

Vanguard Phase of the National Children's Study Amendment YY (3/25/11):
Attachment Q3. Pregnancy Visit 1 VIS, Phase II_Unmarked



National Children's Study

Visit Information Sheet

Pregnancy Visit 1

Thank you for participating in the National Children's Study. When you joined the Study, we explained what it means to take part in this important research effort. This sheet gives more details about what we'd like to do during this visit.

What will happen during today's visit?

1. *During this visit, we would like to ask you some questions.*

- This part of the visit will take about 30 minutes to complete. We will ask you some questions about yourself, your health and pregnancy, your lifestyle, and where you live. We will also ask you to complete some questions on your own about yourself and your experience with the Study. This should take about 10 minutes.
- You can decide what questions you want to answer. If you feel uncomfortable about any question, you can skip it.

2. *During the time before and during pregnancy, we will ask for your permission to collect blood and urine samples from you twice. If you have already completed one Study visit that included sample collection, we would like to collect the second set of samples from you today. If this is your first Study visit, we would like to collect the first set of samples.*

Before this visit, we may have asked you not to eat or drink for 8 hours. Some of the tests we may do work best if you have not had anything to eat or drink for 8 hours.

- If you ate or drank anything in the past 8 hours, please let us know.
- This next part of the visit should take about 20 minutes.

We will ask you to:

- Collect some of your urine (about 2 ½ ounces) in a cup we provide.
 - We may test your urine for chemicals that may be present in the environment.

We also would like to:

- Collect a small amount (about 3 tablespoons) of your blood by using a small needle.
 - We may test your blood for hormones, nutrients, infections and inflammation, and for the presence of metals and other chemicals in the environment.

3. *We may collect environmental samples from your home, or we may provide you with kits so you can collect the samples yourself. This part of the visit will take about 30 minutes.*

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.

- The environmental samples that will be collected are water samples from your faucet and dust from your vacuum cleaner. We may also collect dust from your household using a vacuum cleaner we provide.
- We may test these samples for metals and other chemicals that may be present in the environment.
- If you are asked to collect the environmental samples yourself, we will give you special kits to collect water and dust samples.
- We will ask that you collect the samples at your earliest convenience. After you have collected these samples, please ship them back to us in the pre-paid envelopes we provide.

➤ **Today's visit will take approximately 1 to 1.5 hours.**

Are there any risks from today's visit?

- 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.
- Some of the questions we ask and some of the ways we get samples 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, 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 separate from our information files.

Are there any benefits from today's visit?

- 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.

Will I be paid for taking part in today's visit?

- To thank you for your time, we will give you \$25 for completing the interview portion of today's visit. You will receive an additional \$25 dollars for providing any of the samples.

What if I have questions about this visit?

- If you have any questions about this visit, you can ask the Study representative you are talking with today. If he or she can't 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 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 police 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. 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.
- We may contact you later in your pregnancy to arrange a second pregnancy visit.