

Telephone Consent Script for Low Intensity Data Collection Effort

Note: This telephone script will be administered to obtain consent from eligible adults for participation in the National Children's Study Vanguard Study.

I would like to tell you about the National Children's Study, what you can expect if you choose to participate, and what your rights are as a research participant. I may repeat things you have already heard and understand, but I want to make sure that you are fully informed before you make a decision about participating in the Study.

You can interrupt me to ask questions at any time.

First I'd like to tell you about the goal of the National Children's Study, which is to improve the health of all children in the United States. With your help, the National Children's Study will learn more about how our physical, social, and family environment might affect the health, growth, and development of all our children.

The National Children's Study is led by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development in collaboration with other federal partners.

The National Children's Study consists of several stages. Different stages of the Study will run at the same time and each stage will inform the others.

We are currently in the first stage, called the Vanguard Study. In this stage, we will involve 5,000 children and their families from 37 locations across the United States. Your neighborhood is one of many communities across the country that is taking part in the National Children's Study.

The Main Study is another stage that will occur in the future, and will be planned using what we learn from the Vanguard Study. For the Main Study, we will recruit 100,000 children from 105 locations across the United States.

We need the information from both the Vanguard Study and the Main Study to achieve the goals of the National Children's Study.

The National Children's Study is an observational study. That means we will observe children from birth to age twenty-one. To do that, we will ask questions about you and your experiences, health, and surroundings (for example, your home and work). We need both pregnant women and women who are not pregnant to join the Study.

If you join the Study now, we will ask you to complete questionnaires or interviews. These will come to you through the mail or by phone about three times per year.

Each questionnaire or interview will take between 30 to 60 minutes to complete.

We will also ask for information that will help us contact you.

If you are pregnant or become pregnant, we will also ask questions about your baby and your baby's experiences. Also, we might invite you to participate in additional Study activities, such as visits in your home by Study staff.

We will store your information along with that of other people in the Study indefinitely. Researchers will use this information to find out:

- How the physical, social, and family environment may affect our children's health.
- How conditions that appear later in childhood and adulthood begin in early childhood.
- What are the right questions to ask research participants like you so that we can understand what your environments are like and what your health is like.

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.

We will protect the information you share with us. We will control who is allowed to access data about you, especially your name, address, and other personal information. We will label other information you give us, such as answers to questions, with a unique number. Researchers will use the unique number to analyze your data, not your name.

Researchers who want to use your information will have to go through several steps. For instance, they must agree to use your information for research purposes only, and they will not have access to your name and other forms of personal information.

The National Children's Study monitors researchers to check if they are protecting your information.

The Study cannot be forced to disclose your name or any information about you in any civil, criminal, or other type of court. This is because the U.S.

Department of Health and Human Services (HHS) gave the National Children's Study a legal document, called a Certificate of Confidentiality.

We may only give out your 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. In this case, we still wouldn't reveal answers you gave us to the questions we asked as a part of the Study.

The risks of participating in this Study are low, since we are only asking questions of you at this time. Some of the questions we ask may be uncomfortable. But you can skip any part of the Study.

While we are taking many steps to protect your information, there is always a chance that your information could be disclosed. We are constantly improving how we protect your data.

As for benefits, 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. However, taking part in the National Children's Study may or may not help you right now.

We recognize that taking part in a study takes time and effort on your part. To thank you, we will give you \$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. There is no cost to you for being in the National Children's Study.

Of course, joining the Vanguard Study is your choice. If you do join, you can leave at any time for any reason.

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 you have already given us.

If you join the National Children's Study, we may invite you to take part in other research activities or studies connected to the National Children's Study. If you are invited to be in other studies, you can always say no.

Do you have any questions that you would like to ask?

Would you like to be in the National Children's Study Vanguard Study?

[IF NO:] Thank you for taking the time to learn about the National Children's Study. If you change your mind, please contact the study center at <STUDY CENTER PHONE NUMBER>.

[IF YES:] Thank you for agreeing to join the National Children's Study Vanguard Study. Can we contact you through the phone numbers, email addresses, and home addresses you have provided us?

We will send you an information sheet explaining what we have talked about today and giving additional details about the Study. Please contact the study center at <STUDY CENTER PHONE NUMBER> if you do not receive it.

You can expect to receive an invitation to answer some study questions over the next week or so.

Thank you for joining the National Children's Study.