

National Children’s Study Visit Information Sheet Script: Participants Refusing Biological/Environmental Samples

SUMMARY

As part of the Informed Consent process, potential participants are offered the option to provide consent for collection of biological samples, collection of environmental samples, and use of biological samples to obtain genetic information:

	Yes	No
I give my permission for the Study to collect environmental samples from my home.	<input type="checkbox"/>	<input type="checkbox"/>
I give my permission for the Study to collect biological samples from me.	<input type="checkbox"/>	<input type="checkbox"/>
I give my permission for the Study to use my biological samples to obtain my genetic information.	<input type="checkbox"/>	<input type="checkbox"/>

If a Study participant elects not to provide permission for sample collection during the administration of informed consent, that participant is currently not provided the option to reconsider and decide at a later visit to provide samples—biological and/or environmental. During the administration of the Visit Information Sheet (VIS) for subsequent visits, the following script will be read by data collectors to participants that initially opted not to provide samples on the Informed Consent form inquiring if the participant has changed his/her mind about providing permission for sample collection.

This script will be read to participants who did not provide consent for sample collection on the Informed Consent Form at the Pre-pregnancy Visit, Pregnancy 1 Visit, Pregnancy 2 Visit, and Birth Visit. This script will affect participants in all recruitment schemas except the Two Tier Low Intensity strategy (which is not participating in the biospecimen and environmental sample aspect of Phase II), as the script will be read to participants at in-home study visits rather than at the time of recruitment or enumeration.

PARTICIPANT RE-CONSIDERATION SCRIPT

The participant re-consideration script will be read only to participants that did not consent to provide permission for sample collection during the administration of the Informed Consent Form. The script will be read following the introduction of the sample collection portion of the in-home visits—Pre-pregnancy Visit, Pregnancy Visit 1, Pregnancy Visit 2, and Birth Visit. The script will be inserted into the visit dialogue as follows:

Pre-pregnancy Visit:

2. *During the time before and during pregnancy, we will ask for your permission to collect blood and urine samples from you twice. During this visit, we would like to collect some samples from you.*

[DATA COLLECTOR INSTRUCTIONS: For those participants who did not give permission for sample collection on the Informed Consent Form “What You Should Know about Joining the National Children’s Study Vanguard Study:” please read the following script:]

“We understand that you did not give us your permission to collect biological or environmental samples when you consented to participate in the Study. Once again, you do not have to provide any samples that you do not want to give, but we would like to offer you the opportunity to provide samples during this visit to help us reach the goals of the Study. Would you like to allow us to collect biological samples? Would you like to allow us to collect environmental samples?”

[DATA COLLECTOR INSTRUCTIONS: Participants who say yes to any sample collection should be re-administered consent using the Informed Consent Form “What You Should Know

about Joining the National Children’s Study Vanguard Study” and should make the appropriate selections on the signature page of that form with regard to permission for sample collections.]

Pregnancy 1 Visit:

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.*

[DATA COLLECTOR INSTRUCTIONS: For those participants who did not give permission for sample collection on the Informed Consent Form “What You Should Know about Joining the National Children’s Study Vanguard Study:” please read the following script:]

“We understand that you did not give us your permission to collect biological or environmental samples when you consented to participate in the Study. Once again, you do not have to provide any samples that you do not want to give, but we would like to offer you the opportunity to provide samples during this visit to help us reach the goals of the Study. Would you like to allow us to collect biological samples? Would you like to allow us to collect environmental samples?”

[DATA COLLECTOR INSTRUCTIONS: Participants who say yes to any sample collection should be re-administered consent using the Informed Consent Form “What You Should Know about Joining the National Children’s Study Vanguard Study” and should make the appropriate selections on the signature page of that form with regard to permission for sample collections.]

Pregnancy 2 Visit

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.*

[DATA COLLECTOR INSTRUCTIONS: For those participants who did not give permission for sample collection on the Informed Consent Form “What You Should Know about Joining the National Children’s Study Vanguard Study:” please read the following script:]

“We understand that you did not give us your permission to collect biological or environmental samples when you consented to participate in the Study. Once again, you do not have to provide any samples that you do not want to give, but we would like to offer you the opportunity to provide samples during this visit to help us reach the goals of the Study. Would you like to allow us to collect biological samples? Would you like to allow us to collect environmental samples?”

[DATA COLLECTOR INSTRUCTIONS: Participants who say yes to any sample collection should be re-administered consent using the Informed Consent Form “What You Should Know about Joining the National Children’s Study Vanguard Study” and should make the appropriate selections on the signature page of that form with regard to permission for sample collections.]

Birth Visit

2. *We also would like to collect umbilical cord blood.*

[DATA COLLECTOR INSTRUCTIONS: For those participants who did not give permission for sample collection on the Informed Consent Form “What You Should Know about Joining the National Children’s Study Vanguard Study:” please read the following script:]

“We understand that you did not give us your permission to collect biological or environmental samples when you consented to participate in the Study. Once again, you do not have to provide

any samples that you do not want to give, but we would like to offer you the opportunity to provide samples during this visit to help us reach the goals of the Study. Would you like to allow us to collect biological samples? Would you like to allow us to collect environmental samples?"

[DATA COLLECTOR INSTRUCTIONS: Participants who say yes to any sample collection should be re-administered consent using the Informed Consent Form "What You Should Know about Joining the National Children's Study Vanguard Study" and should make the appropriate selections on the signature page of that form with regard to permission for sample collections.]