Visit Information Sheet

Birth Visit & Follow-up Visit

Vanguard Phase of the National Children's Study
Birth Visit VIS Sample Collection, LOI-ISC-18

THE NATIONAL CHILDREN'S STUDY
HEALTH GROWTH ENVIRONMENT

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?

1) *We would like to collect umbilical cord blood, an umbilical cord sample, and a placental sample shortly after your child is born.*

We will work with hospital, clinic, or birthing center staff to collect the umbilical cord blood, umbilical cord sample, and placental sample shortly after your child's birth. Blood and the umbilical cord sample are collected after the umbilical cord is separated from the baby. Placental samples will be collected after birth. The sample collections take about 5 minutes.

- There is no pain from cord blood, umbilical cord sample, and placental sample collections.
- 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 cord blood for the Study.

2) *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.

What if I am planning to give birth at home?

If you are planning to give birth at your home, we will work with the person delivering your baby to collect the umbilical cord blood, umbilical cord sample, and placental sample. We will set up a time to visit with you to ask you some questions, as described above.

Will I need to do anything after I go home?

- We will give you an Infant Medical Care Log and ask you to write down some information when you take your child to the doctor.

- We will ask you some questions about these doctor's visits when we talk to you on the phone or visit you in person.

- We will contact you to arrange a phone call with you when your child is about three months old and to schedule another visit with you and your child when your child is around six months old.

How may my child's cord blood sample be used?

- We may use your child's cord blood, umbilical cord sample, and placental sample for analyses that include biological, genetic, and environmental testing based on the permission you give at the end of this informed consent process.

- The Study will not do the testing right away. We will store and test those samples in the future.

- Genetic information is collected to help us learn how genes affect our children's health and how our physical environment and experiences affect the way our genes work.

- Some people are sensitive about sharing genetic information. If you do not want us to conduct genetic tests, let us know. You can tell us not to collect your child's genetic information and your child can still be in the Study.

- Future testing of samples may sometimes be done together with other approved researchers who receive permission from the Study. We may share your child's information directly with researchers or we may share it through a secure national research database. The goals of these future studies will be similar to the goals of the National Children's Study.

- To answer the Study's research questions, we may also look at your child's information together with information from other research studies and information sources.

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

- Some of the questions we ask and some of the ways we get samples may be uncomfortable. If you or your child are uncomfortable, you can skip any part of the visit. You are in charge.

- We may learn information about adoption or the biological parents of your child. We will not give out any information about parentage to you or any other members of your family.

- Some people worry that research about genetic causes of disease may give information not only about themselves but about family members. There is always some chance that technology could be developed that would make it possible to reveal your child's identity or that of your family members. We will make every effort to prevent such disclosure. We will continue to review and improve the ways we keep your child's information private.

- We will get information about your child's health, community, and your child's race and ethnicity. We will make files with this information available to approved researchers. In addition to the risks to individuals, the risks of providing information about racial or community groups are unknown. There is a possibility that specific Study findings will be associated with particular racial and ethnic groups.

- Although we are taking many steps to protect your and your child's information, there is always a chance that your information or identity could be disclosed. We will continue to review and improve the ways we

keep your information private. To protect your information, we will keep your name and address and that of your child separate from our information files.

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

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

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

To thank you for your time, we will give you $25 for completing the interview. You will receive an additional $25 dollars for providing the umbilical cord blood, umbilical cord sample, and placental sample.

What if I have questions about these visits?

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

Please remember:

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

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

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

	Yes	**No**
I give my permission for the Study to collect my child's cord blood, umbilical cord sample, and placental sample.	☐	☐
I give my permission for the Study to use my child's cord blood, umbilical cord sample, and placental sample to obtain my child's genetic information.	☐	☐

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)

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.