

Visit Information Sheet

Vanguard Phase of the National Children's Study, Attachment Q7. Birth Visit VIS No Sample Collection, Phase 1
Attachment Q7. Birth Visit VIS No Sample Collection, Phase 1 Birth Follow-up Visit



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

What will happen after the birth of my child?

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's birth, and your plans once your child is born.
- You can decide what questions you want to answer. If you feel uncomfortable about any question, you can skip it.

Will I need to do anything after I go home?

- We will give you an Infant Medical Care Log and ask you to write down some information when you take your child to the doctor.
 - We will ask you some questions about these visits when we talk to you on the phone or visit you in person.
- We will contact you to arrange a phone call with you when your child is about three months old and to schedule another visit with you and your child when your child is around six months old.

Are there any risks from the birth follow-up visit?

- Some of the questions we ask may be uncomfortable. If you are uncomfortable, you can skip any part of the Study. You are in charge.
- Although we are taking many steps to protect your information and your child's information, there is always a chance that your and your child's information or identity could be disclosed. We will continue to review and improve the ways we keep your information private. To protect your information, we will keep your name and address and that of your child separate from our information files.

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

**Vanguard Phase of the National Children’s Study Amendment YY (3/25/11):
Attachment Q7. Birth Visit VIS No Sample Collection, Phase II**

Are there any benefits from the birth follow-up visit?

Taking part in the National Children’s Study may not help you, your child, or your family right now. But the Study may help us learn things about health that could benefit all of us—including your children and grandchildren—in the years to come.

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

To thank you for your time, we will give you \$25 for completing the interview.

What if I have questions about the visit?

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

Please remember:

- Whether or not you 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.
- If you leave the Study, you can rejoin it later.
- If you or your child leave the Study, we will not ask you for any new information, but we will keep using the information you have already given us. We will keep everything that you tell us confidential.
- Leaving the Study will not affect your access to health care or any other benefits you may be receiving, like those from Social Security, Medicaid, WIC, or the Supplemental Nutrition Assistance Program.
- If we learn that you or someone else is harming you, your child, or others around you, we may be required by law to report this to the proper authority or a social services agency in your community.
- This is a research study and we cannot give you medical advice. None of the Study visits take the place of your regular doctor or clinic visits.
- We will ask you for ongoing permission for your child’s participation in the remainder of the Study around the time that your child turns six months old.

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**National Children's Study
Permission for Your Child's Participation in the Study from Birth through 6 Months of Age**

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

Child's Parent/Legal Guardian

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

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

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

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

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

Witness (if required)

I observed the interviewer explain "Visit Information Sheet, Birth Visit and Follow-up Visit" to the participant and she signed or marked this form.

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

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Printed Name of Person Obtaining Consent: _____

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

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

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