

# Participant Information Sheet

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

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

### Sponsors

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

Public reporting burden for this collection of information is estimated to average 40 minutes per response in conjunction with the signature page, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

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

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

## Why is the National Children’s Study important?

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

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

- The National Children's Study is an observational study. That means we will observe and follow children from birth to age twenty-one. To do that, we will:
  - ▶ Ask questions about you and where you live and work. If you are pregnant or become pregnant, we will also ask questions about your baby and your baby's experiences.
  - ▶ At some point, we might invite you to participate in additional Study activities, such as visits in your home by Study staff.
  - ▶ As an observational study, we will not:
    - ▶ Ask you to change what you normally do.
    - ▶ Ask you or your child to take any medicines or drugs.

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

- About 5,000 children from 37 locations across the United States will take part in the Vanguard Study.
- Overall, about 100,000 children from all over the United States will participate in all parts of the Study.
- We are also asking mothers and fathers to join.

## How long will the National Children's Study last?

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

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

- Generally, if you join the questionnaire group of the Study, we will give you questionnaires to fill out and return to us. We will send you two or three questionnaires a year. The questionnaires will ask you for information about your health as well as your home and work environment.
- Parts of the Study will change as the Study continues over the 21 years after children are born.
- Therefore, different families may be asked to participate in different combinations of

parts of the Study.

- Whenever we contact you, we will explain what we are doing and ask for your permission.
- In the future, we may ask you if you would like to participate in additional Study activities.

## **What will the Study do with all this information?**

- The information we get from you may be used in several ways.
- We will store your information along with that of other people in the Study indefinitely.
- Researchers may use this information to find out:
  - How the experiences during pregnancy or early life may affect our children's health.
  - How conditions that appear later in childhood and adulthood begin in early childhood.
- What we learn early in the Study may lead to more questions about our children's health. We may use the information we get from you to answer those questions as well.
- It is possible that scientists could develop new technologies or products in the future based on the information and that we collect from you and store for the Study. You will not receive any money that may result from such new technologies or products.
  - We may also combine the information that we receive from you for this Study with information from other research studies. A committee of doctors, scientists, and community members (the Independent Safety Monitoring and Oversight Committee (iSMOC)) will make sure that your information and samples will only be used to help us better understand child health and growth and answer questions about why some children are more likely to get diseases.
  - By agreeing to be in the Study, you are also agreeing to allow possible future use of your information for future studies on child and maternal health and disease that are consistent with the goals of this Study.

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

- We will share with you what we learn from the Study as a whole. We will keep in touch through newsletters, on our website, and in other ways.
- We will share with you some of the information we learn about you and your child when

it becomes available.

## How will the Study protect my information?

- We will protect your privacy and keep your information safe by:
  - ▶ Using a unique number code to label your information.
  - ▶ Keeping your number code separate from your name and address and other personal information. We will look at the information you give us by using the number code and not your name and address and other personal information.
  - ▶ Keeping your information in a computer database that is protected by advanced security.
- Researchers who want to use your information must go through several steps:
  - ▶ Get certified by the National Children's Study and the Federal government.
  - ▶ Receive permission to use your information. A committee of doctors, scientists, and community members (the iSMOC) will make sure that your information and samples will only be used to help us better understand child health and growth and answer questions about why some children are more likely to get diseases.
  - ▶ Sign an affidavit of nondisclosure. This means promising to use your information for research purposes only. They must also agree not to share your information with anyone who has not made this same promise.
  - ▶ Protect your information by reporting it only as part of a group.
- We will monitor researchers to check if they are protecting your information.
- We will review all of the ways we keep your information and samples safe on a regular basis to keep improving how we protect your privacy.
- In addition, the U.S. Department of Health and Human Services (HHS) gave the National Children's Study a legal document, called a Certificate of Confidentiality. This means the Study cannot be forced by a court order or subpoena to disclose information that might identify you in any civil, criminal, or other type of court.

## When might the Study have to give out my information?

- If we learn that you or someone else is harming you, your child, or others around you, we may be required by law to report this to the police or a social services agency in your community.
- If you give someone or an organization written permission to see the information you gave the Study, we cannot use the Certificate of Confidentiality to protect your information from that person or organization.

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

- Taking part in the National Children’s Study may not help you or your family right now. But the Study may help us learn things about health that could benefit all of us – including your children and grandchildren – in the years to come.
- If you need medical or social services, we will give you names and contact information for people and agencies that can try to help. But the Study cannot and will not pay for your health care or mental health services.

## **What are the possible risks or burdens to me, my child and to my community from being in the National Children’s Study Vanguard Study?**

- The risks from participating in this Study are low.
- Some of the questions we ask may be uncomfortable. But you can skip any part of the Study. You are in charge.
- Completing the questionnaires and forms that we give you may take anywhere from thirty minutes to an hour.
- While we are taking many steps to protect your information, there is always a chance that your information could be disclosed. To protect your information, we will not keep your name and address with any study data files.
- We will collect information about your physical, social, and family environment, your health, your community, as well as your race and ethnicity. In addition to any potential harm to an individual, there may be potential harms to racial and ethnic groups or communities. Study data files with information about racial and ethnic groups will be made available to researchers. The risks of providing information about racial or community groups are unknown. However, there is a possibility that specific study findings will be associated with particular racial and ethnic groups.

## **Will I be paid for being in the National Children’s Study?**

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

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

- You can leave the Study at any time. You also can leave the Study for a short time and come back.
- If you leave the Study, we will not ask you for any new information, but we will keep using the information and samples you have already given us.
- Leaving the Study will not affect your access to health care or any other benefits you may be receiving, like those from Social Security, Medicaid, WIC, or the Supplemental Nutrition Assistance Program.

## **What if I move?**

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

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

- No. There is no cost to you for being in the National Children's Study.

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

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

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

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

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

- The National Children's Study will not share any information about the identities of people participating in the Study with the media.
- Because of the importance of the National Children's Study, it is possible that reporters and news media may go to communities where the National Children's Study is taking place to ask if people participating in the Study would like to talk about their experiences.
- If you are contacted by reporters, you can decide whether or not to talk with them. If you do decide to talk with them, you should be aware that any information that you provide will be publicly available and that the news media organization will have control over any information and material that they gather.
- Additionally, if you decide to talk with the media about your participation or your child's participation in the National Children's Study, you should be aware that your role and your child's role as Study participants will be public knowledge. This will decrease our ability to protect the confidentiality of your data and the data of other participants in your community.

## **Who can I contact if I have questions?**

- If you have any other questions about your or your child's rights as a research participant, now or in the future, you may contact the person(s) listed on the bottom of this page.

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

*[Study Centers will provide contact information for local Principal Investigator and IRB in this space.]*