best effort to protect your privacy and keep information you provide confidential by:
    - Using a number code to label all samples and other information instead of your name.
    - Keeping your question responses, results, and other information in a secure computer or locked file cabinet within a locked office.
    - Storing your samples in a secure place.
    - Reviewing all of the ways we store your information to improve how we protect your privacy.
    - Improving the ways your information is secured by using new technologies.
- We require researchers to keep your information safe. Researchers who want to use your information must:
    - Be authorized by the NCS and the Federal government to receive and store study information.
    - Protect your privacy by combining your responses and information with that of other participants when reporting results.

- The NCS has gotten a Certificate of Confidentiality from the U.S. Department of Health and Human Services (HHS). This legal document says that the Study does not have to give out your personal information, even if ordered to do so by a judge or court.
    - If you give a person or an organization written permission to see the information you gave the Study, we cannot use the Certificate of Confidentiality to protect your information from that person or organization.

When might the NCS Vanguard Study share my information?

- The NCS needs to share your information to do the research described by this informed consent form.
    - The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development runs the National Children's Study.
    - We hire groups and organizations to do work for the Study such as collecting, storing and analyzing data. These groups must be authorized by the Study to protect your information in ways described by Federal Privacy Regulations.
- The NCS may need to share your information to protect public health and safety.
    - If we learn that you or someone else is harming you, your child, or others around you, we may be required by law to report this to the police or a social services agency in your community.

What are the possible benefits of being in the NCS Vanguard Study?

- Taking part in the NCS Vanguard Study will not improve your health right now. But the Study may help us learn things about health that could benefit all of us—including your children and grandchildren—in the years to come.
- If you need medical or social services, we will give you names and contact information for people and agencies that can try to help.

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- 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 parentage (biological fatherhood or motherhood) of your child. We will not give out any information about parentage to you, your child, or anyone else.
- Although we are taking many steps to protect your information, there is always a chance that your information or identity or that of your family members could be disclosed. Such disclosures may also occur if you share information yourself or agree to have your research records released.
- We will continue to review and improve the ways we keep your information private.
- We will get information about your health, your community, and your race and ethnicity. We will make files with this information available to approved researchers. In addition to the risks to individuals, the risks of providing information about racial or community groups are unknown. There is a possibility that specific Study findings will be associated with particular racial and ethnic groups.

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- From time to time, we may also give you small gifts like a tote bag, water bottle, picture frame, or other small items to thank you for being in the Study.

What is the alternative to taking part in the NCS Vanguard Study?

- The alternative to taking part in the NCS Vanguard Study is not taking part in the Study.

What if I want to leave the NCS Vanguard Study?

- You can leave the NCS Vanguard Study at any time.
- If you leave the Study, we will not ask for any new information, but we will keep using the information and samples you have already given us.
- If you want us to destroy any of your unused samples, you can ask us to do so and we will.
- You also can leave the Study for a short time and, if you are still caring for the participating child, you can come back.

- Leaving or not taking part in the Study will not affect your access to health care or any other benefits you may be receiving, like those from Social Security, Medicaid, WIC, or the Supplemental Nutrition Assistance Program.

What if I move?

- We would like to keep in touch with you as long as the NCS Vanguard Study is collecting information and you are still caring for the participating child.
- We hope you will tell us if you are planning to move so you can still be part of the Study in your new home.
- If you move and forget to tell us, we will try to get in touch with you. We will use the information you have given us about family members and friends, as well as publicly available information.
- If we get in touch with you, we will ask whether you want to continue to be part of the Study.

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

- No. There is no cost to you for being in the NCS Vanguard Study.
- The Study will pay for all procedures done as part of the NCS Vanguard Study. Any future analyses done on your samples as part of the NCS Vanguard Study will also be paid for by the NCS.

Does the NCS Vanguard Study pay for health care for my family or me?

- The NCS Vanguard Study cannot and will not pay for health care or mental health services for you or your family. If you need medical or social services, we will give you names and contact information for people and agencies that can try to help.
- The information we collect is for research purposes only. Being part of the NCS Vanguard Study does not take the place of your usual doctor or clinic visits.

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

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

What if the media wants to talk with me about my participation or the participation of my child in the NCS Vanguard Study?

- The NCS will not tell the media anything about the identities of Study participants.
- Because of the importance of the Study, reporters may go to communities where the Study is being done. They may ask participants whether they want to talk about their experiences with the Study.
- If you are contacted by reporters, you can decide whether you want to talk to them. If you do talk to a reporter, he or she can write about anything you say. What you say will be public information. The organization that the reporter works for will have control over any information and material you give it.
- If you talk with the media or post on social media websites about your Study experience, your participation in the Study will be public knowledge. When this information becomes public, it will be harder for the Study to protect the privacy of your information and the information of other participants from your community.

Who can I contact if I have questions about the NCS Vanguard Study?

- If you have questions now, you can ask the Study representative who gave you this informed consent form.
- You may call the NCS toll free at 1-877-865-2619 at any time if you have questions. Ask to speak with a member of the Study staff or to the principal investigator, Dr. Steven Hirschfeld. If you have questions about your rights as a research participant, you may call the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Institutional Review Board at 301-496-8370.

Important things to remember about being in the NCS Vanguard Study.

- After reading this informed consent form, we hope you will decide to participate in the NCS Vanguard Study.
- We will ask you to sign a page that says you have decided to be in the Study.
- You decide what questions to answer. You can also decide what samples to give. If you decide not to answer some questions or give some samples, you still can be in the Study.
- No matter what you decide now, you can quit at any time.

- Before you decide, you may want to talk with your family, friends, or doctor about being in the Study.
- You will receive a copy of this informed consent form.

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

For office use: PID

NICHD IRB Expiration Date: / /_____

National Children's Study: Vanguard Study
Informed Consent Signature Page for Father and Parental Partner Study Participation

- The Study staff has explained the purpose of the NCS Vanguard Study, the procedures involved and the risks and benefits.
- I have asked all the questions I have now, and I know who to contact if I have more questions.
- I understand that participation is voluntary and I can leave the NCS Vanguard Study at any time.
- 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 NCS Vanguard Study I do not want to do, I can skip it and still be in the NCS Vanguard Study.
- I understand that any biological samples and environmental samples that I provide will be stored in a secure facility and that the NCS Vanguard Study will control access to my samples.
- I understand that my data and samples will be used in the future to help researchers learn about children's health and human development.
- I understand that I will not routinely get results back from analyses done on the samples I give to the NCS Vanguard Study.

Please complete the following check boxes, as indicated, and sign in the Participant box. You can answer "no" to any item and still be in the NCS Vanguard Study.	**Yes**	**No**
I give my permission for the Study to collect environmental samples from my home.	☐	☐
I give my permission for the Study to collect biological samples from me.	☐	☐
(If yes complete the line below.)		
If I agree to collection of biological samples, I give my permission for the Study to use them for genetic analyses.	☐	☐

I choose to participate in the NCS Vanguard Study.

Participant

Printed Legal Name of Participant: _____

Signature of Participant: Today's Date: ____/____/____

(mm/dd/yyyy)

Witness (if required)

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

Printed Legal Name of Witness: _____

Signature of Witness Today's Date: /_ /_

(mm/dd/yyyy)

Printed Legal Name of Person Obtaining Consent: _____

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

(mm/dd/yyyy)

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

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

Vanguard Study

Informed Consent Form

- You are caring for a child who is part of the National Children's Study (NCS) Vanguard Study, and we would like you to be a part of it too. Your family is unique and critical to the success of this research study. With your help, the NCS will learn more about how our physical, social, and family environments affect the health, growth, and development of our children.
- The National Children's Study is a research program with several stages. Different stages of the Study will run at the same time. We are currently in the first stage, called the NCS Vanguard Study. The NCS Vanguard Study will help us decide on the design of the next stage, called the NCS Main Study.
- We hope you will be one of thousands of participants from across the United States helping us learn what will improve our children's health. Although what we learn in the NCS Vanguard Study may not help you or your family right now, the things we learn may help people in the future.
- Participating in the NCS Vanguard Study is your choice. You can decide to take part or not take part. You can leave the Study at any time, decide not to answer certain questions, or not to give certain samples.

Sponsors

The National Children's Study is led by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development of the National Institutes of Health (NIH) in collaboration with a consortium of federal government partners.

What is the goal of the National Children's Study (NCS)?

- The goal of the NCS is to improve the health of all children in the United States.
- The NCS will help us learn more about how our physical environment (including air and dust), social surroundings (our neighborhoods and communities), and family life:
    - Affect how children grow, and
    - Help children stay healthy.
- The NCS has several stages. The first stage is called the NCS Vanguard Study.
    - The purpose of the NCS Vanguard Study is to help guide the design of the NCS Main Study.
- The next stage is called the NCS Main Study.
    - This phase of the NCS will look at how our genes act together with our environment to influence health, growth, and development.
- About 100,000 children from all over the United States will be in the NCS Main Study.
- You are being asked to participate in the NCS Vanguard Study.

Why is the NCS important?

- The NCS is important because it will help us understand how we can improve our children's health.
- It is one of the largest ever research studies of children's health and development.
- With your help, we can learn more about how our physical, social, and family environments affect children's health, growth, and development while they are young and when they become adults.
- The Study may also help us better understand why some children develop obesity, diabetes, autism, learning disabilities, asthma, or other problems.

What kind of study is the NCS Vanguard Study?

- The NCS Vanguard Study is an observational study.
- This means that we will not:
    - Ask you to change what you normally do.

  - Ask you or the child you take care of to take any medicines or drugs.
- We will follow children from birth to age 21 by:
  - Visiting with you at home and maybe at other places where the child you take care of spends a lot of time. We may ask you to visit us at a clinic or another location near you.
  - Asking questions about you and where you live and work.
  - Collecting samples from you (like blood, urine, a swab from your rectum, and saliva) and from your home (like dust and air).

How many children will be in the NCS Vanguard Study?

- About 5,000 children will be in the NCS Vanguard Study.
- We are also asking those caring for the children in the Study to participate.

How long will the NCS Vanguard Study last?

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

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

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

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

- We plan to visit you and the child you take care of regularly over 21 years.
    - We plan to visit twice during the first year of the child's life.
    - After that, we plan to visit about every 1 to 3 years.
- Between visits, we may call, e-mail, text or send a letter to:
    - Ask questions about the child's development and health; and
    - Confirm information like your address or phone number.

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

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

  - Use a needle to collect a small amount of your blood from a vein in your arm.
- We may also ask you to get some samples yourself. For example, by collecting:
  - A small amount of your urine in a cup.
  - A small amount of your saliva.
  - A swab from your rectum.
- During some visits, we may also ask for your permission to collect samples from your home, such as air, dust, noise level measurements, and water. For example, we may have our staff collect:
  - Dust samples from your vacuum cleaner or a dust cloth.
  - Samples of the water you drink.
- In addition, we may ask you to collect some dust samples yourself using a kit we provide.
- If there are samples you do not want to give us, you can skip them and still be in the Study.

What about genetic information?

- Genetic information is collected to help us learn how genes affect our children's health and how our physical environment and experiences affect the way our genes work.
- If you agree, we will get information about your genes. We will get this information from blood, saliva, and other samples you give us. We will store your samples and analyze them in the future.
- The risks associated with genetic analyses are unknown. In some cases, the results of these genetic analyses may identify the risk of getting an illness or being a carrier of an illness. We will do our best to keep all results confidential.
  - There is a law that helps protect people from most kinds of health insurance and employment discrimination on the basis of genetics. This law is called the Genetic Information Nondiscrimination Act (GINA). GINA does not protect people against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.
- Some people have concerns about genetic information for cultural or religious reasons. If you do not want us to conduct genetic analyses, let us know. You can tell us not to do genetic analyses and still be in the Study.

What will the NCS Vanguard Study do with all this information?

- We will use what we learn in the NCS Vanguard Study to inform the NCS Main Study and to achieve the goal of the NCS to improve the health of all children.
- The NCS Vanguard Study may use the information and samples we get from you during the NCS Vanguard Study in several ways. Researchers may use this information to find out:
    - What questions and procedures will work best in the NCS Main Study.
    - How children's genes, surroundings, and experiences work together to affect growth, development, and health.
    - How some conditions that appear later in childhood and adulthood begin in early childhood.
- By agreeing to be in the NCS Vanguard Study, you are agreeing to allow the use of your information and samples for:
    - The NCS Main Study.
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- We will ask you to sign a page that says you have decided to be in the Study.
- You decide what questions to answer. You can also decide what samples to give. If you decide not to answer some questions or give some samples, you still can be in the Study.
- No matter what you decide now, you can quit at any time.
- Before you decide, you may want to talk with your family, friends, or doctor about being in the Study.
- You will receive a copy of this informed consent form.

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

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

- The Study staff has explained the purpose of the NCS Vanguard Study, the procedures involved, and the risks and benefits.
- I have asked all the questions I have now, and I know who to contact if I have more questions.
- I understand that participation is voluntary and I can leave the NCS Vanguard Study at any time.
- 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 NCS Vanguard Study I do not want to do, I can skip it and still be in the NCS Vanguard Study.
- I understand that any biological samples and environmental samples that I provide will be stored in a secure facility and that the NCS Vanguard Study will control access to my samples.
- I understand that my data and samples will be used in the future to help researchers learn about children's health and human development.
- I understand that I will not routinely get results back from analyses done on the samples I give to the NCS Vanguard Study.

Please complete the following check boxes, as indicated, and sign in the Participant box. You can answer "no" to any item and still be in the NCS Vanguard Study.	**Yes**	**No**
I give my permission for the Study to collect environmental samples from my home.	☐	☐
I give my permission for the Study to collect biological samples from me.	☐	☐
(If yes, complete the line below.)		
If I agree to collection of biological samples, I give my permission for the Study to use them for genetic analyses.	☐	☐

I choose to participate in the NCS Vanguard Study.

Participant

Printed Legal Name of Participant: _____

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

Witness (if required)

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

Printed Legal Name of Witness: _____

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

Printed Legal Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: Today's Date: /_ /_
(mm/dd/yyyy)

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

What You Should Know about Enrolling Your Child in the National Children's Study (NCS) Vanguard Study

Parental Permission Form for Child from Birth to 6 Months of Age

- Thank you for participating in the National Children's Study (NCS) Vanguard Study. Your family is unique and critical to the success of this research study. With your help, the NCS will learn more about how our physical, social, and family environments affect the health, growth and development of our children.
- We hope your child will be one of thousands of children from across the United States helping us learn what will improve our children's health. Although what we learn in the NCS Vanguard Study may not help your child or your family right now, the things we learn may help people in the future.
- Now, we will tell you more about the kinds of information we would like to collect from you about your child when your child is born and ask for your permission to collect information about your child from birth to 6 months of age. We will also tell you about samples we would like to collect from your child and ask for your permission to collect them.
- Your child's participation in the NCS Vanguard Study is your choice. You can decide whether your child takes part or not. You and your child can leave the Study at any time and you can decide not to answer certain questions, or not to give certain samples.

Sponsors

The National Children's Study is led by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development of the National Institutes of Health (NIH) in collaboration with a consortium of federal government partners.

What is the goal of the National Children's Study (NCS)?

- The goal of the NCS is to improve the health of all children in the United States.
- The NCS will help us learn more about how our physical environment (including air and dust), social surroundings (our neighborhoods and communities), and family life:
  - Affect how children grow, and
  - Help children stay healthy.
- The NCS has several stages. The first stage is called the NCS Vanguard Study.
  - The purpose of the NCS Vanguard Study is to help guide the design of the NCS Main Study.
- The next stage is called the NCS Main Study.
  - This phase of the NCS will look at how our genes act together with our environment to influence health, growth, and development.
- About 100,000 children from all over the United States will be in the NCS Main Study.
- You are being asked for permission for your child to participate in the NCS Vanguard Study.

Why is the NCS important?

- The NCS is important because it will help us understand how we can improve our children's health.
- It is one of the largest ever research studies of children's health and development.
- With your help, we can learn more about how our physical, social and family environments affect children's health, growth, and development while they are young and when they become adults.
- The Study may also help us better understand why some children develop obesity, diabetes, autism, learning disabilities, asthma, or other problems.

What kind of study is the NCS Vanguard Study?

- The NCS Vanguard Study is an observational study.
- This means that we will not:
  - Ask you or your child to change what you normally do.
  - Ask you or your child to take any medicines or drugs.
- 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 may ask you to visit us at a clinic or another location near you.

- Asking questions about you and your child and where you live and work.
- Collecting samples from you and your child (like blood, urine, and saliva) and from your home (like dust and air).

How many children will be in the NCS Vanguard Study?

- About 5,000 children will be in the NCS Vanguard Study.
- We are also asking those caring for the children in the Study to participate.

How long will the NCS Vanguard Study last?

- The Study will follow children until they are 21 years old.
- This parental permission form is asking for your permission to enroll your child in the NCS Vanguard Study from birth to about 6 months of age.
- Around the time that your child turns 6 months old, we will ask you for permission for your child's continued participation in the Study through the age of majority.

What is involved in taking part in the NCS Vanguard Study for the first few months after the birth of my child?

- While you are in the hospital or birthing center and after your baby is born, we would like to collect your child's cord blood and placenta.
    - We will work with the hospital, clinic, or birthing center staff to collect the umbilical cord blood. Blood is collected from the umbilical cord shortly after it is separated from the baby. The procedure takes about 5 minutes.
    - If you have decided to participate in a cord blood bank program to store your child's umbilical cord blood, we will not collect any umbilical cord blood for the Study.
- We would also like to collect a small amount of blood (up to 7 drops) from your child's heel soon after birth. We will work with hospital staff to collect this sample when they collect the baby's blood for routine tests.
    - No additional heel sticks will be performed on your child to collect this blood sample.
- All samples will be collected by trained medical professionals who know how to collect blood safely.
- We may ask you if we can take pictures of your child.
- 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 15 minutes to complete. We will ask you about

yourself, your child and your child's birth, and your plans for after your child is born.

- If there are questions you do not want to answer, you can skip them and your child can still be in the Study.

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 visits when we talk to you on the phone or visit you in person.
- We will contact you to arrange a phone interview with you when your child is about three months old.
- We will schedule another visit with you and your child when your child is around 6 months old.

What about genetic information?

- 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.
- If you agree, we will get information about your child's genes. We will get this information from the samples that we collect from your child. We will store your child's samples and analyze them in the future.
- The risks associated with genetic analyses are unknown. In some cases the results of these genetic analyses may identify the risk of getting an illness or being a carrier of an illness. We will do our best to keep all results confidential.
    - There is a law that helps protect people from most kinds of health insurance and employment discrimination on the basis of genetics. This law is called the Genetic Information Nondiscrimination Act (GINA). GINA does not protect people against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.
- Some people have concerns about genetic information for cultural or religious reasons. If you do not want us to conduct genetic analyses, let us know. You can tell us not to do genetic analyses and your child can still be in the Study.

What will the NCS Vanguard Study do with all this information?

- We will use what we learn in the NCS Vanguard Study to inform the NCS Main Study and to achieve the goal of the NCS to improve the health of all children.
- The NCS Vanguard Study may use the information and samples we get from your

child during the NCS Vanguard Study in several ways. Researchers may use this information to find out:

  - What questions and procedures will work best in the NCS Main Study.
  - How children's genes, surroundings, and experiences work together to affect growth, development, and health.
  - How some conditions that appear later in childhood and adulthood begin in early childhood.

- By agreeing to let your child be in the NCS Vanguard Study, you are agreeing to allow the use of your child's information and samples for:
  - The NCS Main Study.
  - Future studies on children's health and human development. Future studies might be done by other approved researchers.
- We will store the information and samples that participants provide indefinitely.
  - We may combine your child's data and genetic information with data from other research studies or information sources to answer important research questions. To do this, we may share genetic information through a secure national research database.
- In the future, scientists could develop new technologies or products based on the information and samples we collect from your child for the Study. Your child will not receive any money that may result from the development of such technologies or products.

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

- We will share what we learn overall from the NCS Vanguard Study. We will keep in touch with you through newsletters, on our website and in other ways.
- If tests we do during a visit show results important for your child's health care, we will share them with you at that time. For example, we will give you information about your child's height, weight and blood pressure when we measure them.
- We plan to analyze your child's biological and environmental samples in the future.
  - At this time, we do not know when analyses will be done, which analyses will be done and when information from the analyses will be available.
- The analyses we will do on the samples will help us understand how the physical, social, and family environments, genes and other factors affect health and disease.
- These analyses are not intended to help guide your child's health care.
- In case any results of these analyses do turn out to be vital to your child's health care, we have a process in place for deciding this and telling you. We work with a group of doctors, scientists, and community members who advise us about analyses that could provide information vital to your child's health care.
- If we do identify results that provide vital information directly related to your child's health care, we will discuss options for sharing this information with you.

How will the NCS Vanguard Study protect my child's information?

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

When might the NCS Vanguard Study share my child's information?

- The NCS needs to share your child's information to do the research described by this informed consent form.
    - The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development runs the National Children's Study.
    - We hire groups and organizations to do work for the Study such as collecting,

storing and analyzing data. These groups must be authorized by the Study to protect your child's information in ways described by Federal Privacy Regulations.

- The NCS may need to share your child's information to protect public health and safety.
  - 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.

What are the possible benefits of my child's participation in the NCS Vanguard Study?

- Taking part in the NCS Vanguard Study will not improve your child's health right now. But the Study may help us learn things about health that could benefit all of us—including your children and grandchildren—in the years to come.
- If your child needs medical or social services, we will give you names and contact information for people and agencies that can try to help.

What are the possible risks or burdens to my child and to his or her community from being in the NCS Vanguard Study?

- The immediate risks from the NCS Vanguard Study are the same as those in routine health care.
- The heel stick blood sample may cause your child a small amount of pain. Infants sometimes feel brief pain when blood is taken, and there is a very small risk of infection, bruising, or bleeding.
- There is no pain associated with collection of cord blood or the placenta.
- We may learn information about adoption or parentage (biological fatherhood or motherhood) of your child. We will not give out any information about parentage to you or anyone else.
- Although we are taking many steps to protect your child's information, there is always a chance that your child's information or identity or that of your family members could be disclosed. Such disclosures may also occur if you share information yourself or agree to have your child's research records released.
- 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.

Will I be paid for taking part in the birth visit, sample collections from my child, and follow-up phone call?

- We will give you about $25 to $100 in cash or gift cards to thank you each time you participate in a Study visit.
- We may also give you small gifts like a tote bag, water bottle, picture frame, or other small items to thank you for being in the Study.

What is the alternative to taking part in the NCS Vanguard Study?

- The alternative to taking part in the NCS Vanguard Study is not taking part in the Study.

What if I want my child to leave the NCS Vanguard Study?

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

What if my child and I move?

- We would like to keep in touch with you as long as the NCS Vanguard Study is collecting information and your child is still participating in the Study.
- We hope you will tell us whether you are planning to move so your child can still be part of the Study in your new home.
- If you move and forget to tell us, we will try to get in touch with you. We will use the information you have given us about family members and friends, as well as publicly available information.
- If we get in touch with you, we will ask whether you want your child to continue to be part of the Study.

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

- No. There is no cost to you for your child's participation in the NCS Vanguard Study.
- The Study will pay for all procedures done as part of the NCS Vanguard Study. Any future analyses done on your child's samples as part of the NCS Vanguard Study will also be paid for by the NCS.

Does the NCS Vanguard Study pay for health care for my child?

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

If my child is part of the NCS Vanguard Study, will my child have to join other studies?

- If your child is part of the NCS Vanguard 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 NCS.
    - If your child is invited to be in other studies, you can always say no.

What if the media wants to talk with me about my child's participation in the NCS Vanguard Study?

- The NCS will not tell the media anything about the identities of Study participants.
- Because of the importance of the Study, reporters may go to communities where the Study is being done. They may ask participants whether they want to talk about their experiences with the Study.
- If you are contacted by reporters, you can decide whether you want to talk to them. If you do talk to a reporter, he or she can write about anything you say. What you say will be public information. The organization that the reporter works for will have control over any information and material you give it.
- If you talk with the media or post on social media websites about your child's Study experience, your child's participation in the Study will be public knowledge. When this information becomes public, it will be harder for the Study to protect the privacy of your child's information and the information of other participants from your community.

Who can I contact if I have questions about the NCS Vanguard Study?

- If you have questions now, you can ask the Study representative who gave you this parental permission form.
- You may call the NCS toll free at 1-877-865-2619 at any time if you have questions. Ask to speak with a member of the Study staff or to the principal investigator, Dr. Steven Hirschfeld. If you have questions about your child's rights as a research participant, you may call the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Institutional Review Board at 301-496-8370.

Important things to remember about being in the NCS Vanguard Study.

- After reading this parental permission form, we hope you will decide to allow your child to participate in the NCS Vanguard Study.
- We will ask you to sign a page that says you have given your permission for your child to be in the Study.
- You decide what questions to answer. You can also decide what samples to give from your child. If you decide not to answer some questions or give some samples, your child can still be in the Study.
- No matter what you decide now, you and your child can leave the Study at any time.
- Before you decide, you may want to talk with your family, friends, or doctor about your child taking part in the Study.
- You will receive a copy of this parental permission form.
- We will ask you for ongoing permission for your child's participation in the rest of the Study around the time that your child turns 6 months old.

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

For office use: PID

NICHD IRB Expiration Date:_ /___/_____

National Children's Study: Vanguard Study
Parental Permission Signature Page for Child's Participation from Birth to 6 Months of Age

- The Study staff has explained the purpose of my child's participation in the birth and 3-month visits of the NCS Vanguard Study, the procedures involved, and the risks and benefits for my child.
- I have asked all the questions I have now and I know who to contact if I have more questions.
- I understand that participation is voluntary and my child and I can leave the NCS Vanguard Study at any time.
- I understand that if there is a question I do not want to answer or a part of the NCS Vanguard Study that I do not want my child to do, I can skip it and my child can still be in the NCS Vanguard Study.
- I understand that any biological samples that are collected from my child will be stored in a secure facility and that the NCS Vanguard Study will control access to my child's samples.
- I understand that my child's data and samples will be used in the future to help researchers learn about children's health and human development.
- I understand that I will not routinely get results back from analyses done on the samples collected from my child during the NCS Vanguard Study.
- I understand that by signing this form, I give permission for the Study to collect information about my child from birth to 6 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 6 months old.

Please complete the following check boxes, as indicated, and sign in the Child's Parent/Legal Guardian box. You can answer "no" to any item and your child can still be in the NCS Vanguard Study.	**Yes**	**No**
I give my permission for the Study to collect my child's cord blood.	☐	☐
I give my permission for the Study to collect my child's placenta.	☐	☐
I give my permission for the Study to collect blood from my child's heel.	☐	☐
(If yes complete the line below)		
If I agree to collection of any of the samples above, I give my permission for the Study to use them for genetic analyses.	☐	☐

I choose to give my permission for my child to participate in the NCS Vanguard Study from birth to 6 months of age.

Child's Parent/Legal Guardian

By signing this form, I give permission for my child,_____, to join the NCS Vanguard Study.

(Printed Legal Name of Child)

Printed Legal Name of Parent/Legal Guardian: _____

Signature of Parent/Legal Guardian: _____Today's

Date:_ /_ /____(mm/dd/yyyy)

Witness (if required)

I observed the interviewer explain the parental permission form "What You Should Know about Enrolling Your Child in the National Children's Study (NCS) Vanguard Study," to the participant and he or she signed or marked this form.

Printed Legal Name of Witness:_____

Signature of Witness_____Today's Date: _ /_ /_____ (mm/dd/yyyy)

Printed Legal Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent:_____Today's Date: _ /_ /_ (mm/dd/yyyy)

Data Collector: Keep top copy. Give participant bottom copy

What You Should Know about Enrolling Your Child in the National Children's Study (NCS) Vanguard Study

Parental Permission Form for Child from 6 Month Visit to Age of Majority

- Thank you for participating in the National Children's (NCS) Vanguard Study. Your family is unique and critical to the success of this research study. With your help, the NCS will learn more about how our physical, social, and family environments affect the health, growth and development of our children.
- We hope your child will continue to be one of thousands of participants from across the United States helping us learn what will improve our children's health. Although what we learn in the NCS Vanguard Study may not help you or your family right now, the things we learn may help people in the future.
- Now, we will tell you more about the kinds of information we would like to collect about your child starting at about 6 months of age through age 21 and ask for your permission to collect it. We will also tell you about samples we would like to collect from your child and ask for your permission to collect them.
- Your child's participation in the NCS Vanguard Study is your choice. You can decide whether your child takes part or not. You and your child can leave the Study at any time and you can decide not to answer certain questions, or not to give certain samples.

Sponsors

The National Children's Study is led by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development of the National Institutes of Health (NIH) in collaboration with a consortium of federal government partners.

What is the goal of the National Children's Study (NCS)?

- The goal of the NCS is to improve the health of all children in the United States.
- The NCS will help us learn more about how our physical environment (including air and dust), social surroundings (our neighborhoods and communities), and family life:
    - Affect how children grow, and
    - Help children stay healthy.
- The NCS has several stages. The first stage is called the NCS Vanguard Study.
    - The purpose of the NCS Vanguard Study is to help guide the design of the NCS Main Study.
- The next stage is called the NCS Main Study.
    - This phase of the NCS will look at how our genes act together with our environment to influence health, growth, and development.
- About 100,000 children from all over the United States will be in the NCS Main Study.
- You are being asked for permission for your child to participate in the NCS Vanguard Study.

Why is the NCS important?

- The NCS is important because it will help us understand how we can improve our children's health.
- It is one of the largest ever research studies of children's health and development.
- With your help, we can learn more about how our physical, social and family environments affect children's health, growth, and development while they are young and when they become adults.
- The Study may also help us better understand why some children develop obesity, diabetes, autism, learning disabilities, asthma, or other problems.

What kind of study is the NCS Vanguard Study?

- The NCS Vanguard Study is an observational study.
- This means that we will not:
    - Ask you or your child to change what you normally do.

    - Ask you or your child to take any medicines or drugs.
- 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 may ask you to visit us at a clinic or another location near you.
    - Asking questions about you and your child and where you live and work.
    - Collecting samples from you and your child (like blood, urine, a swab from your rectum, and saliva) and from your home (like dust and air).

How many children will be in the NCS Vanguard Study?

- About 5,000 children will be in the NCS Vanguard Study.
- We are also asking those caring for the children in the Study to participate.

How long will the NCS Vanguard Study last?

- The Study will follow children until they are 21 years old.
- Starting at about age 7, young children and adolescents will be asked for their agreement to stay in the Study and can choose not to be in the Study anymore.
- When your child becomes a legal adult, 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.
- This parental permission form is asking for your permission to enroll your child in the NCS Vanguard Study from 6 months of age until your child becomes a legal adult.

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

- We will visit you at home, call, or send a letter to ask questions about you, your child, and your family. Sometimes we will ask you to visit a clinic or doctor's office for tests, exams, and measurements.
- Once your child is old enough, we will ask him or her questions, too.
- Because the NCS Vanguard Study will change over time, different families may be asked to take part in different Study activities.

- Before we do any Study activities, we will always explain what we are doing and will ask your permission first.
- If there are questions you do not want to answer, you can skip them and your child can still be in the Study.

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

- We plan to visit you and your child regularly over 21 years.
    - We plan to visit twice during the first year of your child's life.
    - After that, we plan to visit about every 1 to 3 years.
- Between visits, we may call, e-mail, text, or send a letter to:
    - Ask questions about your child's development and health, and
    - Confirm information like your address or phone number.
- We will ask you to answer questions about your child for the first several years. Once your child is old enough, we will ask him or her questions, too.

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

- We will visit your home to collect information about you, your child, your child's health, your family medical history, and your child's physical, social, and family environments.
- We may ask to take your child's body measurements like height, weight, body composition, and blood pressure.
- We may ask you to answer questions or fill out forms about your child. For example, we may ask you to keep a diary about the food your child eats over a week.
- We may ask for your permission to look at your child's health information and medical records.
    - If you change your mind after you give us permission, we will stop getting new information from your child's medical records, but we will keep using the information we have already gotten.

- During some visits, we may ask for your permission to collect samples from your child, like blood, urine, saliva, swabs from his or her mouth, nostrils, and rectum, a stool sample, and baby teeth that your child has lost.
- Before we ask for any samples during a visit, we will:
    - Explain what type of samples we want and how much we will need,
    - Explain how we will collect the samples and any known risks of the collection.
    - Ask for your verbal permission to collect the samples.
- We may also ask for your help to get some samples from your child, like urine.
- During some visits, we may also ask for your permission to collect samples from your home, such as air, dust, noise level measurements and water. For example, we may have our staff collect:
    - Dust samples from your vacuum cleaner or a dust cloth.
    - Samples of the water you drink.
- We may take some dust, air, or water samples from other places where your child spends time, like a day care center or school.
- In addition, we may ask you to collect some dust samples yourself using a kit we provide.
- We may ask you whether we can take pictures of your child.
- If there are samples you do not want to give us, you can skip them and your child can still be in the Study.

What about genetic information?

- 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.
- If you agree, we will get information about your child's genes. We will get this information from the samples that we collect from your child. We will store your child's samples and analyze them in the future.
- The risks associated with genetic analyses are unknown. In some cases the results of these genetic analyses may identify the risk of getting an illness or being a carrier of an illness. We will do our best to keep all results confidential.
    - There is a law that helps protect people from most kinds of health insurance and employment discrimination on the basis of genetics. This law is called the

Genetic Information Nondiscrimination Act (GINA). GINA does not protect people against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

- Some people have concerns about genetic information for cultural or religious reasons. If you do not want us to conduct genetic analyses, let us know. You can tell us not to do genetic analyses and still be in the Study.

What will the NCS Vanguard Study do with all of this information?

- We will use what we learn in the NCS Vanguard Study to inform the NCS Main Study and to achieve the goal of the NCS to improve the health of all children.
- The NCS Vanguard Study may use the information and samples we get from your child during the NCS Vanguard Study in several ways. Researchers may use this information to find out:
  - What questions and procedures will work best in the NCS Main Study.
  - How children's genes, surroundings, and experiences work together to affect growth, development, and health.
  - How some conditions that appear later in childhood and adulthood begin in early childhood.
- By agreeing to let your child be in the NCS Vanguard Study, you are agreeing to allow the use of your child's information and samples for:
  - The NCS Main Study.
  - Future studies on children's health and human development. Future studies might be done by other approved researchers.
- We will store the information and samples that participants provide indefinitely.
  - We may combine your child's data and genetic information with data from other research studies or information sources to answer important research questions. To do this, we may share genetic information through a secure national research database.
- In the future, scientists could develop new technologies or products based on the information and samples we collect from your child for the Study. Your child will not receive any money that may result from the development of such technologies or products.

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

- We will share what we learn overall from the NCS Vanguard Study. We will keep in touch with you through newsletters, on our website and in other ways.
- If tests we do during a visit show results important for your child's health care, we will share them with you at that time. For example, we will give you information about your child's height, weight and blood pressure when we measure them.
- We plan to analyze your child's biological and environmental samples in the future.
    - At this time, we do not know when analyses will be done, which analyses will be done and when information from the analyses will be available.
- The analyses we will do on the samples will help us understand how the physical, social, and family environments; genes; and other factors affect health and disease.
- These analyses are not intended to help guide your child's health care.
- In case any results of these analyses do turn out to be vital to your child's health care, we have a process in place for deciding this and telling you. We work with a group of doctors, scientists, and community members who advise us about analyses that could provide information vital to your child's health care.
- If we do identify results that provide vital information directly related to your child's health care, we will discuss options for sharing this information with you.

How will the NCS Vanguard Study protect my child's information?

- Study records that identify your child will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access.
- We will make our best effort to protect your child's privacy and keep information you provide confidential by:
    - Using a number code to label all samples and other information instead of your child's name.
    - Keeping your question responses, results, and other information about your child in a secure computer or locked file cabinet within a locked office.
    - Storing your child's samples in a secure place.
    - Reviewing all of the ways we store your child's information to improve how we

protect your child's privacy.

- Improving the ways your child's information is secured by using new technologies.

- We require researchers to keep your child's information safe. Researchers who want to use your child's information must:
  - Be authorized by the NCS and the Federal government to receive and store study information.
  - Protect your child's privacy by combining your responses and your child's information with that of other participants when reporting results.
- The NCS got a Certificate of Confidentiality from the U.S. Department of Health and Human Services (HHS). This legal document says that the Study does not have to give out your child's personal information, even if ordered to do so by a judge or court.
  - If you give a person or an organization written permission to see the information you gave the Study about your child, we cannot use the Certificate of Confidentiality to protect your child's information from that person or organization.

When might the NCS Vanguard Study share my child's information?

- The NCS needs to share your child's information to do the research described by this informed consent form.
  - The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development runs the National Children's Study.
  - We hire groups and organizations to do work for the Study such as collecting, storing and analyzing data. These groups must be authorized by the Study to protect your child's information in ways described by Federal Privacy Regulations.
- The NCS may need to share your child's information to protect public health and safety.
  - 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.

What are the possible benefits of my child's participation in the NCS Vanguard Study?

- Taking part in the NCS Vanguard Study will not improve your child's health right now. But the Study may help us learn things about health that could benefit all of us—including your children and grandchildren—in the years to come.
- If your child needs medical or social services, we will give you names and contact information for people and agencies that can try to help.

What are the possible risks or burdens to my child and to his or her community from being in the NCS Vanguard Study?

- The immediate risks from the NCS Vanguard Study are the same as those in routine health care.
- Some of the questions we ask and some of the ways we get samples may make you or your child feel uncomfortable. If you or your child are uncomfortable, you can skip any part of the NCS Vanguard Study. You are in charge.
- Giving a blood sample may cause a small amount of pain. People sometimes feel brief pain when blood is taken, and there is a very small risk of infection, bruising, bleeding, or fainting.
- The swab collections from your child's nostrils and rectum may cause some minor discomfort.
- 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 parentage (biological fatherhood or motherhood) of your child. We will not give out any information about parentage to you, your child, or anyone else.
- Although we are taking many steps to protect your child's information, there is always a chance that your child's information or identity or that of your family members could be disclosed. Such disclosures may also occur if you share information yourself or agree to have your child's research records released.
- 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.

Will my child be paid for being in the NCS Vanguard Study?

- We will give your family about $25 to $100 in cash or gift cards to thank you each time your child participates in a Study visit.
    - As your child gets older, we may give your child gift certificates or small amounts of money each time he or she participates in a Study visit.
- 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.

What is the alternative to taking part in the NCS Vanguard Study?

- The alternative to taking part in the NCS Vanguard Study is not taking part in the Study.

What if I want my child to leave the NCS Vanguard Study?

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

What if my child and I move?

- We would like to keep in touch with you as long as the NCS Vanguard Study is collecting information and your child is still participating in the Study.

- We hope you will tell us if you are planning to move so your child can still be part of the Study in your new home.
- If you move and forget to tell us, we will try to get in touch with you. We will use the information you have given us about family members and friends, as well as publicly available information.
- If we get in touch with you, we will ask whether you want your child to continue to be part of the Study.

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

- No. There is no cost to you for your child's participation in the NCS Vanguard Study.
- The Study will pay for all procedures done as part of the NCS Vanguard Study. Any future analyses done on your child's samples as part of the NCS Vanguard Study will also be paid for by the NCS.

Does the NCS Vanguard Study pay for health care for my child?

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

If my child is part of the National Children's Study, will he or she have to be in other studies?

- If your child is part of the NCS Vanguard 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 NCS.
    - If your child is invited to be in other studies, you can always say no.

What if the media wants to talk with me about my child's participation in the NCS Vanguard Study?

- The NCS will not tell the media anything about the identities of Study participants.
- Because of the importance of the Study, reporters may go to communities where the Study is being done. They may ask participants whether they want to talk about their experiences with the Study.
- If you are contacted by reporters, you can decide whether you want to talk to them. If you do talk to a reporter, he or she can write about anything you say. What you say will be public information. The organization that the reporter works for will have control over any information and material you give it.
- If you talk with the media or post on social media websites about your child's Study experience your child's participation in the Study will be public knowledge. When this information becomes public, it will be harder for the Study to protect the privacy of your child's information and the information of other participants from your community.

Who can I contact if I have questions about the NCS Vanguard Study?

- If you have questions now, you can ask the Study representative who gave you this parental permission form.
- You may call the NCS toll free at 1-877-865-2619 at any time if you have questions. Ask to speak with a member of the Study staff or to the principal investigator, Dr. Steven Hirschfeld. If you have questions about your child's rights as a research participant, you may call the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Institutional Review Board at 301-496-8370.

Important things to remember about being in the NCS Vanguard Study.

- After reading this parental permission form, we hope you will decide to allow your child to continue to participate in the NCS Vanguard Study.
- We will ask you to sign a page that says you have given your permission for your child to continue to be in the Study.
- You decide what questions to answer. You can also decide what samples to give from your child. If you decide not to answer some questions or give some samples, your child can still be in the Study.

- No matter what you decide now, you and your child can leave the Study at any time.
- Before you decide, you may want to talk with your family, friends, or doctor about your child taking part in the Study.
- You will receive a copy of this parental permission form.

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

For office use: PID

NICHD IRB Expiration Date:___/_ /_____

National Children's Study: Vanguard Study

Parental Permission Signature Page for Child's Participation from 6 Month Visit to Age of Majority

- The Study staff has explained the purpose of my child's participation in the NCS Vanguard Study, the procedures involved, and the risks and benefits for my child.
- I have asked all the questions I have now and I know who to contact if I have more questions.
- I understand that participation is voluntary and my child and I can leave the NCS Vanguard Study at any time.
- I understand that if there is a question I do not want to answer or a part of the Study that I do not want my child to do, I can skip it and my child can still be in the NCS Vanguard Study.
- I understand that any biological samples that are collected from my child will be stored in a secure facility and that the NCS Vanguard Study will control access to my child's samples.
- I understand that my child's data and samples will be used in the future to help researchers learn about children's health and human development.
- I understand that I will not routinely get results back from analyses done on the samples collected from my child during the NCS Vanguard Study.
- I understand that by signing this form, I give permission for the Study to collect information about my child from about 6 months of age until my child reaches the age of majority and can provide his or her own consent to continue to participate.

Please complete the following check boxes, as indicated, and sign in the Child's Parent/Legal Guardian box. You can answer "no" to any item and still be in the NCS Vanguard Study.	**Yes**	**No**
I give my permission for the Study to collect environmental samples from my home.	☐	☐
I give my permission for the Study to collect biological samples from my child.	☐	☐
(If yes complete the line below.)		
If I agree to collection of my child's biological samples, I give my permission for the Study to use them for genetic analyses.	☐	☐

I choose to give my permission for my child to participate in the NCS Vanguard Study from the 6 month visit to the age of majority.

Child's Parent/Legal Guardian

By signing this form, I give permission for my child,_____, to join the NCS Vanguard Study.
(Printed Legal Name of Child)

Printed Legal Name of Parent/Legal Guardian: _____

Signature of Parent/Legal Guardian: _____Today's Date:_ /_ /____(mm/dd/yyyy)

Witness (if required)

I observed the interviewer explain the parental permission form "What You Should Know about Enrolling Your Child in the National Children's Study (NCS) Vanguard Study" to the parent/legal guardian and he or she signed or marked this form.

Printed Legal Name of Witness:_____

Signature of Witness:_____Today's Date: /_ /_ (mm/dd/yyyy)

Printed Legal Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent:_____Today's Date: /_ /_ (mm/dd/yyyy)

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

Multi-Mode Visit Information Script (MMVIS)

Event Category:	Trigger-Based, Pre-Preg, PV1, PV2, Pre-Natal Father, Post-Natal Father, Secondary Residence; Time-Based, Birth, 3M, 6M, 9M, 12M, 18M, 24M, 30M, 36M, 42M, 48M, 54M, 60M
Event:	Pre-Pregnancy, PV1, PV2, Pre-Natal Father, Birth, Post-Natal Father, 3M, 6M, 9M, 12M, 18M, 24M, 30M, 36M, 42M, 48M, 54M, 60M, Secondary Residence
Administration:	Pre-Natal Father, PV1; Post-Natal Father, 9M, 18M; Secondary Residence, 36M, 48M, 60M
Instrument Target:	Pre-Pregnant Woman (Pre-Pregnancy); Pregnant Woman (PV1, PV2); Father/Father Figure (Pre-Natal, Post-Natal); Biological Mother (Birth); Primary Caregiver (3M, 6M, 9M, 12M, 18M, 24M, 30M, 36M, 42M, 48M, 54M, 60M); Secondary Residence Caregiver (Secondary Residence)
Instrument Respondent:	Pre-Pregnant Woman (Pre-Pregnancy); Pregnant Woman (PV1, PV2); Father/Father Figure (Pre-Natal, Post-Natal); Biological Mother (Birth); Primary Caregiver (3M, 6M, 9M, 12M, 18M, 24M, 30M, 36M, 42M, 48M, 54M, 60M); Secondary Residence Caregiver (Secondary Residence)
Domain:	Consent
Document Category:	Questionnaire
Method:	Data Collector Administered
Mode (for this instrument*):	In-Person, CAI; Phone, CAI
OMB Approved Modes:	In-Person, CAI; Phone, CAI; Web-Based, CAI
Estimated Administration Time:	2 minutes
Multiple Child/Sibling Consideration:	Per Event
Special Considerations:	N/A
Version:	2.0
MDES Release:	4.0

*This instrument is OMB-approved for multi-mode administration but this version of the instrument is designed for administration in this/these mode(s) only.

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Multi-Mode Visit Information Script (MMVIS)

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GENERAL PROGRAMMER INSTRUCTIONS: ..... **Error! Bookmark not defined.**
MULTI-MODE INTRODUCTORY VISIT INFORMATION SCRIPT **Error! Bookmark not defined.**

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Multi-Mode Visit Information Script (MMVIS)

GENERAL PROGRAMMER INSTRUCTIONS:

WHEN PROGRAMMING INSTRUMENTS, VALIDATE FIELD LENGTHS AND TYPES AGAINST THE MDES TO ENSURE DATA COLLECTION RESPONSES DO NOT EXCEED THOSE OF THE MDES. SOME GENERAL ITEM LIMITS USED ARE AS FOLLOWS:

DATA ELEMENT FIELDS	MAXIMUM CHARACTERS PERMITTED	DATA TYPE	PROGRAMMER INSTRUCTIONS
ADDRESS AND EMAIL FIELDS	100	CHARACTER	
UNIT AND PHONE FIELDS	10	CHARACTER	
_OTH AND COMMENT FIELDS	255	CHARACTER	• Limit text to 255 characters
FIRST NAME AND LAST NAME	30	CHARACTER	• Limit text to 30 characters
ALL ID FIELDS	36	CHARACTER	
ZIP CODE	5	NUMERIC	
ZIP CODE LAST FOUR	4	NUMERIC	
CITY	50	CHARACTER	
DOB AND ALL OTHER DATE FIELDS (E.G., DT, DATE, ETC.)	10	NUMERIC CHARACTER	• DISPLAY AS MM/DD/YYYY • STORE AS YYYY-MM-DD • HARD EDITS: MM MUST EQUAL 01 TO 12 DD MUST EQUAL 01 TO 31 YYYY MUST BE BETWEEN 1900 AND CURRENT YEAR.
TIME VARIABLES	TWO-DIGIT HOUR AND TWO-DIGIT MINUTE, AM/PM DESIGNATION	NUMERIC	• HARD EDITS: HOURS MUST BE BETWEEN 00 AND 12; MINUTES MUST BE BETWEEN 00 AND 59

Instrument Guidelines for Participant and Respondent IDs:

PRENATALLY, THE **P_ID** IN THE MDES HEADER IS THAT OF THE PARTICIPANT (E.G. THE NON-PREGNANT WOMAN, PREGNANT WOMAN, OR THE FATHER).

POSTNATALLY, A RESPONDENT ID WILL BE USED IN ADDITION TO THE PARTICIPANT ID BECAUSE SOMEBODY OTHER THAN THE PARTICIPANT MAY BE COMPLETING THE INTERVIEW. FOR EXAMPLE, THE PARTICIPANT MAY BE THE CHILD AND THE RESPONDENT MAY BE THE MOTHER, FATHER, OR ANOTHER CAREGIVER. THEREFORE, MDES VERSION 2.2 AND ALL FUTURE VERSIONS CONTAIN A **R_P_ID** (RESPONDENT PARTICIPANT ID) HEADER FIELD FOR EACH POST-BIRTH INSTRUMENT. THIS WILL ALLOW ROCs TO INDICATE

WHETHER THE RESPONDENT IS SOMEBODY OTHER THAN THE PARTICIPANT ABOUT WHOM THE QUESTIONS ARE BEING ASKED.

A REMINDER:

ALL RESPONDENTS MUST BE CONSENTED AND HAVE RECORDS IN THE PERSON, PARTICIPANT, PARTICIPANT_CONSENT AND LINK_PERSON_PARTICIPANT TABLES, WHICH CAN BE PRELOADED INTO EACH INSTRUMENT. ADDITIONALLY, IN POST-BIRTH QUESTIONNAIRES WHERE THERE IS THE ABILITY TO LOOP THROUGH A SET OF QUESTIONS FOR MULTIPLE CHILDREN, IT IS IMPORTANT TO CAPTURE AND STORE THE CORRECT CHILD **P_ID** ALONG WITH THE LOOP INFORMATION. IN THE MDES VARIABLE LABEL/DEFINITION COLUMN, THIS IS INDICATED AS FOLLOWS: **EXTERNAL IDENTIFIER: PARTICIPANT ID FOR CHILD DETAIL.**

MULTI-MODE INTRODUCTORY VISIT INFORMATION SCRIPT

(TIME_STAMP_MIV_ST).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP • PRELOAD **EVENT_TYPE.**

MIV01000. 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 realize that you are busy, and this {call/visit} should take only about {APPROXIMATE EVENT 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.]

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.

INTERVIEWER INSTRUCTIONS
• IF SAMPLES ARE COLLECTED AT THIS EVENT SAY, "If we ask you for samples, you will receive an additional token of appreciation."

PROGRAMMER INSTRUCTIONS

• DISPLAY APPROXIMATE EVENT TIME AS APPROPRIATE:
  ○ IF **EVENT_TYPE** = 11 (PRE-PREG), DISPLAY "20 - 45 min".
  ○ IF **EVENT_TYPE** = 13 (PV1 EVENT), DISPLAY "45 min - 1 1/4 hrs".
  ○ IF **EVENT_TYPE** = 15 (PV2 EVENT), DISPLAY "20 min - 45 min".
  ○ IF **EVENT_TYPE** = 19 (PRE-NATAL FATHER EVENT), DISPLAY "35 min".
  ○ IF **EVENT_TYPE** = XX (POST-NATAL FATHER EVENT), DISPLAY "20 min"
  ○ IF **EVENT_TYPE** = 18 (BIRTH EVENT), DISPLAY "1 1/4 - 1 3/4 hrs".
  ○ IF **EVENT_TYPE** = 23 (3-MONTH EVENT), DISPLAY "1 1/4 hrs".
  ○ IF **EVENT_TYPE** = 24 (6-MONTH EVENT), DISPLAY "2 1/2 - 3 3/4 hrs".
  ○ IF **EVENT_TYPE** = 26 (9-MONTH EVENT), DISPLAY "5 min".
  ○ IF **EVENT_TYPE** = 27 (12-MONTH EVENT), DISPLAY "45 min - 2 1/2 hrs"
  ○ IF **EVENT_TYPE** = 30 (18-MONTH EVENT), DISPLAY "1 hr"
  ○ IF **EVENT_TYPE** = 31 (24-MONTH EVENT), DISPLAY "40 min - 1 3/4 hrs".
  ○ IF **EVENT_TYPE** = 36 (30-MONTH EVENT), DISPLAY "1 hr".
  ○ IF **EVENT_TYPE** = 37 (36-MONTH EVENT), DISPLAY "1 1/2 - 3 3/4 hrs".
  ○ IF **EVENT_TYPE** = 38 (42-MONTH EVENT), DISPLAY "1 hr".
  ○ IF **EVENT_TYPE** = XX (48-MONTH EVENT), DISPLAY "1 1/2 - 3 hrs".
  ○ IF **EVENT_TYPE** = XX (54-MONTH EVENT), DISPLAY "45 min".
  ○ IF **EVENT_TYPE** = XX (60-MONTH EVENT), DISPLAY "1 1/4 - 4 hrs".

PROGRAMMER INSTRUCTIONS
• IF **EVENT_TYPE** = 18, 23, 24, 26, 27, 30, 31, 36, 37, 38, XX, XX, OR XX, DISPLAY “and your child”, “I will ask you questions about you, your child’s health and behavior, and your household.” AND “, your child.” • OTHERWISE, IF **EVENT_TYPE** = 13, 15, OR 19, DISPLAY “I will ask you questions about you and your household.” • IF MODE = CATI, DISPLAY “calling” AND “call”. • IF MODE = CAPI, DISPLAY “here” AND “visit”.

(TIME_STAMP_MIV_ET).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP

INTERVIEWER INSTRUCTIONS
• 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:	Pre-Preg, PV1, PV2, Birth, 6M, 12M, 24M, 36M, 48M, 60M
Domain:	Consent
Type of Document:	Visit Information Sheet Scripts
Version:	3.0
Release:	MDES 4.0

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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.

- WHEN COPYING SAMPLE COLLECTION VIS SCRIPTS, DATA COLLECTORS SHOULD NOT COPY TEXT THAT APPEARS IN BOLD FONT IN THE FIELD DOCUMENT OR IN ALL CAPITAL LETTERS IN THE SAMPLE COLLECTION VIS SCRIPTS DOCUMENT.

- CHECK FORMATTING AFTER INSERTING SCRIPTS AND REFORMAT IF NECESSARY.

- 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

1.0 INTRODUCTORY SCRIPTS

1. THE LANGUAGE BELOW SHOULD BE USED FOR THE PRE-PREGNANCY AND PREGNANCY VISIT 2.

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

2. THE LANGUAGE BELOW SHOULD BE USED FOR THE PREGNANCY VISIT 1 EVENT.

In addition to asking you questions, we would also like to collect some samples from you and some samples in and a vacuum dust sample from your home today.

3. THE LANGUAGE BELOW SHOULD BE USED FOR THE BIRTH EVENT.

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

4. THE LANGUAGE BELOW SHOULD BE USED FOR THE 6-MONTH EVENT.

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

5. THE LANGUAGE BELOW SHOULD BE USED FOR THE 12-MONTH EVENT:

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

6. THE LANGUAGE BELOW SHOULD BE USED FOR THE 24-MONTH EVENT.

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

7. THE LANGUAGE BELOW SHOULD BE USED FOR THE 36-MONTH AND 60-MONTH EVENTS:

In addition to asking you questions, we would also like to collect some samples from you, some samples and measurements from your child, collect vacuum dust and wipe samples and set up noise measurement equipment in your home, and make observations in and around your home today.

8. THE LANGUAGE BELOW SHOULD BE USED FOR THE 48-MONTH EVENT:

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

2.0 ADULT SAMPLE COLLECTION SCRIPTS

9. THE LANGUAGE BELOW SHOULD BE USED FOR THE PRE-PREGNANCY, PREGNANCY VISIT 1, PREGNANCY VISIT 2, BIRTH, 6-MONTH, 12-MONTH, 24-MONTH, 36-MONTH, 48-MONTH, AND 60-MONTH EVENTS.

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

10. THE LANGUAGE BELOW SHOULD BE USED FOR ADULT URINE COLLECTION FOR THE PRE-PREGNANCY, PREGNANCY VISIT 1, PREGNANCY VISIT 2, BIRTH, 6-MONTH, 12-MONTH, 36-MONTH, AND 60-MONTH EVENTS.

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

- You will collect a small amount of your urine (about 5 tablespoons) in the cup provided.
- This will take about 11 minutes.
- We may test your urine for biological substances and chemicals that may be present in the environment.

11. THE LANGUAGE BELOW SHOULD BE USED FOR ADULT BLOOD COLLECTION FOR THE PRE-PREGNANCY, PREGNANCY VISIT 1, PREGNANCY VISIT 2, BIRTH, 6-MONTH, 12-MONTH, 36-MONTH AND 60-MONTH EVENTS.

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

- Collect a small amount (about 2 tablespoons) of your blood using a small needle.
- This will take about 17 minutes.
- We may test your blood for hormones, nutrients, infections and inflammation, and for the presence of metals and other chemicals in the environment. We may use the sample for genetic analyses with your permission.

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.

12. THE LANGUAGE BELOW SHOULD BE USED FOR THE ADULT BREAST MILK COLLECTION FOR THE BIRTH EVENT.

We would like you to collect some **breast milk samples** 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.

13. THE LANGUAGE BELOW SHOULD BE USED FOR ADULT SALIVA COLLECTION FOR THE 36-MONTH AND 60-MONTH EVENTS.

We would like you to collect a sample of your **saliva**.

- This will take about 11 minutes.
- We may measure your saliva sample for biological substances and environmental chemicals. We may use the sample for genetic analyses with your permission.

Are there any risks from this collection?

- This procedure may be a little uncomfortable for you.

14. THE LANGUAGE BELOW SHOULD BE USED FOR ADULT MICROBIOME COLLECTION FOR THE BIRTH EVENT.

We would like to collect **swabs from your mouth, vagina, and rectum**.

- This will take about 10 minutes.
- You will collect your own rectal swab using materials and instructions we provide, we will collect the others.
- We may test your swab samples for genetic material from bacteria that are present in the sample.

Are there any risks from this collection?

- This procedure may be a little uncomfortable for you.

15. THE LANGUAGE BELOW SHOULD BE USED FOR ADULT MICROBIOME COLLECTION FOR THE 6-MONTH, 24-MONTH, AND 48-MONTH EVENTS.

We would like to collect **swabs from your mouth, nose, and rectum**.

- This will take about 10 minutes.
- You will collect your own rectal swab using materials and instructions we provide, we will collect the others.
- We may test your swab samples for genetic material from bacteria that are present in the sample.

Are there any risks from this collection?

This procedure may be a little uncomfortable for you.

3.0 CHILD SAMPLE COLLECTION SCRIPTS

16. THE LANGUAGE BELOW SHOULD BE USED FOR THE BIRTH, 6-MONTH, 12-MONTH, 24-MONTH, 36-MONTH, 48-MONTH, AND 60-MONTH EVENTS.

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

17. THE LANGUAGE BELOW SHOULD BE USED FOR THE PLACENTA COLLECTION FOR THE BIRTH EVENT.

We would like to collect the **placenta** shortly after your child is born.

- We will work with hospital, clinic, or birthing center staff to collect the placenta.

18. THE LANGUAGE BELOW SHOULD BE USED FOR THE CORD BLOOD COLLECTION FOR THE BIRTH EVENT.

We would like to collect **umbilical cord blood** shortly after your child is born.

- We will work with hospital, clinic, or birthing center staff to collect the umbilical cord blood. Blood is collected from the umbilical cord shortly after it is separated from the baby. The procedure takes about 5 minutes.
- All samples will be collected by trained medical professionals who know how to collect blood safely.
- If you have decided to participate in a cord blood bank program to store your child's umbilical cord blood, we will not collect any umbilical cord blood for the study.

19. THE LANGUAGE BELOW SHOULD BE USED FOR THE INFANT BLOOD SPOT CARD COLLECTION FOR THE BIRTH EVENT.

We would like to collect a **blood sample** from your child soon after birth.

- We would like to collect a small amount of blood (up to 4 drops) from the child's heel. We will work with hospital, clinic, or birthing center 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.

20. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD URINE COLLECTION FOR 6-MONTH AND 12-MONTH 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 biological substances and 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.

21. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD URINE COLLECTION FOR 36-MONTH AND 60-MONTH EVENT.

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

- Ask your child to collect his/her urine in a cup we provide or we will use a urine collection bag to collect a urine sample from your child.
- If a urine bag is used to collect your child's urine, 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.
- If a urine collection cup is used to collect your child's urine, then it will take about 14 minutes.
- We may test his/her urine for biological substances and 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.

22. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD BLOOD SAMPLE COLLECTION FOR THE 12-MONTH EVENT.

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

- Collect a small amount (a little less than 1 tablespoon) of your child's blood from the arm by using a small needle.
- This will take about 17 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. We may use the sample for genetic analyses with your permission.

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.

23. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD BLOOD SAMPLE COLLECTION FOR THE 36-MONTH and 60-MONTH EVENT.

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

- Collect a small amount (a little more than 1 tablespoon) of your child's blood from the arm by using a small needle.
- This will take about 17 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. With your permission, we may use the sample for genetic analyses.

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.

24. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD SALIVA COLLECTION FOR THE 12-MONTH, 36-MONTH, AND 60-MONTH EVENTS.

We would like to collect a sample of your child's **saliva**.

- This will take about 11 minutes.
- We may measure your child's saliva sample for biological substances and environmental chemicals. We may use the sample for genetic analyses with your permission.

Are there any risks from this collection?

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

25. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD MICROBIOME COLLECTION FOR THE 6-MONTH AND 48-MONTH EVENTS.

We would like to collect **swabs from your child's mouth, nose, and rectum**.

- This will take about 8 minutes.
- We may test your child's swab samples for genetic material from bacteria that are present in the sample.

Are there any risks from this collection?

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

26. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD MICROBIOME COLLECTION FOR THE 24-MONTH EVENT.

We would like to collect **swabs from your child's mouth, nose, and rectum**. In addition, to these swabs, we would like you to collect a sample of your child's stool to mail-back to us.

- It will take about 8 minutes to collect the swabs.
- We will provide you with materials and instructions to collect and mail us your child's stool sample.
- We may test your child's swab samples and stool sample for genetic material from bacteria that are present in the sample.

Are there any risks from this collection?

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

27. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD TEETH COLLECTION FOR THE 60-MONTH EVENT.

We would like you to collect **the teeth your child loses**. To do this we will:

- Provide you with materials to mail us any baby teeth your child loses.
- We may test your child's teeth samples for biological substances and environmental chemicals. We may use the sample for genetic analyses with your permission.

28. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD ANTHROPOMETRY 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

    - Length of his/her upper and lower arm and upper leg
    - Skinfolds of the back of his/her upper arm and upper back
    - Distance around his/her 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.

29. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD ANTHROPOMETRY AND BLOOD PRESSURE COLLECTION FOR THE 12-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
    - Length of his/her upper and lower arm and upper leg
    - Skinfolds of the back of his/her upper arm and upper back
    - Distance around his/her head, waist, and upper leg
    - 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.

30. THE LANGUAGE BELOW SHOULD BE USED FOR CHILD ANTHROPOMETRY AND BLOOD PRESSURE COLLECTION FOR THE 24-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
    - Height
    - Length of his/her upper and lower arm and upper leg
    - Skinfolds of the back of his/her upper arm and upper back
    - Distance around his/her head, waist, and upper leg
    - 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.

31. THE LANGUAGE BELOW SHOULD BE USED FOR THE CHILD ANTHROPOMETRY AND BLOOD PRESSURE COLLECTION FOR THE 36-MONTH EVENT.

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

- We will measure his/her:
  - Weight
  - Height
  - Distance around his/her head and waist
  - 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.

32. THE LANGUAGE BELOW SHOULD BE USED FOR THE CHILD ANTHROPOMETRY AND BLOOD PRESSURE COLLECTION FOR THE 48-MONTH EVENT.

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

- We will measure his/her:
  - Weight
  - Height
  - Distance around his/her waist
  - Blood pressure and pulse/heart rate
- This will take about 30-35 minutes.

Are there any risks from this collection?

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

33. THE LANGUAGE BELOW SHOULD BE USED FOR THE CHILD ANTHROPOMETRY, BLOOD PRESSURE, AND BIOELECTRIC IMPEDANCE ANALYSIS (BIA) (SUBSAMPLE) COLLECTION FOR THE 48-MONTH EVENT.

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

- We will measure his/her:
  - Weight
  - Height
  - Body Composition

    - Distance around his/her waist
    - Blood pressure and pulse/heart rate
- This will take about 35-40 minutes.

Are there any risks from this collection?

- These procedures may be a little uncomfortable for your child. Body composition is measured by having your child step on a scale. The scale measures body composition through an electrical pulse, which your child will not be able to feel.

34. THE LANGUAGE BELOW SHOULD BE USED FOR THE CHILD ANTHROPOMETRY AND BLOOD PRESSURE COLLECTION FOR THE 60-MONTH EVENT.

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

- We will measure his/her:
    - Weight
    - Height
    - Distance around his/her waist
    - Blood pressure and pulse/heart rate
    - Lung function, to measure lung function we will him/her take a deep breath and blow as hard and as fast as possible into a mouthpiece.
- This will take about 45 minutes.

Are there any risks from this collection?

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

35. THE LANGUAGE BELOW SHOULD BE USED FOR THE CHILD ANTHROPOMETRY, BLOOD PRESSURE, AND BIOELECTRIC IMPEDANCE ANALYSIS (BIA) (SUBSAMPLE) COLLECTION FOR THE 60-MONTH EVENT.

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

- We will measure his/her:
    - Height
    - Weight
    - Body Composition
    - Distance around his/her waist
    - Blood pressure and pulse/heart rate
    - Lung function, to measure lung function we will him/her take a deep breath and blow as hard and as fast as possible into a mouthpiece.
- This will take about 50 minutes.

Are there any risks from this collection?

- These procedures may be a little uncomfortable for your child. Body composition is measured by having your child step on a scale. The scale measures body composition through an electrical pulse, which your child will not be able to feel.

36. THE LANGUAGE BELOW SHOULD BE USED FOR VISION FOR THE 36-MONTH EVENT.

We would also like to measure your child's **vision.** To do this, we will ask your child to identify different sized letters on a computer screen. This will take approximately 3 minutes.

37. THE LANGUAGE BELOW SHOULD BE USED FOR VISION, ENDURANCE, STANDING BALANCE, 9-HOLE PEGBOARD, GRIP STRENGTH FOR THE 60-MONTH EVENT.

We would like to measure your child's physical capabilities.

- We would like to measure how **easily your child can use his/her hands**:
  - We will ask your child to place and remove pegs into a pegboard.
  - This will take approximately 4 minutes.
- We would like to measure your child's **walking ability:**
  - We will ask your child to walk a short distance at his/her usual pace three times.
  - This will take approximately 3 minutes.
- We would like to measure your child's **grip strength**:
  - We will ask your child to squeeze a device as hard as he/she can for three seconds.
  - This will take approximately 3 minutes.
- We would like to measure your child's **balance:**
  - We will ask your child to wear a physical activity monitor.
  - We will then ask your child to copy and hold 5 poses for 50 seconds each.
  - This will take approximately 7 minutes.
- We would like to measure your child's **vision:**
  - We will ask your child to identify different sized letters on a computer screen.
  - This will take approximately 3 minutes.

Are there any risks from this collection?

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

4.0 ENVIRONMENTAL SAMPLE COLLECTION SCRIPTS

38. THE LANGUAGE BELOW SHOULD BE USED FOR THE PREGNANCY VISIT 1, 12-MONTH, 36-MONTH, 48-MONTH, AND 60-MONTH EVENTS.

What sample(s) would you like to collect in and around my home today?

39. THE LANGUAGE BELOW SHOULD BE USED FOR THE ENVIRONMENTAL COLLECTIONS AT THE PREGNANCY VISIT 1 EVENT.

We'd like to collect an environmental sample. You may join us while we conduct this activity, or (with your permission) we can complete this activity while you perform other activities.

- We would like to collect a vacuum **dust** sample. To do this, we will:
  - Collect the vacuum bag or dust sample from your most used vacuum cleaner.
  - This will take about 14 minutes.

40. THE LANGUAGE BELOW SHOULD BE USED FOR THE ENVIRONMENTAL COLLECTIONS AT THE 12-MONTH EVENT.

We'd like to collect an environmental sample, measurements, and make observations in and around your home. You may join us while we conduct this activity, or (with your permission) we can complete these activities while you perform other activities.

- We would like to collect a vacuum **dust** sample. To do this, we will:
  - Collect the vacuum bag or dust sample from your most used vacuum cleaner.
  - This will take about 14 minutes.
- We would like to make some **observations in and around the outside of your home.**
  - We won't go anyplace in or outside of your home that you don't want us to go.
  - We will measure the temperature of your hot water.
  - With your permission, we will open drawers/cabinets in a few rooms in your home.
- This will take about 30 inside your home and 33 minutes outside your home.

41. THE LANGUAGE BELOW SHOULD BE USED FOR THE ENVIRONMENTAL COLLECTIONS AT THE 36-MONTH AND 60-MONTH EVENTS.

We'd like to collect environmental samples and measurements and make observations. You may join us while we conduct these activities, or (with your permission) we can complete these activities while you perform other activities.

- We would like to collect **wipe** samples. To do this, we will:
  - Wipe the floor in the room where your child spends the most time while awake.
  - We may test these wipes for chemicals like pesticides or metals.
  - This will take about 26 minutes.
- We would like to collect a **vacuum dust** sample. To do this, we will:
  - Collect the vacuum bag or dust sample from your most used vacuum cleaner.
  - This will take about 14 minutes.
- We would like to measure **noise** levels in your home. To do this, we will:

- Set up a noise monitor in your home.
- We will leave it in your home for approximately 7 days, and will either return to pick it up, or in some cases, we will ask you to ship it back to us. We will provide a postage-paid shipper and instructions for you to ship it back.
- We will work with you to find a good spot for the noise monitor. Once we've agreed on a good spot, please don't move the noise monitor. If you move it, we won't be able to learn as much as we need to about noise levels in your home.
- You don't need to change your daily routine while the noise monitor is in your home.
- We'll give you instructions to help answer any questions you may have about the noise monitor.
- It will take about 18 minutes to set the noise monitor up.
- It will take about 12 minutes to pick up the noise monitor.

- We would like to make some **observations in and around the outside of your home.**
  - We won't go anyplace in or outside of your home that you don't want us to go.
  - We will measure the temperature of your hot water.
  - With your permission, we will open drawers/cabinets in select areas of your home.
- This will take about 30 inside your home and 33 minutes outside your home.

42. THE LANGUAGE BELOW SHOULD BE USED FOR ENVIRONMENTAL COLLECTIONS FOR THE 48-MONTH EVENT.

We'd like to collect environmental samples. You may join us while we conduct these activities, or (with your permission) we can complete these activities while you perform other activities.

- We would like to collect **wipe** samples. To do this, we will:
  - Wipe the floor in the room where your child spends the most time while awake.
  - We may test these wipes for chemicals like pesticides or metals.
  - This will take about 26 minutes.
- We would like to collect a **vacuum dust** sample. To do this, we will:
  - Collect the vacuum bag or dust sample from your most used vacuum cleaner.
  - This will take about 14 minutes.

43. THE LANGUAGE BELOW SHOULD BE USED FOR PHYSICAL ACTIVITY MONITOR (SUBSAMPLE) FOR THE 36-MONTH, 48-MONTH, AND 60-MONTH EVENTS.

- We may ask to measure the **physical activity** of your child. To do this we will:
  - Place a physical activity monitor on your child's wrist and a global positioning system (GPS) monitor on your child's waist.
  - We ask that you leave the physical activity monitor on the child's wrist for 7 days. It is waterproof so can be worn in the shower, tub, or when swimming.
  - We ask that you leave the GPS monitor on your child's waist for 7 days. It is not waterproof so it cannot be worn when the child is swimming or playing in water.

- We ask that you remove the GPS monitor from your child's waist every evening before your child goes to bed and charge it overnight and then place it back on your child's waist in the morning.
- We will either return to pick the monitors up, or in some cases, we will ask you to ship them back to us. We will provide a postage-paid shipper and instructions for you to ship them back.
- You and your child do not need to change your daily routine while the monitors are worn.
- We'll give you instructions to help answer any questions you may have about the monitors.
- It will take about 25 minutes to set the monitors up.
- It will take about 18 minutes to pick up the monitors.

5.0 CLOSING SCRIPTS

44. THE LANGUAGE BELOW SHOULD BE USED FOR ALL EVENTS.

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

- Taking part in the National Children's Study sample collections 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.

45. THE LANGUAGE BELOW SHOULD BE USED FOR THE PRE-PREGNANCY, PREGNANCY VISIT 1, PREGNANCY VISIT 2, AND BIRTH EVENTS.

Will I be paid for taking part in sample collection?

To thank you for providing your samples, we will give you $25.

46. THE LANGUAGE BELOW SHOULD BE USED FOR THE 6-MONTH, 12-MONTH, 24-MONTH, 36-MONTH, 48-MONTH, AND 60-MONTH EVENTS [USE EITHER #45 OR #46 (NOT BOTH), DEPENDING ON LSOPS].

Will I be paid for taking part in sample collection?

- To thank you for providing your samples, we will give you $25, and to thank you for providing your child's samples, we will give you an additional $25.

47. THE LANGUAGE BELOW SHOULD BE USED FOR THE 6-MONTH, 12-MONTH, 24-MONTH, 36-MONTH, 48-MONTH, AND 60-MONTH EVENTS [USE EITHER #45 OR #46 (NOT BOTH), DEPENDING ON LSOPS].

Will I be paid for taking part in sample collection?

- To thank you for providing your samples, we will give you $25, and to thank you for providing your child's samples, we will give you a non-cash incentive worth about $25.

48. THE LANGUAGE BELOW SHOULD BE USED FOR THE PRE-PREGNANCY, PREGNANCY VISIT 2, BIRTH, 6-MONTH AND 24-MONTH EVENTS.

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.

49. THE LANGUAGE BELOW SHOULD BE USED FOR THE PREGNANCY VISIT 1, 12-MONTH, 36-MONTH, 48-MONTH AND 60-MONTH EVENTS.

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.

Reconsideration Questionnaire - Adult

Event Category:	Trigger-Based, Pre-Preg, PV1, PV2; Time-Based, 6M, 12M, 24M, 36M, 48M, 60M
Event:	Pre-Preg, PV1, PV2, 6M, 12M, 24M, 36M, 48M, 60M
Administration:	N/A
Instrument Target:	Pre-Pregant Woman (Pre-Preg); Pregnant Woman (PV1, PV2); Primary Caregiver (6M, 12M, 24M, 36M, 48M, 60M)
Instrument Respondent:	Pre-Pregant Woman (Pre-Preg); Pregnant Woman (PV1, PV2); Primary Caregiver (6M, 12M, 24M, 36M, 48M, 60M)
Domain:	Consent
Document Category:	Questionnaire
Method:	Data Collector Administered
Mode (for this instrument*):	In-Person, CAI; Phone, CAI
OMB Approved Modes:	In-Person, CAI; Phone, CAI
Estimated Administration Time:	1 minute
Multiple Child/Sibling Consideration:	Per Event
Special Considerations:	N/A
Version:	1.0
MDES Release:	4.0

*This instrument is OMB-approved for multi-mode administration but this version of the instrument is designed for administration in this/these mode(s) only.

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Reconsideration Questionnaire - Adult

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Reconsideration Questionnaire - Adult

GENERAL PROGRAMMER INSTRUCTIONS:

WHEN PROGRAMMING INSTRUMENTS, VALIDATE FIELD LENGTHS AND TYPES AGAINST THE MDES TO ENSURE DATA COLLECTION RESPONSES DO NOT EXCEED THOSE OF THE MDES. SOME GENERAL ITEM LIMITS USED ARE AS FOLLOWS:

DATA ELEMENT FIELDS	MAXIMUM CHARACTERS PERMITTED	DATA TYPE	PROGRAMMER INSTRUCTIONS
ADDRESS AND EMAIL FIELDS	100	CHARACTER	
UNIT AND PHONE FIELDS	10	CHARACTER	
_OTH AND COMMENT FIELDS	255	CHARACTER	• Limit text to 255 characters
FIRST NAME AND LAST NAME	30	CHARACTER	• Limit text to 30 characters
ALL ID FIELDS	36	CHARACTER	
ZIP CODE	5	NUMERIC	
ZIP CODE LAST FOUR	4	NUMERIC	
CITY	50	CHARACTER	
DOB AND ALL OTHER DATE FIELDS (E.G., DT, DATE, ETC.)	10	NUMERIC CHARACTER	• DISPLAY AS MM/DD/YYYY • STORE AS YYYY-MM-DD • HARD EDITS: MM MUST EQUAL 01 TO 12 DD MUST EQUAL 01 TO 31 YYYY MUST BE BETWEEN 1900 AND CURRENT YEAR.
TIME VARIABLES	TWO-DIGIT HOUR AND TWO-DIGIT MINUTE, AM/PM DESIGNATION	NUMERIC	• HARD EDITS: HOURS MUST BE BETWEEN 00 AND 12; MINUTES MUST BE BETWEEN 00 AND 59

Instrument Guidelines for Participant and Respondent IDs:

PRENATALLY, THE **P_ID** IN THE MDES HEADER IS THAT OF THE PARTICIPANT (E.G. THE NON-PREGNANT WOMAN, PREGNANT WOMAN, OR THE FATHER).

POSTNATALLY, A RESPONDENT ID WILL BE USED IN ADDITION TO THE PARTICIPANT ID BECAUSE SOMEBODY OTHER THAN THE PARTICIPANT MAY BE

COMPLETING THE INTERVIEW. FOR EXAMPLE, THE PARTICIPANT MAY BE THE CHILD AND THE RESPONDENT MAY BE THE MOTHER, FATHER, OR ANOTHER CAREGIVER. THEREFORE, MDES VERSION 2.2 AND ALL FUTURE VERSIONS CONTAIN A **R_P_ID** (RESPONDENT PARTICIPANT ID) HEADER FIELD FOR EACH POST-BIRTH INSTRUMENT. THIS WILL ALLOW ROCs TO INDICATE WHETHER THE RESPONDENT IS SOMEBODY OTHER THAN THE PARTICIPANT ABOUT WHOM THE QUESTIONS ARE BEING ASKED.

A REMINDER:

ALL RESPONDENTS MUST BE CONSENTED AND HAVE RECORDS IN THE PERSON, PARTICIPANT, PARTICIPANT_CONSENT AND LINK_PERSON_PARTICIPANT TABLES, WHICH CAN BE PRELOADED INTO EACH INSTRUMENT. ADDITIONALLY, IN POST-BIRTH QUESTIONNAIRES WHERE THERE IS THE ABILITY TO LOOP THROUGH A SET OF QUESTIONS FOR MULTIPLE CHILDREN, IT IS IMPORTANT TO CAPTURE AND STORE THE CORRECT CHILD **P_ID** ALONG WITH THE LOOP INFORMATION. IN THE MDES VARIABLE LABEL/DEFINITION COLUMN, THIS IS INDICATED AS FOLLOWS: **EXTERNAL IDENTIFIER: PARTICIPANT ID FOR CHILD DETAIL.**

RECONSIDERATION QUESTIONNAIRE - ADULT

(TIME_STAMP_RQA_ST).

PROGRAMMER INSTRUCTIONS

• INSERT DATE/TIME STAMP.
• PRELOAD **P_ID** FOR ADULT.
• PRELOAD MOST RECENT **SAMPLE_CONSENT_GIVEN** AND **SAMPLE_CONSENT_TYPE** FROM **PARTICIPANT_CONSENT_SAMPLE** TABLE FOR ADULT.
• PRELOAD **EVENT_TYPE**.
• IF **EVENT_TYPE** = 24 (6-MONTH), 27 (12-MONTH), 37 (36-MONTH), XX (48-MONTH), OR XX (60-MONTH) PRELOAD **C_FNAME** FROM **INSTRUMENT_ID** = XX (PVST).
  o IF **C_FNAME ≠** -1 OR -2, DISPLAY C_FNAME AS APPROPRIATE THROUGHOUT INSTRUMENT.
  o OTHERWISE, IF **C_FNAME** = -1 OR -2, DISPLAY "the child" AS APPROPRIATE THROUGHOUT INSTRUMENT.

RQA01000/(RECON_INTRO). We understand that you {gave/did not give} us your permission to collect some samples from you when you consented to join the Study. You do not have to agree to provide any samples today, but we would like to offer you the opportunity to provide samples during this visit to help us reach the goals of the Study.

INTERVIEWER INSTRUCTIONS
• DURING THE LAST INFORMED CONSENT, THE {PRE-PREGNANT WOMAN/PREGNANT WOMAN/ADULT CAREGIVER} {CONSENTED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES/CONSENTED TO PROVIDE BIOLOGICAL SAMPLES BUT NOT ENVIRONMENTAL SAMPLES/CONSENTED TO PROVIDE ENVIRONMENTAL SAMPLES BUT NOT BIOLOGICAL SAMPLES/REFUSED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES/CONSENTED TO PROVIDE BIOLOGICAL SAMPLES. NO NEW INFORMED CONSENTS FORMS SHOULD BE ADMINISTERED/DID NOT CONSENT TO PROVIDE BIOLOGICAL SAMPLES}. • THIS QUESTIONNAIRE WILL ASK FOR {CONTINUED PERMISSION TO COLLECT BIOLOGICAL AND ENVIRONMENTAL SAMPLES. NO NEW CONSENT FORMS SHOULD BE ADMINISTERED/RECONSIDERATION OF ENVIRONMENTAL SAMPLES/RECONSIDERATION OF BIOLOGICAL SAMPLES/RECONSIDERATION OF BIOLOGICAL AND/OR ENVIRONMENTAL SAMPLES}.

PROGRAMMER INSTRUCTIONS
• IF **EVENT_TYPE** = 11 (PRE-PREGNANCY), DISPLAY "PRE-PREGNANT WOMAN" IN INTERVIEWER INSTRUCTIONS. • IF **EVENT_TYPE** = 13 (PREGNANCY VISIT 1) OR 15 (PREGNANCY VISIT 2), DISPLAY “PREGNANT WOMAN” IN INTERVIEWER INSTRUCTIONS. • IF **EVENT_TYPE** = 24 (6-MONTH), 27 (12-MONTH), 31 (24-MONTHS), 37 (36-MONTH), XX (48-MONTH), OR XX (60-MONTH), DISPLAY “ADULT CAREGIVER” IN INTERVIEWER INSTRUCTIONS.

PROGRAMMER INSTRUCTIONS

- IF **EVENT_TYPE** = 13 (PREGNANCY VISIT 1):
  - AND **SAMPLE_CONSENT_GIVEN** = 1 AND:
    - **SAMPLE_CONSENT_TYPE** INCLUDES BOTH 1 AND 2, DISPLAY "CONSENTED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES" AND "CONTINUED PERMISSION TO COLLECT BIOLOGICAL AND ENVIRONMENTAL SAMPLES. NO NEW INFORMED CONSENT FORMS SHOULD BE ADMINISTERED" IN INTERVIEWER INSTRUCTIONS.
    - **SAMPLE_CONSENT_TYPE** INCLUDES 1 BUT NOT 2, DISPLAY "CONSENTED TO PROVIDE BIOLOGICAL SAMPLES BUT NOT ENVIRONMENTAL SAMPLES" AND "RECONSIDERATION OF ENVIRONMENTAL SAMPLES" IN INTERVIEWER INSTRUCTIONS.
    - **SAMPLE_CONSENT_TYPE** = 2, DISPLAY "CONSENTED TO PROVIDE ENVIRONMENTAL SAMPLES BUT NOT BIOLOGICAL SAMPLES" AND "RECONSIDERATION OF BIOLOGICAL SAMPLES" IN INTERVIEWER INSTRUCTIONS.
  - AND **SAMPLE_CONSENT_GIVEN** = 2, DISPLAY "REFUSED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES" AND "RECONSIDERATION OF BIOLOGICAL AND/OR ENVIRONMENTAL SAMPLES".
- IF **EVENT_TYPE** = 11 (PRE-PRENGANCY), 15 (PREGNANCY VISIT 2), 24 (6-MONTH), 27 (12-MONTH), 31 (24-MONTHS), 37 (36-MONTH), XX (48-MONTH), OR XX (60-MONTH);
  - AND **SAMPLE_CONSENT_GIVEN** = 1:
    - AND **SAMPLE_CONSENT_TYPE** INCLUDES 1, DISPLAY "CONSENTED TO PROVIDE BIOLOGICAL SAMPLES. NO NEW INFORMED CONSENTS FORMS SHOULD BE ADMINISTERED" IN INTERVIEWER INSTRUCTIONS.
    - AND **SAMPLE_CONSENT_TYPE** DOES NOT INCLUDE 1, DISPLAY "DID NOT CONSENT TO PROVIDE BIOLOGICAL SAMPLES".
  - AND **SAMPLE_CONSENT_GIVEN** = 2, DISPLAY "DID NOT CONSENT TO PROVIDE BIOLOGICAL SAMPLES".
- IF **EVENT_TYPE** = 11 (PRE-PRENGANCY), 15 (PREGNANCY VISIT 2), 24 (6-MONTH), 27 (12-MONTH), 31 (24-MONTHS), 37 (36-MONTH), XX (48-MONTH), OR XX (60-MONTH) AND:
  - IF **SAMPLE_CONSENT_GIVEN** = 2 OR **SAMPLE_CONSENT_TYPE** DOES NOT INCLUDE 1, DISPLAY "did not give" IN QUESTION TEXT.
  - OTHERWISE, IF **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** INCLUDES 1, DISPLAY "gave" IN QUESTION TEXT.
- IF **EVENT_TYPE** = 13 (PREGNANCY VISIT 1) AND:
  - IF **SAMPLE_CONSENT_GIVEN** = 2 OR **SAMPLE_CONSENT_TYPE** DOES NOT INCLUDE BOTH 1 AND 2, DISPLAY "did not give" IN QUESTION TEXT.
  - OTHERWISE, IF **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** INCLUDES BOTH 1 AND 2, DISPLAY "gave" IN QUESTION TEXT.

RQA02000/(RECON_BIO). Would you like to {allow us/continue to allow us} to collect biological specimens from you for this Study visit?

INTERVIEWER INSTRUCTIONS

- {PRE-PREGNANT WOMEN/PREGNANT WOMEN/ADULT CAREGIVERS} WHO PROVIDE A CONTRADICTORY RESPONSE TO THE INITIAL CONSENT RESPONSE TO ANY SAMPLE COLLECTION SHOULD BE RE-ADMINISTERED CONSENT USING THE *INFORMED CONSENT FORM WHAT YOU SHOULD KNOW ABOUT BEING IN THE NATIONAL CHILDREN'S STUDY (NCS) VANGUARD STUDY: INFORMED CONSENT FORM {FOR PREGNANT WOMAN}* AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

PROGRAMMER INSTRUCTIONS

- DISPLAY INTERVIEWER INSTRUCTIONS IF EITHER:
  - **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** = 2 (I.E., DOES NOT INCLUDE 1)
  - **SAMPLE_CONSENT_GIVEN** = 2
- IF **EVENT_TYPE** = 11 (PRE-PREGNANCY), DISPLAY "PRE-PREGNANT WOMEN" IN INTERVIEWER INSTRUCTION.
- IF **EVENT_TYPE** = 13 (PREGNANCY VISIT 1) OR 15 (PREGNANCY VISIT 2), DISPLAY "PREGNANT WOMAN" AND "FOR PREGNANT WOMAN" IN INTERVIEWER INSTRUCTIONS.
- IF **EVENT_TYPE** = 24 (6-MONTH), 27 (12-MONTH), 31 (24-MONTH), 37 (36-MONTH), XX (48-MONTH), OR XX (60-MONTH), DISPLAY "ADULT CAREGIVERS" IN INTERVIEWER INSTRUCTIONS.
- IF **SAMPLE_CONSENT_GIVEN** = 2 OR **SAMPLE_CONSENT_TYPE** = 2 (I.E., DOES NOT INCLUDE 1), DISPLAY "allow us" IN QUESTION TEXT.
- OTHERWISE, DISPLAY "continue to allow us" IN QUESTION TEXT.

Label	Code	Go To
YES	**1**	
NO	**2**	
REFUSED	**-1**	
DON'T KNOW	**-2**	

SOURCE

National Children's Study, Vanguard 2 Phase

PROGRAMMER INSTRUCTIONS

- IF **EVENT_TYPE** = 13 (PREGNANCY VISIT 1) GO TO **RECON_ENV**.
- OTHERWISE,
  - IF **EVENT_TYPE** = 24 (6-MONTH), 27 (12-MONTH), 37 (36-MONTH), XX (48-MONTH), OR XX (60-MONTH) AND:
    - **SAMPLE_CONSENT_GIVEN** = 2 OR (**SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** DOES NOT INCLUDE 2 (I.E., = 1 OR = 1 AND 3)) FOR **R_P_ID** (ADULT) AND:
      - **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** INCLUDES 2 FOR **P_ID** (CHILD), GO TO **RECON_ENV_DISC**.

PROGRAMMER INSTRUCTIONS

- **SAMPLE_CONSENT_GIVEN** = 2 OR (**SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** DOES NOT INCLUDE 2 (I.E., = 1 OR = 1 AND 3)) FOR **P_ID** (CHILD), GO TO PROGRAMMER INSTRUCTIONS AFTER **RECON_ENV_DISC**.
  - **SAMPLE_CONSENT_GIVEN** = 1 AND INCLUDES 2, GO TO PROGRAMMER INSTRUCTIONS AFTER **RECON_ENV**.
- IF **EVENT_TYPE** = 11 (PRE-PREGNANCY), 15 (PREGNANCY VISIT 2), OR 31 (24-MONTH), GO TO PROGRAMMER INSTRUCTIONS AFTER **RECON_ENV_DISC**.

RQA03000/(RECON_ENV). Would you like to {allow us/continue to allow us} to collect environmental samples from your home for this Study visit?

INTERVIEWER INSTRUCTIONS

- PREGNANT WOMEN WHO PROVIDE A CONTRADICTORY RESPONSE TO THE INITIAL CONSENT RESPONSE TO ANY SAMPLE COLLECTION SHOULD BE RE-ADMINISTERED CONSENT USING *THE INFORMED CONSENT FORM WHAT YOU SHOULD KNOW ABOUT BEING IN THE NATIONAL CHILDREN'S STUDY (NCS) VANGUARD STUDY: INFORMED CONSENT FORM FOR PREGNANT WOMAN* AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

PROGRAMMER INSTRUCTIONS

- DISPLAY INTERVIEWER INSTRUCTIONS IF EITHER:
  - **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** ≠ 2 (I.E., = 1 OR = 1 AND 3)
  - **SAMPLE_CONSENT_GIVEN** = 2
- DISPLAY "allow us" IN QUESTION TEXT IF EITHER:
  - **SAMPLE_CONSENT_GIVEN** = 2.
  - **SAMPLE_CONSENT_TYPE** ≠ 2 (I.E., = 1 OR = 1 AND 3).
- OTHERWISE, DISPLAY "continue to allow us" IN QUESTION TEXT.

Label	Code	Go To
YES	**1**	
NO	**2**	
REFUSED	**-1**	
DON'T KNOW	**-2**	

SOURCE

National Children's Study, Vanguard 2 Phase

PROGRAMMER INSTRUCTIONS

- GO TO **READM_CON** IF EITHER:
  - **RECON_BIO** = 1 AND EITHER:
    - **SAMPLE_CONSENT_GIVEN** = 2 OR
    - **SAMPLE_CONSENT_TYPE** ≠ 1

PROGRAMMER INSTRUCTIONS
○ **RECON_ENV** = 1 AND EITHER: ▪ **SAMPLE_CONSENT_GIVEN** = 2 OR ▪ **SAMPLE_CONSENT_TYPE** ≠ 2 • OTHERWISE, GO TO **RQA05000**.

RQA03100/(RECON_ENV_DISC). We noticed on your consent form in the past you did not agree to allow us to collect environmental samples, but you agreed to allow us to collect environmental samples on {C_FNAME/the child}'s consent form. Today, would you like to agree to collection of environmental samples on your consent form as you have agreed to environmental collections for {C_FNAME/the child}?

Label	Code	Go To
YES	**1**	
NO	**2**	**RQA05000**
REFUSED	**-1**	**RQA05000**
DON'T KNOW	**-2**	**RQA05000**

RQA04000/(READM_CON). Thank you for agreeing to provide samples. We will now review the consent form to record that you have agreed to provide these samples.

INTERVIEWER INSTRUCTIONS
• RE-ADMINISTER CONSENT USING THE *INFORMED CONSENT FORM WHAT YOU SHOULD KNOW ABOUT BEING IN THE NATIONAL CHILDREN'S STUDY (NCS) VANGUARD STUDY: INFORMED CONSENT FORM {FOR PREGNANT WOMAN}* AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

PROGRAMMER INSTRUCTIONS
• IF **EVENT_TYPE** = 13 (PREGNANCY VISIT 1) OR 15 (PREGNANCY VISIT 2), DISPLAY "FOR PREGNANT WOMAN" IN INTERVIEWER INSTRUCTIONS.

Label	Code	Go To
CONTINUE	**1**	
REFUSED	**-1**	

SOURCE
National Children's Study, Vanguard 2 Phase

RQA05000. Thank you for your time.

(TIME_STAMP_RQA_ET).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP.

Reconsideration Questionnaire - Child

Event Category:	Time-Based
Event:	12M, 36M, 48M, 60M
Administration:	N/A
Instrument Target:	Child
Instrument Respondent:	Primary Caregiver
Domain:	Consent
Document Category:	Questionnaire
Method:	Data Collector Administered
Mode (for this instrument*):	In-Person, CAI; Phone, CAI
OMB Approved Modes:	In-Person, CAI; Phone, CAI
Estimated Administration Time:	1 minute
Multiple Child/Sibling Consideration:	Per Child
Special Considerations:	N/A
Version:	1.0
MDES Release:	4.0

*This instrument is OMB-approved for multi-mode administration but this version of the instrument is designed for administration in this/these mode(s) only.

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Reconsideration Questionnaire - Child

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Reconsideration Questionnaire - Child

GENERAL PROGRAMMER INSTRUCTIONS:

WHEN PROGRAMMING INSTRUMENTS, VALIDATE FIELD LENGTHS AND TYPES AGAINST THE MDES TO ENSURE DATA COLLECTION RESPONSES DO NOT EXCEED THOSE OF THE MDES. SOME GENERAL ITEM LIMITS USED ARE AS FOLLOWS:

DATA ELEMENT FIELDS	MAXIMUM CHARACTERS PERMITTED	DATA TYPE	PROGRAMMER INSTRUCTIONS
ADDRESS AND EMAIL FIELDS	100	CHARACTER	
UNIT AND PHONE FIELDS	10	CHARACTER	
_OTH AND COMMENT FIELDS	255	CHARACTER	• Limit text to 255 characters
FIRST NAME AND LAST NAME	30	CHARACTER	• Limit text to 30 characters
ALL ID FIELDS	36	CHARACTER	
ZIP CODE	5	NUMERIC	
ZIP CODE LAST FOUR	4	NUMERIC	
CITY	50	CHARACTER	
DOB AND ALL OTHER DATE FIELDS (E.G., DT, DATE, ETC.)	10	NUMERIC CHARACTER	• DISPLAY AS MM/DD/YYYY • STORE AS YYYY-MM-DD • HARD EDITS: MM MUST EQUAL 01 TO 12 DD MUST EQUAL 01 TO 31 YYYY MUST BE BETWEEN 1900 AND CURRENT YEAR.
TIME VARIABLES	TWO-DIGIT HOUR AND TWO-DIGIT MINUTE, AM/PM DESIGNATION	NUMERIC	• HARD EDITS: HOURS MUST BE BETWEEN 00 AND 12; MINUTES MUST BE BETWEEN 00 AND 59

Instrument Guidelines for Participant and Respondent IDs:

PRENATALLY, THE **P_ID** IN THE MDES HEADER IS THAT OF THE PARTICIPANT (E.G. THE NON-PREGNANT WOMAN, PREGNANT WOMAN, OR THE FATHER).

POSTNATALLY, A RESPONDENT ID WILL BE USED IN ADDITION TO THE PARTICIPANT ID BECAUSE SOMEBODY OTHER THAN THE PARTICIPANT MAY BE COMPLETING THE INTERVIEW. FOR EXAMPLE, THE PARTICIPANT MAY BE THE CHILD AND THE RESPONDENT MAY BE THE MOTHER, FATHER, OR ANOTHER CAREGIVER. THEREFORE, MDES VERSION 2.2 AND ALL FUTURE VERSIONS CONTAIN A **R_P_ID** (RESPONDENT PARTICIPANT ID) HEADER FIELD FOR EACH POST-BIRTH INSTRUMENT. THIS WILL ALLOW ROCs TO INDICATE WHETHER THE RESPONDENT IS SOMEBODY OTHER THAN THE PARTICIPANT ABOUT WHOM THE QUESTIONS ARE BEING ASKED.

A REMINDER:

ALL RESPONDENTS MUST BE CONSENTED AND HAVE RECORDS IN THE PERSON, PARTICIPANT, PARTICIPANT_CONSENT AND LINK_PERSON_PARTICIPANT TABLES, WHICH CAN BE PRELOADED INTO EACH INSTRUMENT. ADDITIONALLY, IN POST-BIRTH QUESTIONNAIRES WHERE THERE IS THE ABILITY TO LOOP THROUGH A SET OF QUESTIONS FOR MULTIPLE CHILDREN, IT IS IMPORTANT TO CAPTURE AND STORE THE CORRECT CHILD **P_ID** ALONG WITH THE LOOP INFORMATION. IN THE MDES VARIABLE LABEL/DEFINITION COLUMN, THIS IS INDICATED AS FOLLOWS: **EXTERNAL IDENTIFIER: PARTICIPANT ID FOR CHILD DETAIL.**

RECONSIDERATION QUESTIONNAIRE - CHILD

(TIME_STAMP_RQC_ST).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP. • PRELAOD **EVENT_TYPE.** • PRELOAD **P_ID** FOR CHILD. • PRELOAD FIRST NAME OF CHILD (**C_FNAME**) FROM **INSTRUMENT_ID** = XX (PARTICIPANT VERIFICATION, SCHEDULING, & TRACING QUESTIONNAIRE) • IF **C_FNAME ≠** -1 OR -2, DISPLAY APPROPRIATE NAME IN "C_FNAME" THROUGHOUT THE INSTRUMENT. • OTHERWISE, IF **C_FNAME** = -1 OR -2, DISPLAY "the child" IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT. • PRELOAD **CHILD_SEX** FROM **INSTRUMENT_ID** = XX (PARTICIPANT VERIFICATION, SCHEDULING, & TRACING QUESTIONNAIRE). • IF **CHILD_SEX** = 1, DISPLAY "him" IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT. • IF **CHILD_SEX** = 2, DISPLAY "her" IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT. • PRELOAD MOST RECENT **SAMPLE_CONSENT_GIVEN** AND **SAMPLE_CONSENT_TYPE** FROM **PARTICIPANT_CONSENT_SAMPLE** TABLE FOR CHILD (PARENTAL PERMISSION FORM FOR CHILD FROM 6 MONTH VISIT TO AGE OF MAJORITY).

RQC01000/(RECON_INTRO). We understand that you {gave/did not give} us your permission to collect some samples from {C_FNAME/the child} when you consented for {him/her} to participate in the Study. You do not have to agree to provide any samples from {C_FNAME/the child} today, but we would like to offer you the opportunity to provide samples during this visit to help us reach the goals of the Study.

INTERVIEWER INSTRUCTIONS
• DURING THE LAST INFORMED CONSENT, THE LEGAL GUARDIAN {CONSENTED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES/ CONSENTED TO PROVIDE BIOLOGICAL SAMPLES BUT NOT ENVIRONMENTAL SAMPLES/ENVIRONMENTAL SAMPLES BUT NOT BIOLOGICAL SAMPLES/ REFUSED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES} • THIS QUESTIONNAIRE WILL ASK FOR {CONTINUED PERMISSION TO COLLECT BIOLOGICAL AND ENVIRONMENTAL SAMPLES. NO NEW INFORMED CONSENT FORMS SHOULD BE ADMINISTERED/RECONSIDERATION OF ENVIRONMENTAL SAMPLES/RECONSIDERATION OF BIOLOGICAL SAMPLES/RECONSIDERATION

INTERVIEWER INSTRUCTIONS
OF BIOLOGICAL AND/OR ENVIRONMENTAL SAMPLES}.

PROGRAMMER INSTRUCTIONS

• IF **SAMPLE_CONSENT_GIVEN** = 2 OR **SAMPLE_CONSENT_TYPE** DOES NOT INCLUDE 1 AND 2, DISPLAY “did not give” IN QUESTION TEXT.
• OTHERWISE, DISPLAY “gave” IN QUESTION TEXT.
• IF **SAMPLE_CONSENT_GIVEN** = 1 AND
  ○ **SAMPLE_CONSENT_TYPE** INCLUDES 1 AND 2, DISPLAY “CONSENTED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES”, “CONTINUED PERMISSION TO COLLECT BIOLOGICAL AND ENVIRONMENTAL SAMPLES. NO NEW INFORMED CONSENT FORMS SHOULD BE ADMINISTERED" IN INTERVIEWER INSTRUCTIONS.
  ○ **SAMPLE_CONSENT_TYPE** INCLUDES 1 BUT NOT 2, DISPLAY “CONSENTED TO PROVIDE BIOLOGICAL SAMPLES BUT NOT ENVIRONMENTAL SAMPLES” AND “RECONSIDERATION OF ENVIRONMENTAL SAMPLES” IN INTERVIEWER INSTRUCTIONS.
  ○ **SAMPLE_CONSENT_TYPE** = 2, DISPLAY “CONSENTED TO PROVIDE ENVIRONMENTAL SAMPLES BUT NOT BIOLOGICAL SAMPLES” AND “RECONSIDERATION OF BIOLOGICAL SAMPLES” IN INTERVIEWER INSTRUCTIONS.
• **SAMPLE_CONSENT_GIVEN** = 2, DISPLAY “REFUSED TO PROVIDE BOTH BIOLOGICAL AND ENVIRONMENTAL SAMPLES” AND “RECONSIDERATION OF BIOLOGICAL AND/OR ENVIRONMENTAL SAMPLES” IN INTERVIEWER INSTRUCTIONS.

RQC02000/(RECON_BIO). Would you like to {allow us/continue to allow us} to collect biological specimens from {C_FNAME/the child} for this Study visit?

INTERVIEWER INSTRUCTIONS
• LEGAL GUARDIANS WHO PREVIOUSLY REFUSED BIOLOGICAL SAMPLE COLLECTIONS AND AGREE TO BIOLOGICAL SAMPLE COLLECTION DURING THE RECONSIDERATION QUESTIONNAIRE SHOULD BE RE-ADMINISTERED CONSENT USING THE INFORMED CONSENT FORM *WHAT YOU SHOULD KNOW ABOUT ENROLLING YOUR CHILD IN THE NATIONAL CHILDREN’S STUDY (NCS) VANGUARD STUDY: PARENTAL PERMISSION FORM FOR CHILD FROM 6 MONTH VISIT TO AGE OF MAJORITY* AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

PROGRAMMER INSTRUCTIONS

• DISPLAY “allow us” IN QUESTION TEXT IF EITHER:
  ○ **SAMPLE_CONSENT_GIVEN** = 2
  ○ **SAMPLE_CONSENT_TYPE** ≠ 1
• OTHERWISE, DISPLAY “continue to allow us” IN QUESTION TEXT.

PROGRAMMER INSTRUCTIONS

• DISPLAY INTERVIEWER INSTRUCTIONS IF EITHER:
  ○ **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** = 2
  ○ **SAMPLE_CONSENT_GIVEN** = 2

Label	Code	Go To
YES	**1**	
NO	**2**	
REFUSED	**-1**	
DON'T KNOW	**-2**	

SOURCE
National Children's Study, Vanguard 2 Phase

RQC03000/(RECON_ENV). Would you like to {allow us/continue to allow us} to collect environmental samples from {C_FNAME/the child}'s home for this Study visit?

INTERVIEWER INSTRUCTIONS
• LEGAL GUARDIANS WHO PREVIOUSLY REFUSED A SAMPLE COLLECTION AND AGREE TO ANY SAMPLE COLLECTION DURING THE RECONSIDERATION QUESTIONNAIRE SHOULD BE RE-ADMINISTERED CONSENT USING THE INFORMED CONSENT FORM *WHAT YOU SHOULD KNOW ABOUT ENROLLING YOUR CHILD IN THE NATIONAL CHILDREN'S STUDY (NCS) VANGUARD STUDY: PARENTAL PERMISSION FORM FOR CHILD FROM 6 MONTH VISIT TO AGE OF MAJORITY* AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

PROGRAMMER INSTRUCTIONS

• DISPLAY "allow us" IN QUESTION TEXT IF EITHER:
  ○ **SAMPLE_CONSENT_GIVEN** = 2
  ○ **SAMPLE_CONSENT_TYPE** ≠ 2
• OTHERWISE, DISPLAY "continue to allow us".
• DISPLAY INTERVIEWER INSTRUCTIONS IF EITHER:
  ○ **SAMPLE_CONSENT_GIVEN** = 1 AND **SAMPLE_CONSENT_TYPE** ≠ 2 (I.E., = 1 OR = 1 AND 3)
  ○ **SAMPLE_CONSENT_GIVEN** = 2

Label	Code	Go To
YES	**1**	
NO	**2**	
REFUSED	**-1**	
DON'T KNOW	**-2**	

SOURCE
National Children's Study, Vanguard 2 Phase

PROGRAMMER INSTRUCTIONS

• GO TO **READM_CON** IF EITHER:
  ○ **RECON_BIO** = 1 AND EITHER:
  ▪ **SAMPLE_CONSENT_GIVEN** = 2
  ▪ **SAMPLE_CONSENT_TYPE** ≠ 1
  ○ **RECON_ENV** = 1 AND EITHER:
  ▪ **SAMPLE_CONSENT_GIVEN** = 2
  ▪ **SAMPLE_CONSENT_TYPE** ≠ 2
• OTHERWISE, GO TO **RQC05000**.

RQC04000/(READM_CON). Thank you for agreeing to provide samples from {C_FNAME/the child}. We will now review the consent form to record that you have agreed for {C_FNAME/the child} to provide these samples.

INTERVIEWER INSTRUCTIONS
• RE-ADMINISTER CONSENT USING THE INFORMED CONSENT FORM *WHAT YOU SHOULD KNOW ABOUT ENROLLING YOUR CHILD IN THE NATIONAL CHILDREN'S STUDY (NCS) VANGUARD STUDY: PARENTAL PERMISSION FORM FOR CHILD FROM 6 MONTH VISIT TO AGE OF MAJORITY* AND SHOULD MAKE THE APPROPRIATE SELECTIONS ON THE SIGNATURE PAGE OF THAT FORM WITH REGARD TO PERMISSION FOR SAMPLE COLLECTIONS.

Label	Code	Go To
CONTINUE	**1**	
REFUSED	**-1**	

SOURCE
National Children's Study, Vanguard 2 Phase

RQC05000. Thank you for your time.

(TIME_STAMP_RQC_ET).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP.

National Children's Study

HIPAA Authorization for the Use and Disclosure of Health Information

Primary health care provider

Facility

Place Label

Street address

City

State Zip

- -

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

Name of other health care provider

Facility

Place Label

Street address

City

State Zip

- -

Phone number

Name of other health care provider

Facility

Place Label

Street address

City

State Zip

- -

Phone number

Name of other health care provider

Facility

Place Label

Street address

City

State Zip

- -

Phone number

Name of other health care provider

Facility

Place Label

Street address

City

State Zip

- -

Phone number

This is a permission form called a HIPAA Authorization Form for the Use and Disclosure of Health Information. It is required by the Health Insurance Portability and Accountability Act of 1996 (known as HIPAA)[1] in order to collect protected health information from your/your child(ren)'s medical and health records to use in the National Children's Study (NCS). Protected health information (PHI) is any identifiable health information about your/your child(ren)'s past, present, or future physical or mental health condition or payment for health care. Examples of PHI are medical and dental records, billing records, x-rays, ultrasound, and laboratory reports.

If you sign this form, you agree that you are voluntarily participating in the NCS and you authorize the health care providers identified above to release your/your child(ren)'s PHI to members of the NCS research team. If you sign this form, you are authorizing the release of PHI from you and your child(ren) regarding prenatal, medical, mental health, clinical, or diagnostic services such as ultrasound, labor and delivery, or perinatal services, treatments, testing, and test results provided to you/your child(ren) during and following your current pregnancy. This authorization form covers any care you/your child(ren) received from other health care providers associated with the above identified health care providers or facility(s) who provided care to you/your child(ren), such as laboratories and diagnostic centers.

The NCS and its contractors will use this information for research purposes only and to supplement the information you have already given to the research team. Once your information is released to the NCS, it is no longer covered by HIPAA but is covered by the Privacy Act of 1974, Titles II and III of the E-Government Act (FISMA) and the Public Health Service Act[2], which prohibits the release of information that would identify you and your child(ren) or health care providers without your permission or that of your health care providers. Any NCS generated information incorporated into your/your child(ren)'s medical record(s) maintained at the facility(s) mentioned above will be covered by the same HIPAA privacy laws as the rest of your/your child(ren)'s medical information. Your decision to sign or not to sign this form will have no effect on your/your child(ren)'s eligibility for treatment with the health care provider identified above or at this facility. In addition, it will have no effect on payment, enrollment, or eligibility for any benefits to which you/your child(ren) are entitled.

You have the right to stop this HIPAA authorization at any time. You must do so in writing by sending a letter to the Study representative as indicated below. Stopping this HIPAA authorization will not stop information sharing that has already happened. Otherwise, this authorization does not have an expiration date. For questions about this release, please contact the NCS Office at [(XXX) XXX-XXXX].

You will be given a copy of this HIPAA Authorization Form.

I authorize the NCS to use the information I have given in this form to access and obtain copies of my/my child(ren)'s medical records or PHI.

_____
Printed name of participant (first, middle, last)

_____
Other names under which records may be filed

Date of birth: ☐☐/☐☐/☐☐☐☐
m m d d y y y y

_____
Signature of participant

Date signed: ☐☐/☐☐/☐☐☐☐
m m d d y y y y

_____
Witness or Proxy's signature

Date signed: ☐☐/☐☐/☐☐☐☐
m m d d y y y y

_____
Signer's relationship to participant

Reasons for Witness or Proxy's Signature:
❒ Patient Disabled ❒ Patient Deceased

If the participant is a non emancipated minor, according to state law, a parent/guardian must sign and date.

_____
Signature of parent/guardian

Date signed: ☐☐/☐☐/☐☐☐☐
m m d d y y y y

1. Health Insurance Portability and Accountability Act: 42 U.S.C. 1320d-2 and 1320d-4 and the implementing regulation, 45 CFR 164.508, require a detailed authorization for your health care provider to disclose health information from your records for research purposes.

2. Public Health Service (PHS) Act: 42 U.S.C. 242m(d) protects the confidentiality of data collected under the research authorities of the National Institutes of Health. The National Children's Study will be carried out in compliance with these provisions as well as those in the Children's Health Act of 2000 (Public Law 106-310 Sec. 1004).

Affix label with local contacts:

1. Rights as a Human Subject

OMB #: 0925-0593
OMB Expiration Date: 8/31/2014

National Children's Study

Authorization to Obtain Bodily Fluids and Tissues

Name of health care provider

Facility

Place Label

Street address

City

State Zip

Phone number

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

This form is a permission form called an Authorization to Obtain Bodily Fluids and Tissues. It is required by the Health Insurance Portability and Accountability Act of 1996 (known as HIPAA) in order to collect protected health information from your medical and health records to use in the National Children's Study. Protected health information (PHI) is any identifiable health information about your past, present, or future physical or mental health condition or payment for health care. Examples of PHI are medical and dental records, billing records, x-rays, and laboratory reports.

If you sign this form, you authorize the health care provider identified above to allow the National Children's Study research team to obtain and/or collect samples, such as blood, from you as well as samples from your child(ren) such as your child(ren)'s blood, umbilical cord, umbilical cord blood, placenta, and meconium. The specific samples that we plan to collect are described in the National Children's Study informed consent forms. This authorization form covers the period of time when you or your child(ren) receive care at this facility for labor, delivery, and/or perinatal services during and following your current pregnancy.

This authorization form covers any care you or your child(ren) received from other health care providers associated with the above identified health care provider or facility who provided care to you or your child(ren), such as laboratories and diagnostic centers who may have taken part in analyzing or evaluating your or your child(ren)'s biological samples.

The National Children's Study and its contractors will use these samples and information for research purposes only and to supplement the information you have already given to the research team. Once your information is released to the National Children's Study, it is no longer covered by HIPAA but is covered by the Privacy Act of 1974, Titles II and III of the E-Government Act (FISMA) and the Public Health Service Act(2), which prohibits the release of information that would identify you and your child(ren) or your health care providers outside the sponsoring agency and its contractors without your permission or that of your health care providers.

Any National Children's Study generated information incorporated into your medical record maintained at the facility mentioned above will be covered by the same HIPAA privacy laws as the rest of your medical information.

Your decision to sign or not to sign this authorization form will have no effect on your eligibility for treatment with the health care provider or facility identified above. In addition, it will have no effect on payment, enrollment, or eligibility for any benefits to which you are entitled. You have the right to stop this HIPAA authorization at any time. You must do so in writing by sending a letter to the Study representative as indicated below. Stopping this HIPAA authorization will not stop information sharing that has already happened. Otherwise, this authorization does not have an expiration date.

You will be given a copy of this Authorization to Obtain Bodily Fluids and Tissues Form.

Printed name of participant (first, middle, last)

Other names under which records may be filed

Signature of participant

Date of birth: m m / d d / y y y y

Date signed: m m / d d / y y y y

If the participant is a non emancipated minor, according to state law, a parent/guardian must sign and date.

Signature of parent/guardian

Date signed: m m / d d / y y y y

1. Health Insurance Portability and Accountability Act: 42 U.S.C. 1320d-2 and 1320d-4 and the implementing regulation, 45 CFR 164.508, require a detailed authorization for your health care provider to disclose health information from your records for research purposes.
2. Public Health Service (PHS) Act: 42 U.S.C. 242m(d) protects the confidentiality of data collected under the research authorities of the National Institutes of Health. The National Children's Study will be carried out in compliance with these provisions as well as those in the Children's Health Act of 2000 (Public Law 106-310 Sec. 1004).

Affix label with local contacts:

1. Rights as a Human Subject

OMB #: 0925-0593
OMB Expiration Date: 08/31/2014

National Children's Study

Authorization for Release of Health-Related Birth Certificate Information

Full Name of Child

Sex of child: ☐ Male ☐ Female

Date of Birth: ☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

Place of Birth- Hospital/Clinic (if applicable) ☐☐

Place of Birth- City

Place of Birth- State

The measurement of children's health is a primary research aim of the National Children's Study (NCS). Information from the birth certificate, such as birth weight, will help us better understand children's growth and development throughout childhood. We are asking you to authorize the state office of vital records to release the health-related birth certificate information of the child named above to researchers from the NCS.

Your child's birth certificate information will be used for research purposes only. All information will be kept strictly confidential. Names and other identifying information will not be released without your permission.

☐ **I PERMIT** the NCS to obtain my child's health-related birth certificate information.

☐ **I DO NOT PERMIT** the NCS to obtain my child's health-related birth certificate information.

Printed parent/guardian name (first, middle, last)

Signature of parent/guardian

Relationship to Child

Date signed: ☐☐/☐☐/☐☐☐☐
m m d d y y y y

☐☐☐-☐☐☐-☐☐☐☐
Phone number

Questions related to the collection of health-related birth certificate information can be answered by NCS staff at 1-877-865-2619.

OMB #: 0925-0593
OMB Expiration Date: 08/31/2014

National Children's Study

Authorization Form for Release of Child Death Certificate Information

Full Name of Deceased Child

Sex of child: ☐ Male ☐ Female Date of Death or Stillbirth: ☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

Place of Death or Stillbirth- Hospital/Clinic (if applicable) ☐☐

Place of Death or Stillbirth- City Place of Death or Stillbirth- State

Name of Doctor (if applicable) Name of Funeral Director

Place of Burial

☐☐☐ - ☐☐☐ - ☐☐☐☐ ☐ Not applicable

The measurement of children's health is a primary research aim of the National Children's Study (NCS). Information from the death certificate will only be used for statistical purposes in health research. We are asking you to authorize the state office of vital records to release the death certificate information of the child named above to researchers from the NCS.

Your child's death certificate information will be used for research purposes only. All information will be kept strictly confidential. Names and other identifying information will not be released without your permission.

☐ **I PERMIT** the NCS to obtain my child's death certificate information.

I DO NOT PERMIT the NCS to obtain my child's death certificate information.

Printed parent/guardian name (first, middle, last) Signature of parent/guardian

Relationship to Child

Questions related to the collection of health-related death certificate information can be answered by NCS staff at 1-877-865-2619.

OMB #: 0925-0593
OMB Expiration Date: 08/31/2014

National Children's Study

Authorization Form for Release of Parent/Guardian Death Certificate Information

Full Name of Deceased

Sex of Deceased: ☐ Male ☐ Female

Date of Death: ☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

☐☐

City of Death

State of Death

County of Death

☐☐☐ ☐☐☐ ☐☐☐☐
- -
Social Security Number of Deceased

The measurement of children's health is a primary research aim of the National Children's Study (NCS). Information from the death certificate will only be used for statistical purposes in health research. We are asking you to authorize the state office of vital records to release the death certificate information of the person named above to researchers from the NCS.

Death certificate information will be used for research purposes only. All information will be kept strictly confidential. Names and other identifying information will not be released without your permission.

☐ **I PERMIT** the NCS to obtain_____'s death certificate information.

I DO NOT PERMIT the NCS to obtain_____'s death certificate information.

Printed relative name (first, middle, last)

Signature of relative

Relationship to deceased

Date signed: ☐☐/☐☐/☐☐☐☐ ☐☐☐-☐☐☐-☐☐☐☐

Questions related to the collection of death certificate information can be answered by NCS staff at 1-877-865-2619.