

Appendix B

Other Respondent Materials

Appendix B.1

Informed Consent

National Children's Study Pilot—Evaluation of Consent Methods

Background

The NCS is designed to examine the effects of environmental influences on the health and development of children across the United States. The data from the study will facilitate the improved health and well being of children. The study plans for a sample of more than 100,000 children, with individual data collection extending from the pre-natal stage to the age of 21. Across the 21 years of data collection, participants will provide data multiple times through a multi-mode data collection design that includes self-response to different types of paper questionnaires, keeping diary records, responding to interviewer-administered automated questionnaires (in-person and by telephone), environmental samples taken from their home, physical examinations, blood pressure readings, and various biospecimens including blood, urine, saliva, and hair samples. When children are born to participating mothers, person-level data collection activities will focus on the child, the actual target sample unit.

Participation in the study will require a lot of time and effort from respondents, as well as the potential to experience slight discomforts in completing some of the measures such as blood or urine samples or vaginal swabs. Given these requirements, the study design includes a fairly rigorous consent process that incorporates an assessment of how well the sampled person (initially, the pregnant woman) understands what is expected of her. The consent process includes two components: (1) overall consent to the study based on a broad understanding of the measures taken in the study over the 21-year period, including how individual results will be handled and privacy protected, and (2) verbal consent given at each visit or exam covering the specific activities to be conducted during that visit.

Because of the need to ensure that sampled persons fully understand what their participation will require, the consent process in and of itself requires a time-investment. Similarly, the description of the various measures, especially some of the biological sample collections, can be difficult and perhaps even viewed as intimidating. Thus the consent process itself could serve as a barrier to participation.

The primary objective of the consent methods evaluation contained in the NCS pilot is to determine whether two methods for obtaining study consent result in different study enrollment

rates. Screening and enrollment begin in July of 2008 for the first wave of PSUs in the pilot, and in November 2008 for the second wave of PSUs in the pilot.

Evaluative Conditions and Procedures

As stated, this evaluation will assess what effect, if any, the method of communication for providing the overall consent information for the survey has on enrollment rates. The test manipulates two different methods for communicating the consent information and obtaining consent:

- An interactive video that provides the overall study consent information and obtains consent at the end of the video using an electronic signature.
- A hard-copy booklet of the overall study consent information reviewed with an interviewer. The interviewer asks the person to give consent on a signature page included at the end of the booklet.

About half the English- and Spanish-speaking women eligible for the pilot study will complete the consent process in the interactive video condition. The other half will complete the consent process using the hard-copy booklet. (The evaluation will not include women who speak a language other than English or Spanish.) The Information Management System (IMS) will randomly assign households to a condition, outside of the control of the interviewer.

Interviewers will ask women for their (verbal) consent to participate in the consent evaluation. If any respondent indicates that she does not want to participate in the consent evaluation, she will receive the video condition as the default. Respondents in both conditions will receive a hard-copy of the consent information to keep for their records.

Description of video condition

The interactive consent video includes several features to help potential respondents understand what participating in the NCS entails. First, the video includes a brief (2-3 minute) introduction to the study that provides the goals and motivations for the NCS as a whole. Second, at different points, the video asks potential respondents to answer knowledge questions about several critical aspects of the study pertinent to informed consent. The interactive question-answer process built into the video may facilitate understanding of what participating in the NCS means. Lastly, the media itself may

increase comprehension for potential participants who may have difficulty reading a 10-page consent booklet.

However, the video also may introduce some barriers to participation in the study. First, depending on how well potential respondents do in answering the questions embedded in the video, the video could last more than 30 minutes. Second, the knowledge questions may seem like a test to potential respondents, perhaps discouraging them from continuing to participate. Lastly, by using a video to communicate the consent information, the interviewer is somewhat removed from the process, which may make it awkward or less easy for the respondent to ask questions. Similarly, since the interviewer is somewhat removed from this early interaction with respondents, interviewers in the video condition have less opportunity to build rapport with the respondent and less time to directly assess the respondents interest and ability to participate.

Description of hard-copy booklet condition

The other half of the eligible woman in the pilot study will receive the overall consent materials as a paper booklet, similar to a more traditional consent approach. The booklet contains the same substantive content as that contained in the video condition though the exact language reflects a printed rather than video medium. The format reflects the NHANES design using a question-answer presentation and, like NHANES, assumes interviewers will read through the booklet with respondents. (If the respondent indicates a preference for reading the consent booklet on her own, the interviewer does not have to read it aloud with her.) The amount of time required to read through the booklet will vary, depending on the respondents' level of reading comprehension and the interviewers' skill at reading through the materials and answering questions. To some extent the length of time can be "customized" to fit the situation though the interviewer must always cover the full set of questions and answers in the booklet.

The booklet also provides the interviewer with more opportunity to directly interact with the respondent and continue to develop the rapport between them. The greater amount of direct interaction may also provide the interviewer with more information about the respondent's interests in the study and ability to participate in the study. The interviewer

can then use this information to guide the discussion throughout the visit, perhaps aiding his/her ability to persuade a reluctant respondent to participate.

On the other hand, reading through a 10-page document may take more effort and concentration on the potential respondents' part to stay engaged. Additionally, as noted earlier, the document may prove difficult for potential respondents with lower levels of literacy.

In both conditions, if the screener interview identifies a household with a woman in her first trimester of pregnancy, the interviewer doing the pregnancy screening will leave a short promotional DVD that provides information about the study goals and discusses the importance of the study in terms of contributing to the health and well-being of children. Thus potential respondents in each condition will have equal opportunity to view the promotional materials before the arrival of the interviewer who completes the consent process and initiates the first data collection. (This data collection interviewer will contact the household to set up the first appointment with the target woman. When setting up the appointment the interviewer can ask the potential respondent if she has any questions about the DVD, thus reminding her of the opportunity to watch the DVD prior to the appointment).

Upon arrival, the interviewer who conducts the consent process will reintroduce herself, answer any questions the respondent may have and then get verbal consent to proceed with the consent evaluation. The interviewer's laptop will contain the script for this verbal consent process as well as a set of Frequently Asked Questions (FAQs) to help answer any questions the respondent might have about the evaluation.

After obtaining verbal consent to participate in the evaluation, the interviewer will proceed with the overall study consent completing the video or booklet consent materials as appropriate. Once the participant signs the electronic (video treatment) or hard-copy (booklet treatment) consent page, the interviewer still must provide the detailed information about each component of data collection associated with the first trimester visit and obtain the respondents verbal consent for each component. (The overall study consent addresses the various types of data collection more generally throughout the many years of the study.) In both conditions, the detailed information about each component of data collection for the visit is given on the "Visit Information Card" or VIC.

In both conditions, the interviewer will review the VIC with the participant before beginning the data collection. In addition to discussing the individual components of the T1 data collection, the VIC reminds respondents that their participation is voluntary and they may decline to participate in any of the data collection components. The VIC informs women that during this first year of the study, we will ask for their thoughts on how well some of the Study procedures and materials work and that information from this first year of the Study will be used to make improvements for the coming years.

After completing the booklet or video consent, the interviewer will go over the VIC covering the interviews, questionnaires, diary and medical visit log and obtain verbal consent to proceed with the T1 interview.

General Study Design

The study will include only English- and Spanish-speaking women in their first trimester of pregnancy as identified in the pregnancy screener. (Data collection will start with the first trimester visit for women who enroll at that point in their pregnancy). The evaluation does not include women who are not pregnant at the time of the screening interview because they complete slightly different consent materials. Of the women asked to complete the consent process after completing the screening interview, we estimate between 55% and 65% will be in their first trimester of pregnancy.

Table 1 shows the number of consent opportunities anticipated by February through June 2009 in the pilot areas for women identified as in their first trimester in the screening interview. In order to inform design and procedures for the National Children Study, results of this test must be available sometime between March and June 2009, depending on the anticipated complexity of modifications to the NCS consent materials and procedures resulting from the evaluation.

Table 1: The estimated number of consent opportunities in each condition, by different possible ending months in 2009.

Month (in 2009) complete evaluation	Video Consent	Booklet Consent
February	239	239
March	298	298
April	355	355
May	385	385
June	403	403

If data collection for the consent evaluation ends in February, about 239 women will have had the opportunity to review the video consent materials and about 239 women will have had the opportunity to review the booklet consent materials. If we continue with the data collection through May, each condition will include approximately 385 women. Table 2 shows the estimated size of the difference in enrollment rates detectable at 80% power and a 90% confidence interval, assuming 50% as the enrollment rate for the condition with the highest enrollment rate under a simple random sample. The size of the difference detectable at 80% power and a 95% confidence interval ultimately will be larger when reflecting the impact of clustering. Thus, even with extending the evaluation through June, the small number of cases will result only in statistically significant differences if enrollment between the two conditions differs by more than 10%.

Table 2: The detectable difference in enrollment rates with 80% power and a 90% confidence interval under the assumption of simple random sampling.

Month (in 2009) complete evaluation	Enrollment Rate; Condition 1	Enrollment Rate; Condition 2	Detectable Difference
February	50%	36.9%	13.1%
March	50%	38.3%	11.7%
April	50%	39.3%	10.7%
May	50%	39.7%	10.3%
June	50%	39.9%	10.1%

As indicated above, respondents will be randomly assigned to condition, though the unit of implementation still needs discussion. The only currently known requirement is that all women in the same household receive the same treatment. However, from an implementation perspective, assignment to each group will likely reflect some level of geographic clustering in order to manage the demands placed upon any individual interviewer, and similarly contain the costs of implementation.

In addition to measuring whether the two consent conditions impact enrollment differentially, the study also will measure differences in comprehension and in several aspects of the respondent's subjective experience with the consent process. Interviewers will ask all women who complete the consent process (regardless of whether they ultimately give consent) to respond to a short set of questions covering the consent material via a self-administered paper questionnaire. The initial few questions on the questionnaire collect feedback on format and presentation of the consent materials, as well as general attitude about the study. Following those questions, the respondent will complete a short set of questions to assess comprehension. The questionnaires contain essentially the same questions for both conditions, with only slight wording differences necessary to reflect the appropriate video or booklet condition. (Appendix A1_video and A2_booklet contain the draft questionnaires.)

Respondents who decide not to enroll in the study after reviewing the consent materials also will complete an evaluation questionnaire for their condition, but the questionnaires for non-enrolled women are shorter. Rather than asking details about the consent materials she reviewed, the

non-enrolled questionnaire includes questions to assess how much of the consent process she completed, and why she chose not to participate in the study, as well as a couple of additional opinion questions about the study in general. Women who enroll in the study will answer the same opinion questions but at a later point in the data collection, not as part of the consent evaluation questionnaire. (See attachments A3_video_notenrolled and A4_booklet_notenrolled.)

The interviewer will ask the enrolled respondents to complete the consent questionnaire after completing the T1-first visit near the checkout process. The visit is expected to last about 3 hours on average and we anticipate that some respondents will prefer to continue with some portion of the data collection components on another day. If the respondent does prefer to continue on another day, the consent evaluation will be completed on the day the remaining components are completed. If the respondent refuses to complete any further components of the visit, the consent evaluation will be completed during the checkout process for that day. The interviewer will record in the Information Management System on what date the respondent completed the consent evaluation questionnaire (relative to when she reviewed the consent materials) and what data collection components she completed before filling out the evaluation questionnaire.

Regardless of the consent condition, most respondents will complete a self-administered paper questionnaire collecting feedback on their consent process, at about the same point in the interview (i.e., after completing all data collection components of the T1 visit). With each respondent completing an evaluation questionnaire, we can calculate a standard score for each respondent comparable across conditions. Additionally, to assess differences in retention of the consent information, interviewers will ask respondents to complete the comprehension questions again at the end of data collection for the third trimester visit (T3 visit). The next section defines the specific research questions addressed with this design.

Specific Research Questions and Evaluation Measures

The following table shows the specific research questions addressed by this study, as well as the measures proposed to answer the questions.

	Research Question	Evaluation Measure
1.	Does the method of communicating the consent information—an interactive video versus a booklet reviewed with an interviewer—differentially impact enrollment rates?	(Statistical) comparison of enrollment rates between the two groups.
2.	Does the method of communicating the consent information—an interactive video versus a booklet reviewed with an interviewer—result in differences in the amount and types of information understood by the respondent? Are their differences in retention of the consent information by the method of communication?	(Statistical) comparison of percent of women in each group who answer each set of knowledge questions correctly. <i>Answers collected at the T1 visit will assess initial comprehension. Answers collected at the end of the T3 visit will assess knowledge retention.</i> (Statistical) comparison of mean score for comprehension by consent group. – will also look at by whether the woman actually gave consent
3.	Does the study attrition rate differ by consent condition?	(Statistical) comparison of attrition rates between the two groups at each of the subsequent data collection visits prior to the birth visit.
4.	How do respondents rate the consent materials in regards to several characteristics such as: how engaging they find the materials; appropriateness of the level of detail provided in the consent materials; clarity of the materials; importance of the consent materials in their decision to participate; how the consent method impacts their interaction with the interviewer; and an open-ended comment section	Comparisons of ratings for each characteristic between consent conditions.
5.	Do the consent conditions differ in the amount of time needed to complete the consent process? If so, is the length of time needed to complete the process related to the decision to participate?	Comparison of the average time to complete the consent process. <i>Interviewers in both conditions will enter the time to administer the consent materials into the IMS for each case.</i>

<p>6.</p>	<p>Do the respondents’ attitudes about the survey topic and objective correlate with their decision to participate in the survey? What differences exist, if any, in enrollment rates by consent condition when controlling for attitude about the survey?</p> <p><i>* Those who chose not to enroll after reviewing the consent materials will complete a slightly modified questionnaire as those who do enroll. The non-enrolled questionnaire only includes one critical knowledge question, a question about how much of the consent process they completed, a couple of opinion questions about the consent process, and one additional question from a satisfaction questionnaire that study participants complete at a later point.</i></p>	<p>By condition, measure correlation between enrollment and responses to questions asked on a separate questionnaire that respondents will complete at the T1 follow-up visit when study staff come to pick up the environmental equipment. <i>(This other questionnaire will be used to evaluate the outreach and promotion activities, as well as general satisfaction with their study experiences to date.)</i></p>
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The evaluation also may include feedback collected by interviewer debriefing data or comments collected from observers on a structured questionnaire as additional sources of information about the consent process. The debriefing will ask interviewer’s for their perceptions of how the consent process influenced the rapport between herself and the respondent, if at all, as well as collect feedback on ease or difficulty of implementing the two different consent processes.

**National Children's Study
PRECONCEPTION VERSION Script
Based on Script 06-11-2007**

T1-S1

Your neighborhood is one of many communities across the United States that has been chosen to take part in an important research study.

It's called the National Children's Study, and its goal is to improve the health and well being of our nation's children. We need both pregnant women and women who are not pregnant to volunteer to be part of this Study.

Because, your community has been selected to be part of the National Children's Study, we're inviting you to take part.

Here's more on what the Study is all about...

ALEXANDER: The National Children's Study is our effort to understand one of the great mysteries in pediatrics today: What role does environment play in causing diseases that we don't know the cause of otherwise?

JONES: The study was conceived to look at child development from pre-conception all the way through until they're 21 years old. We have not ever done this.

SCHEIDT: Doctors today need to know about the causes of ongoing epidemics of important childhood diseases such as asthma

MADDOX: Infant mortality.

CHENG: Obesity.

SCHEIDT: Diabetes.

GUERRA: Any number of risk-taking behaviors.

CHENG: Learning disabilities.

SHANNON: Cardiovascular disease.

SCHEIDT: And even injuries.

MADDOX: We are asking individuals to participate in this study as volunteers.

ALEXANDER: It will involve 100,000 children and families over the course of 21 years.

CHENG: Those 100,000 children will represent 100,000 mothers, 100,000 fathers, aunts and uncles, in communities scattered all across the United States. And from this, we will learn very important lessons about health and about disease.

SCHEIDT: In addition, we will learn how the environment affects our genes and how genes affect children's health and development

SHANNON: This study is large enough and rigorous enough to answer very important questions and really make a difference in the health of children.

GUERRA: It will give us information and evidence that will provide better explanations and understanding for so many conditions that today are affecting not just an individual or groups of individuals, but entire populations.

MADDOX: It will be a representation of the nation's children, which means that it will include children from all socioeconomic groups, and children from all races and ethnic groups.

JONES: As a participant, they're going to tell you a lot about the study. You can go home; you can talk it over with your family members so that everybody knows what this is going to be like.

CHENG: A child's health is very much dependent not only on the child's social and physical environment, but also on how genetics and the environment interact. We're going to learn a lot from the National Children's Study.

T1-S2

You're probably wondering why we're asking you to be in a study of children's health. You're not pregnant now, and you may not be trying to get pregnant. But things around you *now* – like the air you breathe and the water you drink – might influence the health and development of your future children, if you ever do get pregnant.

So we'd like to collect some information about your health and environment, and to keep in touch with you in case you get pregnant in the future.

T1-S3

Then, if you do get pregnant, we'll come back and ask you to take part in more of the National Children's Study. At that point, we hope you will enroll yourself and your future child in the full study.

T1-S4

We've put together some information to help you decide if you want to volunteer to participate in this first part of the Study.

Use the stylus to move through the information.

- To move forward, touch the NEXT button.
- To move backward, touch the BACK button.

If you have any questions, the Study representative will be happy to answer them for you.

Touch the NEXT button now, to continue.

T1-S5

The overall purpose of the study is to help researchers learn what things in the environment may affect children's health, growth, and development, and what may cause children to develop diseases later when they are adults. To do that, the National Children's Study will be studying women before and during pregnancy and children from the time they are born until they are 21 years old.

T1-S6

Some things affect children's health, before the Mom becomes pregnant, so that's why we are inviting women to participate in the Study, even before they become pregnant.....*even* before they may be *thinking* about becoming pregnant.

T1-S7

Later, if you do become pregnant, we hope you will let us know. At that point, we can discuss your interest in taking part in the full study and enrolling your child as well. But for now, we are only asking if you are willing to take part in the "pre-pregnancy" part of the Study.

T1-S8

The Study is being conducted as a partnership among local institutions in your community and three federal agencies. The three federal agencies are the National Institutes of Child Health and Human Development, which is part of the National Institutes of Health; the Centers for Disease Control and Prevention; and the Environmental Protection Agency.

T1-S9

This is the local institution in your community.

Your local sponsor has established its own Study Center with a team of community members, health professionals, and others trained to carry out the national study in your community.

T1-S10

Taking part in the Study is your choice. You can choose not to take part. And if you *do* take part, you can leave at any time.

If you decide not to take part in the Study, or you take part and later stop, you will not lose any benefits (like health insurance or health care) to which you are already entitled.

If you do take part in the Study, we may learn things that may help people in the future, but may not help you or your family personally.

T2-S1

If you decide to join the Study, we will come to your home to collect information about you, your health, and your environment.

The visit will last about 2 to 3 hours.

Its purpose is to ask questions about things that might affect your health, like “Is there a history of diabetes in your family?” Or, “How well do you sleep at night?”

T2-S2

During the visit, we’d also like to examine you to get body measurements, like height and blood pressure.

TS-S3

And we’ll collect samples from you, like blood, urine, hair and saliva.

T2-S4

And from your home,
...like air, dust,
...water and soil.

T2-S5

We’d like to schedule the visit, so that it would occur in the next few weeks, at a time that is good for you.

If you give us permission to come to your home, we will explain exactly what we’re going to do, *and* we will ask you if it’s okay to do it.

If there’s something you don’t want to do, or that you don’t want us to do, you can skip that part and still be in the Study. Or you can leave the Study at any time.

T2-S6

In addition to this home visit, we would also like to stay in touch with you in case you get pregnant.

If you agree to be in this part of the study, we will contact you from time to time to ask you a few questions. We will phone, and we may try to reach you by mail or computer as well.

T2-S7

If your situation changes, we will change how often we contact you. For example, if many months pass and you don't get pregnant, we will call you less often. Or if you decide you do want to try to get pregnant, we will call you more often, and visit you again.

T2-S8

The information you give us will be stored with information from all the other women in the Study. Doctors and researchers will use all this information, which they call "data," to look for patterns or relationships between environment and health. These patterns will give researchers clues about what causes many diseases.

Written data—like your answers to questions and your height measurements—will be stored in computers, and studied by researchers.

The samples we collect from you will be stored so they can be tested.

T2-S9

Some tests on your samples will be done right away. Others will be performed at a later date. Samples will be stored for at least the duration of the study, so we can do many other tests.

Right now we can't tell you what all of those future tests might be, because science is always improving and new tests are always being developed. But we *can* tell you that

before any new kinds of tests are done on your samples, a Study Committee of doctors, scientists, and community members will make sure the tests relate to child health, growth and development and to improving our understanding of why some children are more likely to get diseases when they grow up.

If you decide to join the Study and agree to give us samples, you will be allowing us to test those samples both now and in the years ahead.

T2-S10

The Study also plans to look at DNA, or genes, the basic building blocks of our bodies, because doctors know that genes affect the health, growth, and development of children, and that the environment affects how genes work. If you agree to participate in the Study, you do not have to agree to this part of the study. We will ask your permission for the genetic part separately.

T3-S1

You might be wondering: What do I get out of all this? What's in it for me?

There may be no direct benefit to you or your family. But the Study could uncover important new medical knowledge that could benefit all of us in the years to come—maybe even your children and grandchildren. That's something we think you might feel proud to be a part of.

As the Study unfolds, our scientists will learn a lot about children in general, and why some children are more likely than others to get certain diseases when they grow up. We might learn things like what causes asthma or what contributes to making children do well in school. We are also likely to learn about what promotes healthy pregnancies and how to reduce miscarriages and premature births.

And, as we make these discoveries, we will share them with you.

T3-S2

We will send out news through newsletters, a Web site, and other means, and we will publish this information in books and magazines.

T3-S3

That’s all about health in general, but we will also give you some medically important information we learn—from the exams we’ve done or from the samples we’ve taken—about you and your environment. Hopefully, this will keep you better informed about your health and your environment. Later, if you decide to participate in the full Study with your future child, we will also provide medically important information we may discover about your child.

We will give you reports about the routine information we are collecting. In addition, if our research shows something that is a medically important for you or your family, *and* there is something you could do about it, we’ll let you know, so that you can follow up with your doctor. If you need the help of medical or social services, we can give you names and contact information. But keep in mind, the Study will not pay for any medical treatment. We will only tell you what we learn and give you names of people and agencies that can help you.

T4-S1

The risks of this study are very low. It’s an observational study, which means we will collect information and do some routine medical exams and take some samples.

The Study does not include any experimental drugs or medicines.

Even though the risks are low, there are some things that might be a risk or discomfort to you, if you decide to join the Study.

T4-S2

You might feel uncomfortable about some of the questions we ask. If so, you can skip those questions. You will be in charge, and you can decide which questions to answer.

T4-S3

People sometimes feel brief pain when blood is taken, and there's a very small risk of infection, bruising, or bleeding. The professionals who will take your blood are trained to make you feel comfortable.

T4-S4

Having us come to your home for a visit may be an inconvenience. The visit may interrupt your daily routine and other people living in your home may also be affected. To minimize this, we will set up the visit at a time that works for you, and we will be happy to change the date or time if you need to.

T4-S5

If we learn that a child is being neglected or abused, then we must report this to the proper authorities.

T4-S6

As we've said, if any of your tests or samples indicate something that is medically important for you to know about, and that you could do something about, we'll let you know. Information like that can be beneficial. But it can also be upsetting. And, because of the information we've shared with you, you might decide to spend money to undergo additional tests, which might not ultimately reveal a significant problem.

T4-S7

We will not share all environmental test results with you, but if any of our tests show known chemical or other kinds of known health hazards in or around your home, we'll let you know.

Knowing about home health hazards can be a good thing, because if you know about it, you may be able to fix it.

But there is also a risk to getting this information.

T4-S8

Some federal and state laws require homeowners to tell potential renters or buyers about certain health hazards, like lead or mold. That means if you own your home, and we tell you about a home health hazard, you may be required to report that hazard when you sell or rent your home.

T5-S1

Giving personal information to anyone always involves some risk. Therefore this Study will make every effort to protect the identities of all participants.

To protect your personal information, we will:

- Label your samples and other information with a unique number code, so our labs will not know whose samples they are testing
- Separate your number code from your name, address, and other identifying information

T5-S2

- Store your test results and other information in a computer database protected by sophisticated security technology
- Report only group information, not individually identifiable information

T5-S3

In addition to taking all these steps to protect your privacy, we have obtained a legal document designed to protect the privacy of people who take part in research studies. The document is called a Certificate of Confidentiality. It will help protect your information from people who are not part of the Study.

T5-S4

Certificates of Confidentiality help make sure that the Study researchers cannot be forced to tell anyone who is not connected with the Study—including the courts—about your participation or your personal information without your written consent.

We have described the steps we will take to protect your confidentiality. We will do everything we can to ensure that your personal health information is never revealed to anyone outside the Study.

T6-S1

We understand that your time is valuable and we appreciate your helping us. The Study will pay you for your time spent during any home visit when someone from the Study Center comes to ask you questions and take samples. Payment for each visit will be about \$50 depending on the amount of time and effort involved.

T6-S2

From time to time, we may also give you small gifts—like, a T-shirt, a tote bag, or a music CD—to thank you for your efforts.

T7-S1

NARRATOR V/O

Finally, we'd like to answer some common questions people may have about being in the study.

*OTHER VOICE**What if I want to leave the Study early?*

NARRATOR V/O

You can leave the Study at any time without penalty. You can also leave the Study for a short time and then rejoin it. Leaving the Study will not affect your access to health care in any way. The Study also has the right to end your participation at any time.

T7-S2*OTHER VOICE**What happens to my samples and information if I leave the Study?*

NARRATOR V/O

If you do leave the Study, no new information will be collected from you, but data and samples that have already been collected will continue to be analyzed. If you want us to get rid of any of those samples, you may ask us to destroy them.

T7-S3*OTHER VOICE**What if I move?*

NARRATOR V/O

We hope you'll tell us if you are planning to move so you can keep working with the Study in your new home. If you move and forget to tell us, we will look for you using the information you've given us about family members and friends, as well as publicly

available information about you. If we are able to find you, we will ask you if you want to continue to be in the Study.

T7-S4*OTHER VOICE*

Will it cost me anything to take part in the Study?

NARRATOR V/O

No. There is no cost to you—all the tests and procedures related to the Study will be paid for by the Study. Any future tests done on your samples will also be paid for by the Study.

T7-S5*OTHER VOICE*

Does the Study provide health care for me or my family?

NARRATOR V/O

No, the Study is not able to pay for your health care. Study procedures are for research purposes only, and taking part in the Study is not a substitute for your usual visits to the doctor. The Study also does not affect your health insurance coverage.

T7-S6*OTHER VOICE*

Will data from this study be used in other ways?

NARRATOR V/O

Yes. At certain points during the Study we will remove all personal identifiers and create what is called a public use data set—a set of totally anonymous data that scientists and researchers can use to study other things. Anyone outside the Study who uses the public use data will not be able to connect the information to a specific person.

T7-S7

OTHER VOICE

In addition to the tests the National Children's Study will do on my samples, would these samples be used in any other way?

NARRATOR V/O

It is possible that scientists could create new medicines or health products in the future based on stored study samples. In agreeing to participate in this Study, you are also agreeing to allow possible future use of your biological materials for these kinds of purposes.

T7-S8

OTHER VOICE

If I take part in this study, will I have to be part of other studies?

NARRATOR V/O

No. But you may be invited to be in other studies connected with the National Children's Study. For any other studies, you will be asked for your permission, and you can always say "no thanks."

C1-S1

In order to conduct the Study, we will need information from your medical records. The Study will also ask your doctors for information about your health and will seek information about any visits you may have made to the emergency room or to other health facilities. To get this kind of personal health information, we need your permission.

If you agree to allow us to obtain and use your personal health information, you have the right to change your mind and withdraw your permission at any time, by submitting a letter to the Study Coordinator at _____. Once the Study Coordinator has received your withdrawal letter, no new information from your medical records will be collected. However, information that has already been collected may still be studied.

C1-S2

Some people feel differently about genetic information than other kinds of information. So we will be asking you specifically to agree to genetic analysis of your samples. However, if you do not agree to the genetic aspect of the Study, you can still take part in the rest of the Study.

Some of the genetic analyses we would like to do may be done right away. Others may be done in the future, as the Study learns more, or as new tests and techniques are developed.

Because results of individual tests can be very difficult to interpret, the National Children's Study will not give genetic information about you to you or to anyone else. In the unlikely case that the Study learns something from this genetic information that is important to your health or your family's health, *and* if there is something you could do about it, we will tell you that the information is available. In that case, we will give you the option of learning more about it.

C1-S3

Let's pause now so that you can ask the Study Representative any questions you may have.

In addition, before deciding, you may wish to discuss what you have learned about the pre-pregnancy part of the National Children's Study with your family, friends, or your doctor.

If you have more questions about the research or about your rights as a research participant, contact any of the following.

C1-S4

Please check one of the boxes below to indicate whether you would like to volunteer to participate in the pre-pregnancy part of National Children's Study:

- I am ready to participate in the Pre-Pregnancy part of the National Children's Study
- I need more time to think about participation in the Study. I'd like to discuss it some more in the future.
- I do not wish to participate in the Pre-Pregnancy part of the National Children's Study.

Click Next, when you have made your choice.

On the next screen, you will be asked for your signature. If you sign, you are agreeing to take part in a research study. This means that you have completed this informational program, and that you have made the decision to be in the Pre-Pregnancy part of the Study voluntarily.

C1-S5

If you are ready to volunteer participate in the Pre-Pregnancy part of the National Children's Study, you may do so now. By signing below, you are indicating the following:

- I have completed the informational program about the Pre-Pregnancy part of the National Children's Study.
- I understand what is involved, and what the risks and benefits are if I join.
- I understand that I am also giving my permission for the National Children's Study to obtain and use my personal health information.
- I understand that I may leave the Study at any time.
- I have asked and received answers to all my questions about the Study.
- I understand that I may ask further questions at any time and that I will get a paper copy of the consent form for my records.

And, please check one of these two boxes:

- I also give permission to the National Children's Study to collect and analyze genetic information about me.
- At this time, I do not give permission for the National Children's Study to collect and analyze genetic information about me.

I voluntarily agree to participate in the Pre-Pregnancy part of the National Children's Study.

C1- DEFER

Thank you.

We understand that you have not agreed to participate in the National Children’s Study at this time, but that you are still open to learning more about it in the future.

The Study staff person visiting with you today will talk with you about when we might contact you again.

If you like, we can leave you some materials to review yourself or with your family.

C1- DECLINE

Thank you for being willing to hear about the National Children’s Study. We’d very much like to know why you’ve chosen not to participate. Please select any or all of the choices below.

I’m not interesting in participating because:

- I don’t think my husband or boyfriend will want me to do this.
- I don’t think other family members will want me to do this
- I don’t want someone visiting my home
- I don't want the Study to have access to my medical records
- I don’t want the Study staff to examine me or take samples
- I don’t want the Study staff to take samples from my yard or home environment
- I just don't feel like it
- Or for another reason. Please tell the recruiter, who will record your answer

EARLY_EXIT

You clicked the EXIT button – are you sure you want to exit the program?

CLOSING_OPT-IN

Thanks again!

We are very pleased that you've agreed to participate in the Pre-Pregnancy part of the National Children's Study!

CLOSING_OPT-OUT1

Thank you for your time thinking about participation in the National Children's Study!

We look forward to talking with you again in the future.

CLOSING_OPT-OUT2

Thank you for your time thinking about participation in the National Children's Study!



MAKING AN INFORMED CHOICE ABOUT BEING IN THE NATIONAL CHILDREN'S STUDY

Your neighborhood is one of many communities across the United States that has been chosen to take part in an important research study. It is called the National Children's Study, and its goal is to improve the health and well-being of our nation's children.

We are asking you to take part in this study for two reasons. First, because you live in a neighborhood that has been selected; and second, because you may become pregnant and have a baby. We are asking you to join thousands of women and their babies from across the United States to learn things that may help many people in the future, even if the information may not help you or your family personally, right now.

Sponsors:

The National Children's Study is a partnership between (LOCAL CENTER) and other local institutions in your community, and is lead by the U.S. Department of Health and Human Services through the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the U.S. Environmental Protection Agency (EPA).

Joining the Study is your choice. You can decide not to join. If you do join, we hope you and your child will remain in the study for the full 21 years, but you can leave for any reason at any time.

What is the purpose of the National Children's Study?

The goal of the National Children's Study (NCS) is to improve the health and well-being of the nation's children. The Study aims to understand how the environment affects children's health, growth, and development. We also are interested in how the environment interacts with a person's characteristics, such as genes, to prevent disease and promote health.

What kind of study is the National Children's Study?

The NCS is an observational study, which means that we will be collecting information about you and your child and your child's environment. Studying this information will allow us to find out which things in the environment offer special benefits for child development and which are associated with illness or disease. Observational studies do not involve asking you to change what you normally do. We will not be asking you or your child to try out new drugs or experimental treatments of any kind.

Why is the National Children's Study important?

This is the largest and most detailed study in history to learn about the health and development of children in the United States. We will learn what things in the environment affect whether or not children will develop diseases, both while they are young and also later, when they become adults. Finally, there are new medical conditions that weren't around 30 or 40 years ago, or not at the levels we now see: obesity, diabetes, autism, learning disabilities, to name just a few. The National Children's Study will help us understand why and what we can do about these problems.

How many people will be in the National Children's Study?

The Study will include about 100,000 women and their babies from all over the United States. Fathers will also be asked to participate. In this area, we expect to study about 1,000 women and their babies.

How long will the National Children's Study last?

We hope you and your child will stay in the Study until your child turns 21 years old. You will start in the Study during your pregnancy, and your child will start when he or she is born.

What is involved in being in the National Children's Study?

We will schedule visits with you and your child to collect information about your health and environment. Some of these visits will take place in your home, and others will be at the Study Center.

The first visit will take place in your home if you become pregnant. There will be other visits while you are pregnant that will take place at the Study Center.

When you give birth, we will visit you and your baby in the hospital, or wherever you give birth, to get information about the birth and to ask you questions about your plans.

When your baby is little, we will visit you and your baby in your home and also invite you and your baby to the Study Center. When your child gets a little older, you and your child will come to the Study Center for visits.

We also might ask you about any places where your child spends a lot of time, like daycare, a babysitter's home, a school, or a grandparent's house. We might also want to visit those places.

Between visits, we will contact you from time to time. We may ask you some questions on the telephone, or we may send you questions in the mail or by computer.

How will the National Children's Study collect information?

There are several ways we will collect information: We will ask you questions, ask you to complete forms, do physical exams, collect samples, collect information from medical records, and take pictures and videos of your child.

We also may ask you to keep track of certain things you do—like what you eat.

We also will ask you to obtain some samples of things like urine, or drinking water in your home, or breast milk (if you are breast feeding), and mail them back to us in postage-paid containers that we will provide.

As your child grows older, you also may be asked to complete other types of activities. Before every visit, we will give you details and describe exactly what the visit will involve.

What kinds of information will be collected?

If you become pregnant, we will ask you questions about things that might affect your pregnancy. We will ask about your medical history, about the foods you eat, and your thoughts about different topics.

While you are pregnant, we will measure your height, weight, and blood pressure, and do one or two ultrasounds which may be in addition to the tests you receive from your doctor. If your doctor does an ultrasound, we will want to look at that as well.

When you give birth, we will examine, measure, and take pictures of your baby. As your child grows up, we will continue to follow your child's health, growth, and development.

We also will examine you and your child and do some tests. These exams and tests do not replace the regular visits you have with your own doctors.

Finally, we will want to collect biologic samples from you and your child, as well as samples from your home environment.

The biologic samples we collect—like blood, urine, hair, and saliva—will tell us about your health. The environmental samples—like dirt, air, dust, and drinking water—will help us learn what in the environment might affect your health.

Our trained staff will make these collections as easy as possible for you.

For blood samples, we will use a small needle in your or your child's arm. For urine samples, we will give you a plastic container. There's even a special container to collect urine from babies. For hair samples, we'll ask you for a few hairs from your head and your child's. When your baby is born, we will work with your doctor and hospital to obtain a sample of blood from the umbilical cord, and a sample of the cord and the afterbirth or placenta, and your baby's first bowel movement.

To test the air in your home, we will leave an air pump in your home for a few days, and then come back to pick it up. To test the dust or water in your home, or the soil around your home, we will collect small samples. Some of these samples you'll be able to collect yourself with a kit and return to us at the Study Center.

We hope you will want to participate in all parts of the Study, but if you don't want to give certain samples, answer certain questions, or have certain types of exams, that is fine—you can say no at any time and for any reason, and you can still be part of the Study.

How many visits should I expect?

If you become pregnant, there will be several visits while you are pregnant, one when you give birth, and the rest —about 10 or 12 in total—will be spread out over the next 21 years.

Will the Study need access to my medical records and my child's medical records?

Yes, we will want to get information from your medical records when you give birth, because we want to learn how your delivery went.

Later, we will want to look at your child's medical records, such as records of doctor and emergency room visits, to learn about your child's health, illnesses, accidents, injuries, and vaccinations. The Study also may ask your doctors to provide personal health information about you and your child. You will be asked to sign a separate authorization form giving us permission to obtain copies of these types of medical records from your doctor or hospital. This kind of information will help us learn your child's health.

If you agree to allow us to obtain and use your personal health information and your child's, you have the right to change your mind and withdraw your permission at any time by submitting a letter to the Study Coordinator (whose contact information is presented on page X of this document). Once the Study Coordinator has received your withdrawal letter, no new information from your medical records or your child's will be collected. However, information that has already been collected may still be studied.

What will happen to all this information?

The information you give us will be stored with information from all other women and children in the Study. Doctors and researchers will use all this information, which they call “data,” to look for patterns or relationships between children’s environments and their health.

Written data—like your answers to questions and your height measurements—will be stored in computers. The samples we collect from you and your child will be stored so that they can be tested. We plan to store these samples at least for the 21 years of the study.

Some tests on these samples will be done in a few weeks or months. Other tests will be performed years later. Right now, we do not know what all of those future tests might be, because science is always improving and new tests are always being developed. But we can tell you that before any new kinds of tests are done on your samples, they will be evaluated by a Study Committee of doctors, scientists, and community members to make sure the tests only relate to child health, growth, and development, or to why some children are more likely to get diseases when they grow up.

If you decide that you and your child will join the Study and agree to give us samples, you will be allowing us to test those samples both now and in the years ahead.

Will you be obtaining genetic information about me and my child?

Yes, but only if you give us specific permission to do so.

In addition to telling us about your current health, the samples you provide us, like blood or saliva, also can enable us to look at your DNA or genes. Collecting samples that allow us to look at *both* genes *and* the environment is important, because genes affect children’s health and development, and the environment affects how genes work. By collecting both genetic and environmental information, the Study will learn a great deal about children’s health and development.

Some people feel differently about genetic information than other kinds of information. So we will be asking you specifically to agree to genetic testing on your and your child’s samples. However, if you do not agree to the genetic part of the Study, you can still be in the rest of the Study.

We will not be doing the genetic testing until some time in the future, as the Study learns more, or as new tests and techniques are developed.

Because individual genetic results can be very difficult to interpret, the Study will not give genetic information about you or your child to you or to anyone else. In the unlikely case that the Study learns something from this genetic information that is important to your health or your family’s health, *and* if there is something you could do about it, we will then tell you that the information is available. In that case, we will give you the option of learning more about it.

What are the possible benefits of being in the National Children's Study?

There may be no direct benefit to you or your family. But the Study could help provide important new medical knowledge that could benefit all of us in the years to come—maybe even your children and grandchildren. That's something we think you might feel proud to be a part of.

However, there may be some indirect benefits. First, we will share some of our findings with you. As the Study goes on, our scientists will learn a lot about children in general, and why some children are more likely than others to get certain diseases when they grow up. We will learn things like what helps children do well in school and in relationships with other people. We will publish this information in books and magazines. We also will share it with you through newsletters, a Web site, and other means.

We also will give you reports about the routine information we collect about you and your child and your environment. And, if our research shows something that is medically important and that you could do something about, we will let you know, so that you can follow-up with your doctor.

If you need the help of medical or social services, we can give you names and contact information. But keep in mind that the Study will not pay for any medical treatment. We will only tell you what we learn, and give you the names of people or agencies that can help you.

What are the possible risks or burdens to me and my child from being in the National Children's Study?

The risks of this study are very low. It's an observational study only. It does not include any experimental drugs or medicines or treatments. However, there are some minimal risks and possible discomforts.

You might feel uncomfortable about some of the questions we ask. If so, you can skip those questions. You will be in charge, and you can decide which questions to answer.

But we do hope you will share some private information with us, because it is important to make this study successful. We will carefully protect what you tell us. Your data will be linked to a number, not your name, so the people who later look at your answers cannot identify you personally.

Another risk—a very small one—has to do with giving blood samples. People sometimes feel brief pain when blood is taken, and there is a very small risk of infection, bruising, or bleeding. The professionals who will take your blood are trained to make you feel comfortable.

Home visits are likely to take 2 to 3 hours, but we will schedule the visits at a time that is good for you. Having to go to the Study Center and having us come to your home may interfere with your daily routine. Other people living in your home also may be affected by the visits. To minimize this, we will schedule visits at a time that works for you, and we will be happy to change the date or time if you need to.

If, during our visits, we learn that you or your child are in danger, or are a danger to yourselves or others, then we must report this to the proper authorities.

As we have said, if any of your tests or samples indicate something that is medically important for you to know about, we will let you know. Information like that can be helpful. But it also can be upsetting to some people. And, because of the information we have shared with you, you might decide to spend money to undergo additional tests, which might not end up finding any problems.

We will not share all results with you, but if any of our tests show chemical or other kinds of known environmental health hazards in or around your home, we will let you know. Knowing about a home environmental health hazard can be a good thing, because if you know about it, you may be able to fix it. But there also is a risk to getting this information. Some federal and state laws require homeowners to tell potential renters or buyers about certain health hazards, like lead or mold. That means if you own your home, and we tell you about a home health hazard, you may be required to report that hazard when you sell or rent your home.

How will my privacy be protected?

The Study will make every effort to protect the identities of all participants. We will use a unique number code and separate your name, your child's name, and other things that could identify either of you from the samples and other information you give us. The stored data will have only these numbers, not names, so that individuals cannot be identified.

The Study will store information in a computer database protected by very effective computer security methods. Your data will be combined with data collected from all the other tens of thousands of people in the Study. All the information, including yours and your child's, will be confidential and reported only as a group. Specific data about you personally, or about your child, will never be reported in any Study publication.

In addition to taking all these steps to protect your and your child's privacy, there is one more thing we have done. We have obtained a legal document called a Certificate of Confidentiality. This will help protect your information from people who are not part of the Study. Certificates of Confidentiality are intended to assure that the Study researchers cannot be forced to tell anyone who is not connected with the Study—including the courts—about your participation or your personal information without written consent from you.

Will I be paid for being in the National Children's Study?

We will pay you for time spent in study-related activities, like a home or Study Center visit, and for answering questions. Payments for each set of activities will be about \$50, depending on the amount of time and effort involved. We will pay you for each completed set of activities even if you, or your child, do not finish the whole study.

You will also be paid for your expenses related to visits to the Study Center—for example, travel expenses or parking.

From time to time, we also will give you or your child small gifts—like a T-shirt, a tote bag, or a music CD—to thank you for helping us.

What if I want to leave the National Children’s Study?

We hope you will stay in the Study for the entire 21 years, but you or your child can leave the Study at any time without penalty. You also can leave the Study for a short time and then rejoin later. Leaving the Study will not affect your access to health care or your relationship with this institution in any way. The Study also has the right to end your participation at any time.

If you do leave the Study, no new information will be collected from you or your child, but samples and data which have already been collected will continue to be studied. If you want us to get rid of those samples, you may ask us to destroy them by submitting a letter to the Study Coordinator (whose contact information is presented on page X of this document).

When my child gets older, will he or she be able to decide whether to continue in the National Children’s Study?

Yes. Young children and adolescents will be asked their permission to continue in the Study. When the children become legal adults (at about age 18, depending on your state law), they will be asked to sign a document themselves, like this one, to indicate whether they wish to continue or not.

What if I move?

We hope you will tell us if you are planning to move, so you can continue to be in the Study in your new home. If you move and forget to tell us, we will try to learn your new address or phone number by using the information you have given us about family members and friends, as well as publicly available information about you. If we are able to find you, we will ask you if you want to continue in the Study.

Will it cost me anything to be in the National Children’s Study?

No. There is no cost to you. All tests and activities related to the Study will be paid for by the Study. Any future tests done on your samples will also be paid for by the Study.

Does the National Children’s Study pay for health care for me or my family?

No. The Study is not able to pay for your health care. Study activities are for research purposes only, and taking part in the Study does not take the place of your usual visits to the doctor.

Will data from the National Children’s Study be used in other ways?

Yes. At certain points in the Study, we will make what is called a public use data set. That data set will not include any information that could identify individual people in the Study. Scientists and researchers can use the public use data sets to try to learn more about children’s health. Anyone outside the Study who uses the public use data set will not be able to connect it to a specific person.

In addition to the tests the National Children’s Study will do on our samples, will our samples be used in any other way?

It is possible that scientists could create new medicines or health products in the future based on stored study samples. In agreeing to be in this study, you also are agreeing to allow possible future use of your and your child’s biological materials for these kinds of purposes.

If I take part in the National Children’s Study, will I have to be part of other studies?

No. But you may be invited to be in other studies connected with the National Children’s Study. If so, we will ask your permission.

Who can I contact if I have further questions?

Feel free to ask the Study Representative, who has talked to you about being in the Study, any questions you have. Also, if you have any questions about the Study or about your or your child’s rights of being in the Study, now or in the future, you may contact any of the following:

National contact:

Local contact #1(Study coordinator or PI):

Local contact #2 (IRB):

On the next page, you will be asked to indicate your consent to participate and to sign the consent document. Before signing, you may wish to discuss what you have learned about the National Children’s Study with your family, friends, or your doctor. Thank you for taking the time to learn about this important Study.

Participant’s Statement

- I have read “Making an Informed Choice about being in the National Children’s Study”.
- I understand what is involved, and what the risks and benefits are, if my child and I join the Study.
- I understand that I am also giving my permission for the National Children’s Study to obtain and use my personal health information and my child’s.
- I understand that my child and I may leave the Study at any time.
- I have asked and received answers to all my questions about the Study.
- I understand that I may ask further questions at any time, and that I will receive a copy of this consent form for my records.

I freely choose to be in the National Children’s Study, and I give permission for my child to participate in the Study as well.

- And, please check **one** of these two boxes:
- I also give permission to the National Children’s Study to collect and test genetic information about me and my child.
- At this time, I do not give permission for the National Children’s Study to collect and test genetic information about me and my child.

Printed Name of Participant: _____

Signature of Participant: _____

Date: _____

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____

Date: _____

THANK YOU



OMB #: _____

Expiration Date: _____

Visit Information Card for Pre-Pregnancy Visit

When you gave your permission to be part of the National Children's Study (NCS), we told you all about what it means to be in the study. This card tells you more details about what we would like to do at this study visit.

Interview

We will ask you some questions which should take about 30 minutes. The questions will be about such things as your home, the people who live with you, any pets you have, your jobs, your activities, your health, and any medicines you take.

Physical Measures

We also will ask to do the following:

- Measure parts of your body including your arm, hip, and waist, and the skin on the back of your arm and upper back. You will not have to undress for us to take these measurements.
- Measure your weight and height.
- Measure your blood pressure.
- Give you a report to keep which shows your height, weight, body mass index, heart rate, and blood pressure.

Biological Specimens

We also will ask do the following:

- Ask you for a sample of your urine.
- Ask you to collect 3 vaginal swabs. You will do this yourself in complete privacy using cotton swabs.
- Collect less than 2 ounces of your blood using a small needle. Two ounces is approximately four tablespoons.
- Collect a small sample of your hair.
- Provide you with some pregnancy tests and instructions to begin using the tests the first day of your missed period.
- Provide you with instructions and a urine cup to collect a urine sample the first morning after you have a positive pregnancy test. We will ask you to freeze the sample, and we will collect the urine cup within 7 days.

Your urine and hair may be tested for a variety of environmental exposures. The vaginal swabs may be tested for measures of infection and inflammation. These measures will be done at a later time and you will not receive the results of these tests.

On the same day that we collect your blood, we will test a small sample for hemoglobin and calculate your hematocrit levels. Your hemoglobin/hematocrit results will be sent to you within several weeks. However, if anything abnormal is detected, you will be notified sooner. The rest of your blood will be stored for future analyses, which may include measures of environmental



OMB #: _____

Expiration Date: _____

Visit Information Card for Pre-Pregnancy Visit

exposure, hormone and nutrient levels, and measures of infection and inflammation. You will not receive the results of the tests that may be done in the future.

Environmental Samples

We also will do the following:

- Test the air in your home for chemicals and dust using an air pump and an air badge. We will leave these in your home for about a week, and then we will come back to pick them up.
- Look at the environment inside and outside your home. If you want to, you can walk with us while we do this.
- Collect dust from the floor of your home that will be tested for pesticides at a later time. We will choose the rooms where we collect the dust using Study rules.

You will not receive the results of any of these tests.

Questionnaires and Other Forms for You to Complete

We will give you two forms to fill out on your own. These forms ask questions about what you eat.

We will pick up the forms from you when we return to get the equipment we need to leave here. Also, when we return to pick up the equipment, we will ask you to complete a short form about your thoughts on all of the things we did at this visit.

Compensation

After we have completed the interview part of the visit and collected all initial environmental and biological specimens, we will give you \$80 for your time. We also will give you \$20 once we have received the environmental and biologic specimens and the questionnaires and other forms.

We would like to remind you that being in this Study is voluntary. You can decide to be in the Study or not. You have the right to not answer any question, or to ask us not to take any sample or measurement that you do not want us to take. If you decide not to participate, it will not affect any benefits which you receive now, or may receive in the future.

If you have any further questions about this Study visit, I can try to answer them, or you can call my supervisor at xxx-xxx-xxxx.

**National Children's Study
DRAFT CONSENT VIDEO SCRIPT FOR PREGNANT WOMEN
Based on Script 06-11-2007**

T1-S1

Your neighborhood is one of many communities across the United States that has been chosen to take part in an important research study. It's called the National Children's Study, and its goal is to improve the health and well being of our nation's children.

We're asking you to take part in the National Children's Study for two reasons: first, because you live in a neighborhood that has been selected to take part; and second, because you're pregnant.

Here's more on what the Study is all about.

ALEXANDER: The National Children's Study is our effort to understand one of the great mysteries in pediatrics today: What role does environment play in causing diseases that we don't know the cause of otherwise?

JONES: The study was conceived to look at child development from pre-conception all the way through until they're 21 years old. We have not ever done this.

SCHEIDT: Doctors today need to know about the causes of ongoing epidemics of important childhood diseases such as asthma.

MADDOX: Infant mortality.

CHENG: Obesity.

SCHEIDT: Diabetes.

GUERRA: Any number of risk-taking behaviors.

CHENG: Learning disabilities.

SHANNON: Cardiovascular disease.

SCHEIDT: And even injuries.

MADDOX: We are asking individuals to participate in this study as volunteers.

ALEXANDER: It will involve 100,000 children and families over the course of 21 years.

CHENG: Those 100,000 children will represent 100,000 mothers, 100,000 fathers, aunts and uncles, in communities scattered all across the United States. And from this, we will learn very important lessons about health and about disease.

SCHEIDT: In addition, we will learn how the environment affects our genes and how genes affect children's health and development.

SHANNON: This study is large enough and rigorous enough to answer very important questions and really make a difference in the health of children.

GUERRA: It will give us information and evidence that will provide better explanations and understanding for so many conditions that today are affecting not just an individual or groups of individuals, but entire populations.

MADDOX: It will be a representation of the nation's children, which means that it will include children from all socioeconomic groups and children from all races and ethnic groups.

JONES: As a participant, they're going to tell you a lot about the study. You can go home; you can talk it over with your family members so that everybody knows what this is going to be like.

CHENG: A child's health is very much dependent not only on the child's social and physical environment, but also on how genetics and the environment interact. We're going to learn a lot from the National Children's Study.

T1-S2

The National Children's Study is a partnership between local institutions in your community and three federal agencies. The federal agencies are The National Institute of Child Health and Human Development, which is part of the National Institutes of Health; the U.S. Environmental Protection Agency; and the Centers for Disease Control and Prevention.

T1-S3

This is the local institution in your community.

There is a Study Center with a team of community members, health professionals and others trained to carry out the national study in your local area.

T1-S4

We'd like to tell you more about what's involved, so you can decide whether you want to be in the Study and enroll your child.

This presentation will take about 30 minutes. We'll show you some video and ask you a few questions to make sure that we've explained things clearly.

T2-S1

If you decide to join the Study, we will schedule visits with you and your child, and if it is okay with you, your child's father, to collect information about your health and environment.

At each visit, we will explain exactly what we are going to do, so if there is something you do not want to do, you can tell us. The first visit when you are pregnant will be at your home. Most or all of the other visits during the course of your pregnancy will be at the Study Center.

When you give birth, we will visit you and your baby in the hospital to get information about the birth, to examine your baby, and to take pictures or videos of your child.

When your baby is little, we will visit you and your baby in your home and also invite you to the Study Center. When your child gets a little older, you'll come to the Study Center for visits.

We also might ask you about any places where your child spends a lot of time, like daycare, school, or a grandparent's house. We might also want to visit those places.

Between scheduled visits, we will contact you from time to time. We may ask you some questions on the phone, or may send you questions in the mail or by computer.

Altogether there will be a total of about 15 visits spread out over the 21 years of the Study.

T2-S2

There are several ways we will collect information from you—we'll ask questions, do physical exams, collect samples, collect information from medical records, and take pictures or videos of your child.

First, we'll ask you questions about things that might influence your pregnancy.

We could ask about your medical history, or about the foods you eat, or your thoughts about different topics.

When you are pregnant, we will measure things like your height, weight, and blood pressure, and do one or two ultrasounds to look at the growth of the baby inside. These tests may be in addition to the tests you normally receive from your doctor. If your doctor does an ultrasound, we will want to look at that also.

When you give birth, we'll examine and measure and take pictures of your baby. And as your child grows up, we'll continue to follow your child's health, growth, and development.

We'll also examine you and your child, and do some simple tests. These exams and tests do not replace the regular visits you have with your own doctors.

Finally, we'll want to collect samples from you, your child, and your environment.

Some of the samples we collect—like blood, urine, a vaginal swab, hair, and saliva—will tell us about your health. Other samples—like dirt, air, dust, and water—will help us learn what might affect your health.

Our trained staff will make these collections as easy as possible.

For blood samples, we will use a small needle in your or your child's arm.

For urine samples, we'll give you a plastic container. There's even a special container to collect urine from babies.

For hair samples, we'll ask you for a few hairs from your head and your child's.

And when your baby is born, we will work with your doctor and hospital to obtain a sample of blood from the umbilical cord and a sample of the cord and the afterbirth or placenta.

To test the air in your home, we will leave a device in your home for a few days, and then come back to pick it up.

To test the dust or water in your home, or the soil around your home, we will collect small samples. Some of these samples you'll be able to collect yourself, with a kit, and return to us at the Study Center.

We hope you will want to participate in all parts of the Study, but if you don't want to give certain samples, answer certain questions, or have certain types of exams, that's fine—you can say no, at any time, and for any reason, and you can still be part of the Study.

Ok, let's review...

We want to be sure we've explained the Study as clearly as possible, by pausing to ask a few questions.

T2Q1-Q

Touch the box that best describes:

The length of the National Children's Study

- 1 year
- 10 years
- 21 years

T2Q1-F1

No, the Study will last more than 1 year. Try again.

T2Q1-F2

No, the Study will last more than 10 years. Try again.

T2Q1-F3

Right! If you decide to take part, the Study will follow you through your pregnancy and then you and your child for 21 years. If you decide to join, you can change your mind and stop at any time.

Okay, here's another question:

T2Q2-Q

If you decide to join, your role will be to give the local Study Center information about your health and your environment.

Touch the box that best describes:

Something you will be asked to do

- Take experimental medicines
- Run on a treadmill
- Give samples

T2Q2-F1

No, the Study Center will not ask you to take experimental medicine, although we may ask you about what medicines you take. Try again.

T2Q2-F2

No, you will not have to run on a treadmill, although you may be asked to stand on a scale so that Study staff can weigh you. Try again.

T2Q2-F3

Right! You and your child will be asked to give samples of things like blood and urine from your bodies and dust and water from your home. The Study Center will also ask you questions and do physical exams and tests.

T2Q3-Q

Now touch the box that best describes:

What happens if you don't want to give a sample

- I can still be in the Study
- I will have to leave the Study
- I'm not allowed to say no

T2Q3-F1

Right! You may choose not to give a sample, answer a question, or have a physical exam for any reason, and you can still be in the Study.

Great, now I'm going to explain a little more about the Study.

T2Q3-F2

Not true. If you don't want to give a sample, you can say no and you will not have to leave the Study. Try again.

T2Q3-F3

Not true. You can say no for any reason, and at any time. Try again.

T2-S3

The information you give us will be stored with information from all the other women and children in the Study. Doctors and researchers will use all this information, which they call “data,” to look for patterns or relationships between children's environments and their health. These patterns will give researchers clues about what causes many diseases.

Written data—like your answers to questions and your height measurements—will be stored in computers, and studied by researchers.

The samples we collect from you and your child will be tested.

Some tests will be done right away. Others will be performed at a later date.

Samples will be stored at least for the duration of the entire study so that we can do many other tests.

Right now we can't tell you what all of those future tests might be because science is always improving and new tests are always being developed. But we can tell you that before any new kinds of tests are done on your samples, they'll be evaluated by a Committee of doctors, scientists, and community members, to make sure the tests only relate to child health, growth, and development, or why some children are more likely than others to get diseases when they grow up.

If you decide that you and your child will join the Study and agree to give us samples, you will be allowing us to test those samples both now and in the years ahead.

The Study also plans to look at DNA, or genes, the basic building blocks of our bodies. Doctors know that genes affect the health, growth, and development of children, and that the environment affects how genes work. That is why we plan to analyze the genes of all study participants. As we will explain later, if you agree to participate in the Study, you do not have to agree to this part of the study.

One other aspect of participation is that the Study needs to get information from your medical records when you give birth, because we want to learn how things during your pregnancy and at the time of delivery can affect the health of your child, like the type of delivery or medications that you get at the hospital.

Later, we will want to look at your child's medical records, such as records of doctor and emergency room visits, to learn about your child's health, illness, accidents, injuries, and vaccinations. This kind of information will help us study possible relationships between your environment and your child's health.

Let's try a couple more questions...

T2Q4-Q

If you decide to take part, the Study Center will schedule visits to collect information about your health, your child's health, and environment.

Touch the box that best describes:

Places where you will have visits

- Only in your home
- Only at the Study Center
- In your home and at the Study Center

T2Q4-F1

Not quite. You will have visits in your home, but this is not the only place you'll meet with Study staff. Try again.

T2Q4-F2

Not quite. You will have visits at the Study Center, but this is not the only place you'll meet with Study staff. Try again.

T2Q4-F3

Right! Most visits will be in your home or at the Study Center. You will have about 15 visits over the course of the Study. There will be several while you are pregnant, one when you give birth, and the rest spread out over 21 years.

T2Q5-Q

I want to make sure I was clear about what will happen to blood and urine and other samples if you join the Study.

Touch the box that best describes:

What the Study Center will do with the samples we collect from you and your child

- Test them right away, and then destroy them
- Test some right away, and store the rest for possible future uses
- Store them, but never test them

T2Q5-F1

It's true that your samples and your child's may be tested right away, but they won't be destroyed. Try again.

T2Q5-F2

Right! If you agree to participate in the National Children's Study, researchers will test you and your child's samples, and will also store them for possible future tests. Ok, now that you understand what participation would involve, I'm going to explain some of the risks and benefits of participating in the Study.

T2Q5-F3

Your and your child's samples will be stored, but they will also be tested. Try again.

T3-S1

You might be wondering: What do I get out of all this? What's in it for me?

There may be no direct benefit to you or your family. But the Study could uncover important new medical knowledge that could benefit all of us in the years

to come—maybe even your children and grandchildren. That’s something we think you might feel proud to be a part of.

As the Study unfolds, our scientists will learn a lot about children in general, and why some children are more likely than others to get certain diseases when they grow up. We might learn things like what causes asthma or what contributes to making children do well in school. And, we will share our discoveries with you. We will send out news through newsletters, a Web site, and other means, and we will publish this information in books and magazines.

That’s all about child health and development in general, but we will also give you some information we learn—from the exams we’ve done or from the samples we’ve taken—about you, your child, and your environment. Hopefully, this will keep you better informed about your health and your environment.

We will give you reports about the routine information we are collecting about you and your child. Also, if our research shows something that is medically important *and* that you could do something about, we’ll let you know, so that you can follow up with your doctor.

If you need the help of medical or social services, we can give you names and contact information.

But keep in mind that the Study will not pay for any medical treatment. We will only tell you what we learn, and give you the names of people or agencies that can help you.

T3Q1-Q

Let's go over that one more time...

Touch the box that best describes:

An indirect benefit you will receive if you participate in the Study

- Payment for health care
- Medically important information specific to my family and my environment
- Personal information about other women and children in the Study

T3Q1-F1

No, the Study is not able to pay for your health care. Try again.

T3Q1-F2

Right! If you participate in the National Children's Study, you'll receive news of the Study's discoveries as well as some results of your own and your child's exams. What's more, if we learn of any known dangers, which you could do something about, we will share that information with you too.

T3Q1-F3

No, the Study will not give you any personal information about other people in the Study, and will not share your personal information with anyone else – that information will be kept confidential. Try again.

T4-S1

The risks of this study are very low. It's an observational study, which means we will collect information from you, your child, and other participants over a number of years. This study does *not* include any experimental drugs or medicines.

Let's go over the things that might be a risk or discomfort to you, if you decide to join the Study.

T4-S2

One thing is that you might feel uncomfortable about some of the questions we ask. If so, you can skip those questions. You will be in charge, and you can decide which questions to answer.

T4-S3

Another risk – a very small one – has to do with giving blood samples. People sometimes feel brief pain when blood is taken, and there's a very small risk of infection, bruising, or bleeding. The professionals who will take your blood are trained to make you feel comfortable.

T4-S4

Home visits are likely to take two to three hours, and the visits may be inconvenient. Having to go to the Study Center and having us come to your home

may interfere with your daily routine. Other people living in your home may also be affected by the visits.

To minimize this, we will set up visits at a time that works for you, and we will be happy to change the date or time if you need to.

T4-S5

If you tell us, or we observe, that a child is being abused or neglected, then we must report this to the proper authorities.

T4-S6

As we've said, if any of your tests or samples indicate something that is medically important for you to know about, we'll let you know. Information like that can be beneficial. But it can also be unsettling.

And, because of the information we've shared with you, you might decide to spend money to undergo additional tests, which might not ultimately reveal a significant problem.

T4-S7

We will not share all environmental test results with you, but if any of our tests show known chemical or other kinds of known health hazards in or around your home we'll let you know.

Knowing about a home health hazard can be a good thing, because if you know about it, you may be able to fix it.

But there is also a risk to getting this information. Some federal and state laws require homeowners to tell potential renters or buyers about certain health hazards, like lead or mold. That means if you own your home, and we tell you about a home health hazard, you may be required to report that hazard when you sell or rent your home.

T4-S8

The Study will make every effort to protect the identities of all participants.

We will use a unique number code, and separate your and your child's name—and things that could identify either of you—from the samples and other information you give us. The stored data will only have these code numbers, not names, so that individuals cannot be identified.

The Study's Coordinating Center will store information in a computer database protected by sophisticated security technology. Your data will be combined with data collected from all the participants in the Study—tens of thousands of people. All the information—including yours and your child's—will be confidential and reported only as a group. Specific data about you personally, or about your child, will never be reported in any Study publication.

In addition to taking all these steps to protect your and your child's privacy, there's one more thing we have done.

We have obtained a legal document designed to protect your privacy. The document is called a Certificate of Confidentiality. It will help protect your information from people who are not part of the Study.

Certificates of Confidentiality are intended to assure that the Study researchers cannot be forced to tell anyone who is not connected with the Study—including the courts—about your participation or your personal information, without your written consent.

T4Q1-Q

I'd like to review some things we've discussed.

Touch the box that best describes:

The main reason the National Children's Study is hoping you will volunteer to participate

- Because I will directly benefit
- To help scientists discover new knowledge that can enhance children's health
- To receive health care

T4Q1-F1

No, you are not likely to benefit directly from participation in the study. However, as we've mentioned, there may be some indirect benefits to your family, like hearing from the Study about new discoveries for protecting children's health or being alerted to a known health hazard, if we discover one. Try again.

T4Q1-F2

Right. The main reason to participate in the Study is to know that you are contributing to a landmark effort that will bring benefits to generations of future American children.

T4Q1A-F3

No. Participation in the Study will not affect your health care in any way. You will need to continue receiving health care services in the usual way you have been doing. The Study does not offer health care nor pay for it. Try again.

T4Q2-Q

Now I would like to review some of the risks we just went over.

Touch the box that best describes:

A possible risk of participating in this study.

- I might learn about health risks that might prompt me to spend money on tests that might not ultimately reveal a problem.
- I might learn something about others in the study that would upset me.
- I might have to answer questions I don't want to answer.

T4Q2-F1

Right. Information about health risks can be helpful, particularly if there is something that can be done to correct the problem. But, because of the information we've shared with you, you might decide to spend money on additional tests, which might not ultimately reveal a significant problem.

T4Q2-F2

No, we will never provide you or anyone else with specific information about other individuals in the study. Try again.

T4Q2-F3

You will never have to answer questions you do not wish to answer. You can always tell the interviewer that you want to pass on a question. Try again.

T4Q3-Q

Now touch the box that best describes:

What the Study will do if they learn that a child is being abused or neglected

- Nothing
- Tell the proper authorities
- Make me leave the Study

T4Q3-F1

No, Study team members won't sit by and do nothing. Try again.

T4Q3-F2

Right! If Study team members learn that a child is being abused or neglected, the Study will tell the proper authorities as required by law.

T4Q3-F3

No, you won't have to leave the Study. Try again.

T4Q4-Q

Now touch the box that best describes:

What the Certificate of Confidentiality will do

- Remove your name and personal identifiers from all Study files
- Protect the privacy of your data from people outside the Study
- Prevent the Study from reporting harm or abuse

T4Q4-F1

No, your personal information will be kept on file by the Study. But your name and personal identifiers will be removed from all your data, so the researchers won't know whose data they are looking at. Try again.

T4Q4-F2

Right! The Certificate of Confidentiality will protect your privacy by preventing the government, courts, health insurance agencies, and others not connected with the Study from seeing your personal information.

Good job, we're almost done.

T4Q4-F3

No. If the Study learns that someone is being hurt or is in danger, they are required to report this information no matter what. The Certificate of Confidentiality does not protect against this. Try again.

T5-S1

Let’s talk about payment for your time. We will pay for time spent in Study-related activities, like a home or Study Center visit, and for answering questionnaires. Payments for each activity will be about \$50, depending on the amount of time and effort involved. You will be paid for each completed task, even if you or your child don’t finish the whole study.

T5-S2

From time to time, we will also give you or your child small gifts—like a T-shirt, a tote bag, or a music CD—to thank you for helping us.

T5-S3

You will also be paid for any expenses related to visits to the Study Center—for example, travel expenses or parking.

T6-S1

NARRATOR (V/O)

Finally, we’d like to answer some common questions people have about being part of the Study.

OTHER VOICE

What if I want to leave the Study early?

NARRATOR (V/O)

We hope you will stay in the Study for the entire 21 years, but you or your child can leave the Study at any time without penalty. You can also leave the Study for a short time and then rejoin it. Leaving the Study will not affect your access to health care in any way. The Study also has the right to end your participation at any time.

If you do leave the Study, no new information will be collected from you or your child, but data and samples that have already been collected will continue to be analyzed. If you want us to get rid of any of those samples, you may ask us to destroy them.

T6-S2***[NEW] OTHER VOICE***

When my child gets older will he or she be able to decide whether to continue in the Study?

NARRATOR (V/O)

Yes. Children and adolescents will be asked their permission to continue in the Study. When the children become legal adults (at about age 18 depending on your state law), they will be asked to fully consent for themselves, indicating whether they wish to continue or not.

T6-S3***OTHER VOICE***

What if I move?

NARRATOR (V/O)

We hope you'll tell us if you are planning to move so you can keep working with the Study in your new home. If you move and forget to tell us, we will look for you using the information you've given us about family members and friends, as well as publicly available information about you. If we are able to find you, we will ask you if you want to continue to be in the Study.

T6-S4***OTHER VOICE***

Will it cost me anything to take part in the Study?

NARRATOR (V/O)

No. There is no cost to you—all the tests and procedures related to the Study will be paid for by the Study. Any future tests done on your samples will also be paid for by the Study.

T6-S5***OTHER VOICE***

Does the Study pay for health care for me or my family?

NARRATOR (V/O)

No, the Study is not able to pay for your health care. Study procedures are for research purposes only, and taking part in the Study is not a substitute for your usual visits to the doctor.

T6-S6***OTHER VOICE***

Will data from this study be used in other ways?

NARRATOR (V/O)

Yes. At certain points during the Study we will remove all personal identifiers and create what is called a public use data set—a set of totally anonymous data that scientists and researchers can use to study other things. Anyone outside the Study who uses the public use data will not be able to connect the information to any specific person.

T6-S7***OTHER VOICE***

In addition to the tests the National Children’s Study will do on our samples, would our samples be used in any other way?

NARRATOR (V/O)

It is possible that scientists could create new medicines or health products in the future based on stored study samples. In agreeing to participate in this study, you are also agreeing to allow possible future use of yours and your child’s biological materials for these kinds of purposes.

T6-S8***OTHER VOICE***

If I take part in this study, will I have to be part of other studies?

NARRATOR (V/O)

No. But you may be invited to be in other studies connected with the National Children’s Study. For any other studies, you will be asked for your permission and you can always say “no thanks!”

T7-S1 [NEW]

NARRATOR (V/O)

Here is some additional information for you to look over.

THIS IS WHERE CENTERS MAY INSERT ADDITIONAL INFORMATION AND/OR CENTER-SPECIFIC INFORMATION, SUCH AS CENTER’S POLICY CONCERNING PROVIDING COMPENSATION IN CASE OF INJURY RESULTING FROM PARTICIPATION

C1-S1

NARRATOR (V/O)

The purpose of the Study is to learn how things in the environment affect children’s health, growth, and development. In order to accomplish this goal, we need your permission to obtain personal health information about you and your child.

For example, when your child is born, someone from your local Study Center will look at your medical records for information about your pregnancy and delivery, including all tests and exams, and for information about your child’s birth and health. As the Study continues, the Study Center will collect information about your child’s visits to the doctor or hospital to learn about health, illness, accidents, injuries, and vaccinations.

If you agree to allow us to obtain and use your personal health information and your child’s, you have the right to change your mind and withdraw your permission at any time, by submitting a letter to the Study Coordinator. Once the Study Coordinator has received your withdrawal letter, no new information from your medical records or your child’s will be collected. However, information that has already been collected may still be studied.

C1-S2

Some people feel differently about genetic information than other kinds of information. So we will be asking you specifically to agree to genetic analysis on your and your child’s samples. However, if you do not agree to the genetic aspect of the Study, you can still take part in the rest of the Study.

Some of the genetic analyses we would like to do may be done right away. Others may be done in the future, as the Study learns more, or as new tests and techniques are developed.

Because results of individual tests can be very difficult to interpret, the National Children’s Study will not give genetic information about you or your child to you or to anyone else. In the unlikely case that the Study learns something from this genetic information that is important to your health or your family’s health, *and* if there is something you could do about it, we will tell you that the information is available. In that case, we will give you the option of learning more about it.

C1-S3

Let’s pause now so that you can ask the Study Representative any questions you may have.

In addition, before deciding, you may wish to discuss what you have learned about the National Children’s Study with your family, friends, or your doctor.

If you have more questions about the research or about yours, or your child’s, rights as a research participant, contact any of the following.

C1-S4

Please check one of the boxes below to indicate whether you would like to volunteer to be part of the National Children’s Study:

- I am ready to participate in the National Children’s Study
- I need more time to think about participation in the Study. I’d like to discuss it some more in the future.
- I do not wish to participate in the National Children’s Study.
- Click Next, when you have made your choice.

On the next screen, you will be asked for your signature. If you sign, you are agreeing that both you and your child will participate in a research study. This means that you have completed this informational program about the Study and that you have made this decision voluntarily.

C1-S5

If you are ready to volunteer to be part of the National Children’s Study, you may do so now. By signing below, you are indicating the following:

- I have completed the informational program about the National Children’s Study.
- I understand what is involved, and what the risks and benefits are if my child and I join.
- I understand that I am also giving my permission for the National Children’s Study to obtain and use my personal health information and my child’s.
- I understand that my child and I may leave the Study at any time.
- I have asked and received answers to all my questions about the Study.
- I understand that I may ask further questions at any time and that I will get a paper copy of the consent form for my records.

And, please check one of these two boxes:

- I also give permission to the National Children’s Study to collect and analyze genetic information about me and my child.

- At this time, I do not give permission for the National Children’s Study to collect and analyze genetic information about me and my child.

I voluntarily agree to join the Study, and I give permission for my child to participate in the Study as well.

C1-DEFER

Thank you.

We understand that you have not agreed to participate in the National Children’s Study at this time, but that you are still open to learning more about it in the future.

The Study staff person visiting with you today will talk with you about when we might contact you again.

If you’d like, we can leave you some materials to review yourself or with your family.

C1-DECLINE

Thank you for being willing to hear about the National Children’s Study. We’d very much like to know why you’ve chosen not to participate. Please select any or all of the choices below.

I’m not interested in participating because:

- I don't want to commit to something for 21 years
- I don’t think my husband or boyfriend will want me to do this.
- I don’t think my family will want me to do this.
- I don’t want someone visiting my home

- I don't want the Study to have access to my or my child's personal health information
- I don't want the Study staff to examine me or my child
- I don't want the Study staff to take samples from me or my child
- I don't want the Study staff to take samples from my yard or home environment
- I just don't feel like it
- Or for another reason. Please tell the recruiter, who will record your answer

EARLY_EXIT

You clicked the EXIT button—are you sure you want to exit the program?

CLOSING_OPT-IN

Thanks again!

We are very pleased that you've agreed to participate in the National Children's Study!

CLOSING_OPT-OUT1

Thank you for your time thinking about participation in the National Children's Study!

We look forward to talking with you again in the future.

CLOSING_OPT-OUT2

Thank you for your time thinking about participation in the National Children's Study!



MAKING AN INFORMED CHOICE ABOUT BEING IN THE NATIONAL CHILDREN'S STUDY

Your neighborhood is one of many communities across the United States which has been chosen to take part in an important research study. It is called the National Children's Study, and its goal is to improve the health and well being of our nation's children.

We are asking you to take part in this study for two reasons. First, because you live in a neighborhood that has been selected; and second, because you are pregnant. We are asking you to join thousands of women and their babies from across the United States to learn things that may help many people in the future, even if the information may not help you or your family personally, right now.

Sponsors:

The National Children's Study is a partnership between (LOCAL CENTER) and other local institutions in your community, and is led by the U.S. Department of Health and Human Services through the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the U.S. Environmental Protection Agency (EPA).

Joining the Study is your choice. You can decide not to join. If you do join, we hope you and your child will remain in the study for the full 21 years, but you can leave for any reason at any time.

What is the purpose of the National Children's Study?

The goal of the National Children's Study (NCS) is to improve the health and well being of the nation's children. The Study aims to understand how the environment affects children's health, growth, and development. We also are interested in how the environment interacts with a person's characteristics, such as genes, to prevent disease and promote health.

What kind of study is the National Children's Study?

The NCS is an observational study, which means that we will be collecting information about you and your child, and your child's environment. Studying this information will allow us to find out which things in the environment offer special benefits for child development and which are associated with illness or disease. Observational studies do not involve asking you to change what you normally do. We will not be asking you or your child to try out new drugs or experimental treatments of any kind.

Why is the National Children's Study important?

This is the largest and most detailed study in history to learn about the health and development of children in the United States. We will learn what things in the environment affect whether or not children will develop diseases, both while they are young and also later, when they become adults. Finally, there are new medical conditions that weren't around 30 or 40 years ago, or not at the levels we now see: obesity, diabetes, autism, learning disabilities, to name just a few. The National Children's Study will help us understand why, and what we can do about these problems.

How many people will be in the National Children's Study?

The Study will include about 100,000 women and their babies from all over the United States. Fathers also will be asked to participate. In this area, we expect to study about 1,000 women and their babies.

How long will the National Children's Study last?

We hope you and your child will stay in the Study until your child turns 21 years old. You will start in the Study during your pregnancy, and your child will start when he or she is born.

What is involved in being in the National Children's Study?

We will schedule visits with you and your child, and if it is OK with you, your child's father, to collect information about your health and environment. Some of these visits will take place in your home, and others will be at the Study Center.

The first visit when you are pregnant is at your home. The other visits when you are pregnant will be at the Study Center.

When you give birth, we will visit you and your baby in the hospital or wherever you give birth to get information about the birth and to ask you questions about your plans.

Consent Brochure
T1 Visit

When your baby is little, we will visit you and your baby in your home and also will invite you and your baby to the Study Center. When your child gets a little older, you and your child will come to the Study Center for visits.

We also might ask you about any places where your child spends a lot of time, like daycare, a babysitter's home, a school, or a grandparent's house. We might also want to visit those places.

Between visits, we will contact you from time to time. We may ask you some questions on the telephone, or we may send you questions in the mail or by computer.

How will the National Children's Study collect information?

There are several ways we will collect information: We will ask you questions, ask you to complete forms, do physical exams, collect samples, collect information for medical records, and take pictures and videos of your child.

We may also ask you to keep track of certain things you do—like what you eat.

We also will ask you to obtain some samples of things like urine, or drinking water in your home, or breast milk (if you are breast feeding), and mail them back to us in postage-paid containers that we will provide.

As your child grows older, you also may be asked to complete other types of activities. Before every visit, we will give you details and describe exactly what the visit will involve.

What kinds of information will be collected?

First, we will ask you questions about things that might affect your pregnancy. We will ask about your medical history, the foods you eat, and your thoughts about different topics.

While you are pregnant, we will measure your height, weight, and blood pressure and do one or two ultrasounds that may be in addition to the tests you receive from your doctor. If your doctor does an ultrasound, we will want to look at that as well.

When you give birth, we will examine, measure, and take pictures of your baby. As your child grows up, we will continue to follow your child's health, growth, and development.

We also will examine you and your child, and do some tests. These exams and tests do not replace the regular visits you have with your own doctors.

Finally, we will want to collect biologic samples from you and your child, and samples from your home environment.

The biologic samples we collect—like blood, urine, hair, and saliva—will tell us about your health. The environmental samples—like dirt, air, dust, and drinking water—will help us learn what in the environment might affect your health.

Our trained staff will make these collections as easy as possible for you.

For blood samples, we will use a small needle in your or your child's arm. For urine samples, we will give you a plastic container. There's even a special container to collect urine from babies. For hair samples, we'll ask you for a few hairs from your head and your child's. When your baby is born, we will work with your doctor and hospital to obtain a sample of blood from the umbilical cord and a sample of the cord and the afterbirth or placenta, as well as your baby's first bowel movement.

To test the air in your home, we will leave an air pump in your home for a few days and then come back to pick it up. To test the dust or water in your home, or the soil around your home, we will collect small samples. Some of these samples you'll be able to collect yourself with a kit and return to us at the Study Center.

We hope you will want to participate in all parts of the Study, but if you don't want to give certain samples, answer certain questions, or have certain types of exams, that is fine—you can say no, at any time, and for any reason, and you can still be part of the Study.

How many visits should I expect?

If you become pregnant, there will be several visits while you are pregnant, one when you give birth, and the rest—about 10 or 12 in total—will be spread out over the next 21 years.

Will the Study need access to my medical records and my child's medical records?

Yes, we will want to get information from your medical records when you give birth, because we want to learn how your delivery went.

Later, we will want to look at your child's medical records, such as records of doctor and emergency room visits, to learn about your child's health, illnesses, accidents, injuries, and vaccinations. The Study also may ask your doctors to provide personal health information about you and your child. You will be asked to sign a separate authorization form giving us permission to obtain copies of these types of medical records from your doctor or hospital. This kind of information will help us learn about your child's health.

If you agree to allow us to obtain and use your personal health information and your child's, you have the right to change your mind and withdraw your permission at any time by submitting a letter to the Study Coordinator (whose contact information is presented on page X of this document). Once the Study Coordinator has received your withdrawal letter, no new information from your medical records or your child's will be collected. But information that has already been collected may still be studied.

What will happen to all this information?

The information you give us will be stored with information from all other women and children in the Study. Doctors and researchers will use all this information, which they call "data," to look for patterns or relationships between children's environments and their health.

Written data—like your answers to questions and your height measurements—will be stored on computers. The samples we collect from you and your child will be stored so that they can be tested. We plan to store these samples at least for the 21 years of the study.

Some tests on these samples will be done in a few weeks or months. Other tests will be done years later. Right now, we do not know what all of those future tests might be, because science is always improving and new tests are always being developed. But we can tell you that before any new kinds of tests are done on your samples, they will be evaluated by a Study Committee of doctors, scientists, and community members to make sure the tests only relate to child health, growth, and development, or why some children are more likely to get diseases when they grow up.

If you decide that you and your child will join the Study and you agree to give us samples, you will be allowing us to test those samples both now and in the years ahead.

Will you be obtaining genetic information about me and my child?

Yes, but only if you give us specific permission to do so.

In addition to telling us about your current health, the samples you provide us, like blood or saliva, also can enable us to look at your DNA or genes. Collecting samples that allow us to look at *both* genes *and* the environment is important, because genes affect children's health and development, and the environment affects how genes work. By collecting both genetic and environmental information, the Study will learn a great deal about children's health and development.

Some people feel differently about genetic information than other kinds of information. So we will be asking you specifically to agree to genetic testing on your and your child's samples. However, if you do not agree to the genetic part of the Study, you can still be in the rest of the Study.

We will not be doing the genetic testing until some time in the future, as the Study learns more, or as new tests and techniques are developed.

Because individual genetic results can be very difficult to interpret, the Study will not give genetic information about you or your child to you or to anyone else. In the unlikely case that the Study learns something from this genetic information that is important to your health or your family's health, *and* if there is something you could do about it, we will then tell you that the information is available. In that case, we will give you the option of learning more about it.

What are the possible benefits of being in the National Children's Study?

There may be no direct benefit to you or your family. But the Study could help provide important new medical knowledge that could benefit all of us in the years to come—maybe even your children and grandchildren. That's something we think you might feel proud to be a part of.

However, there may be some indirect benefits. First, we will share some of our findings with you. As the Study goes on, our scientists will learn a lot about children in general, and why some children are more likely than others to get certain diseases when they grow up. We will learn things like what

helps children do well in school and in relationships with other people. We will publish this information in books and magazines. We also will share it with you through newsletters, a Web site, and other means.

We also will give you reports about the routine information we collect about you and your child and your environment. And, if our research shows something that is medically important and that you could do something about, we will let you know, so that you can follow up with your doctor.

If you need the help of medical or social services, we can give you names and contact information. But keep in mind that the Study will not pay for any medical treatment. We only will tell you what we learn and give you the names of people or agencies that can help you.

What are the possible risks or burdens to me and my child from being in the National Children's Study?

The risks of this study are very low. It's an observational study only. It does not include any experimental drugs or medicines or treatments. However, there are some minimal risks and possible discomforts.

You might feel uncomfortable about some of the questions we ask. If so, you can skip those questions. You will be in charge, and you can decide which questions to answer.

But we do hope you will share some private information with us because it is important to make this study successful. We will carefully protect what you tell us. Your data will be linked to a number, not your name, so the people who later look at your answers cannot identify you personally.

Another risk—a very small one—has to do with giving blood samples. People sometimes feel brief pain when blood is taken, and there is a very small risk of infection, bruising, or bleeding. The professionals who will take your blood are trained to make you feel comfortable.

Home visits are likely to take two to three hours, but we will schedule the visits at a time that is good for you. Having to go to the Study Center and having us come to your home may interfere with your daily routine. Other people living in your home also may be affected by the visits. To minimize this, we will schedule visits at a time that works for you, and we will be happy to change the date or time if you need to.

If, during our visits, we learn that you or your child are in danger, or are a danger to yourselves or others, then we must report this to the proper authorities.

As we have said, if any of your tests or samples indicate something that is medically important for you to know about, we will let you know. Information like that can be helpful. But it also can be upsetting to some people. And, because of the information we have shared with you, you might decide to spend money to undergo additional tests, which might not end up finding any problems.

We will not share all results with you, but if any of our tests show chemical or other kinds of known environmental health hazards in or around your home, we will let you know. Knowing about a home environmental health hazard can be a good thing, because if you know about it, you may be able to fix it. But there also is a risk to getting this information. Some federal and state laws require homeowners to tell potential renters or buyers about certain health hazards, like lead or mold. That

means if you own your home and we tell you about a home health hazard, you may be required to report that hazard when you sell or rent your home.

How will my privacy be protected?

The Study will make every effort to protect the identities of all participants. We will use a unique number code and separate your name, your child's name, and other things that could identify either of you from the samples and other information you give us. The stored data will have only these numbers, not names, so that individuals cannot be identified.

The Study will store information in a computer database protected by very effective computer security methods. Your data will be combined with data collected from all the other tens of thousands of people in the Study. All the information, including yours and your child's, will be confidential and reported only as a group. Specific data about you personally or about your child will never be reported in any Study publication.

In addition to taking all these steps to protect your and your child's privacy, there is one more thing we have done. We have obtained a legal document called a Certificate of Confidentiality. This will help protect your information from people who are not part of the Study. Certificates of Confidentiality are intended to assure that the Study researchers cannot be forced to tell anyone who is not connected with the Study—including the courts—about your participation or your personal information without written consent from you. However, if we learn during our visits that you or your child are in danger, or are a danger to yourselves or others, then we must report this to the proper authorities.

Will I be paid for being in the National Children's Study?

We will pay you for time spent in study-related activities, like a home or Study Center visit, and for answering questions. Payments for each set of activities will be about \$50, depending on the amount of time and effort involved. We will pay you for each completed set of activities even if you or your child do not finish the whole study.

You also will be paid for your expenses related to visits to the Study Center—for example, travel expenses or parking.

From time to time, we will also give you or your child small gifts—like a T-shirt, a tote bag, or a music CD—to thank you for helping us.

What if I want to leave the National Children's Study?

We hope you will stay in the Study for the entire 21 years, but you or your child can leave the Study at any time without penalty. You also can leave the Study for a short time and rejoin later. Leaving the Study will not affect your access to health care or your relationship with this institution in any way. The Study also has the right to end your participation at any time.

If you do leave the Study, no new information will be collected from you or your child, but samples and data that already have been collected will continue to be studied. If you want us to get rid of those samples, you may ask us to destroy them by submitting a letter to the Study Coordinator (whose contact information is presented on page X of this document).

When my child gets older, will he or she be able to decide whether to continue in the National Children's Study?

Yes. Young children and adolescents will be asked their permission to continue in the Study. When the children become legal adults (at about age 18 depending on your state law), they will be asked to sign a document themselves, like this one, to indicate whether they wish to continue or not.

What if I move?

We hope you will tell us if you are planning to move, so you can continue to be in the Study in your new home. If you move and forget to tell us, we will try to learn your new address or phone number by using the information you have given us about family members and friends, as well as publicly available information about you. If we are able to find you, we will ask you if you want to continue in the Study.

Will it cost me anything to be in the National Children's Study?

No. There is no cost to you. All tests and activities related to the Study will be paid for by the Study. Any future tests done on your samples will also be paid for by the Study.

Does the National Children's Study pay for health care for me or my family?

No. The Study is not able to pay for your health care. Study activities are for research purposes only, and taking part in the Study does not take the place of your usual visits to the doctor.

Will data from the National Children's Study be used in other ways?

Yes. At certain points in the Study, we will make what is called a public use data set. That data set will not include any information that could identify individual people in the Study. Scientists and researchers can use the public use data sets to try to learn more about children's health. Anyone outside the Study who uses the public use data set will not be able to connect it to a specific person.

In addition to the tests the National Children's Study will do on our samples, will our samples be used in any other way?

It is possible that scientists could create new medicines or health products in the future based on stored study samples. In agreeing to be in this study, you also are agreeing to allow possible future use of your and your child's biological materials for these kinds of purposes.

If I take part in the National Children's Study, will I have to be part of other studies?

No. But you may be invited to be in other studies connected with the National Children's Study. If so, we will ask your permission.

Who can I contact if I have further questions?

Feel free to ask the Study Representative, who has talked to you about being in the Study, any questions you have. Also, if you have any questions about the Study or about your or your child's rights of being in the Study, now or in the future, you may contact any of the following:

National contact:

Local contact #1 (Study coordinator or PI):

Local contact #2 (IRB):

On the next page, you will be asked to indicate your consent to participate and to sign the consent document. Before signing, you may wish to discuss what you have learned about the National Children's Study with your family, friends, or your doctor. Thank you for taking the time to learn about this important Study.

Participant’s Statement

- I have read “Making an Informed Choice About Being in the National Children’s Study.”
- I understand what is involved and what the risks and benefits are if my child and I join the Study.
- I understand that I am also giving my permission for the National Children’s Study to obtain and use my personal health information and my child’s.
- I understand that my child and I may leave the Study at any time.
- I have asked and received answers to all my questions about the Study.
- I understand that I may ask further questions at any time, and that I will receive a copy of this consent form for my records.

I freely choose to be in the National Children’s Study, and I give permission for my child to participate in the Study as well.

- And, please check **one** of these two boxes:
- I also give permission to the National Children’s Study to collect and test genetic information about me and my child.
- At this time, I do not give permission for the National Children’s Study to collect and test genetic information about me and my child.

Printed Name of Participant: _____

Signature of Participant: _____

Date: _____

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____

Date: _____

THANK YOU



OMB #: _____

Expiration Date: _____

Visit Information Card for Pregnancy Visit

When you gave your permission to be part of the National Children's Study (NCS), we told you all about what it means to be in the study. This card tells you more details about what we would like to do at this study visit.

Interview

We will ask you some questions which should take about one hour. The questions will be about such things as your home, the people who live with you, household products you use, whether you have any pets, as well as about your jobs, your activities, your health, your pregnancy, your baby's father and your plans for your child. In the last part of the interview, we will ask to answer some questions using our computer. You can listen to the questions privately using headphones, you can listen without headphones, or you can have the interviewer read the questions to you.

Physical Measures

We also will do the following:

- Measure parts of your body including your arm, head, and the skin on the back of your arm and upper back. You will not have to undress for us to take these measurements.
- Measure your weight, your standing height and your sitting height.
- Measure your blood pressure.
- Give you a report to keep which shows your height, weight, heart rate, and blood pressure.

Biological Specimens

We also will do the following:

- Ask you for a sample of your urine.
- Ask you to collect 3 vaginal swabs. You will do this yourself in complete privacy using cotton swabs.
- Collect less than 2 ounces of your blood using a small needle. Two ounces is approximately four tablespoons.
- Collect a small sample of your hair.
- Give you a kit with straws to collect 6 samples of your saliva over the next 2 days. We will ask you to freeze the samples, and we will collect them when we come back to pick-up some equipment we will leave here.

Your urine and hair may be tested for a variety of environmental exposures. The vaginal swabs may be tested for measures of infection and inflammation. Your saliva may be measured for cortisol, a chemical your body produces when you are under stress. These measures will be done at a later time and you will not receive the results of these tests.

On the same day that we collect your blood, we will test a small sample for hemoglobin and calculate your hematocrit levels. Your hemoglobin and hematocrit results will be sent to you within a few weeks. However, if anything abnormal is found, you will be told sooner. The rest of your blood will be stored for future tests, which may include tests for environmental exposure, hormones, nutrients, and measures of infection and inflammation. You will not receive the results of the tests that may be done in the future.

Environmental Samples

We also will do the following:



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Visit Information Card for Pregnancy Visit

- Test the air in your home for chemicals, metals, and dust using an air pump and air badges. We will leave these in your home for about a week, and then we will come back to pick them up.
- Look at the environment inside and outside your home. If you want to, you can walk with us while they do this.
- Collect dust from the floor of your home that will be tested at a later time for things some people can be allergic to, as well as chemicals and pesticides. We will choose the rooms where we collect the dust using Study rules.
- In some homes, a small amount of water will be collected and tested for chemicals.

You will not receive the results of any of these tests.

Questionnaires and Other Forms for You to Complete

If you have already had an ultrasound done or if you are scheduled to have an ultrasound done soon, you may be asked to read and sign a form before the end of the visit. By signing this form, you will give the Study permission to get a copy of your ultrasound results. If you have not had an ultrasound done and one is not scheduled to be done, we will schedule one for you. The purpose of this ultrasound is to make some measurements of your infant that will provide an estimate of your infant's age.

We also will give you several forms to complete on your own after we leave. These include:

- Two forms about what you eat.
- A Pregnancy Diary to write down the name of medicines you take, any illness you experience, and some types of food you eat, such as fish and nuts.
- A Pregnancy Medical Care Log to keep track of doctor's visits.
- A 3-Day Time and Place Diary for you to make a note of where you spend your time during the week and on the weekend.

At the end of this visit, we will ask you to fill out a short form with a few questions about your thoughts on the information we gave you when we asked for your permission to be in the Study.

We will pick up most of these forms up from you when we return to get the equipment we need to leave here. We will not collect the Pregnancy Diary or the Pregnancy Medical Care Log from you because you will be using those for the entire time you are pregnant. Also, when we return to pick up the environmental equipment, we will ask you to complete a short form about your thoughts on all of the things we did at this visit.

Compensation

After we have completed the interview part of the visit and collected all initial environmental and biological specimens, we will give you \$80 for your time. We also will give you \$20 once we have received the environmental and biologic specimens and the questionnaires and other forms.

We would like to remind you that being in this Study is voluntary. You can decide to be in the Study or not. You have the right to not answer any question, or to ask us not to take any sample or measurement that you do not want us to take. If you decide not to participate, it will not affect any benefits which you receive now, or may receive in the future.

If you have any further questions about this Study visit, I can try to answer them, or you can call my supervisor at xxx-xxx-xxxx.



OMB #: _____

Expiration Date: _____

Visit Information Card for Pregnancy Visit

When you gave your permission to be part of the National Children's Study (NCS), we told you all about what it means to be in the study. This card tells you more details about what we would like to do at this study visit.

Interview

We will ask you some questions which should take about one hour. The questions will be about such things as your home, the people who live with you, any products you use, whether you have any pets, as well as about your jobs, your activities, and your health. In the last part of the interview, you will be asked to answer some questions using our computer. You can listen to the questions privately using headphones, without headphones, or you can have the interviewer read the questions to you.

Physical Measures

We also will do the following:

- Measure parts of your body including your arm, head, and the skin on the back of your arm and upper back. You will not have to undress for us to do this.
- Measure your weight, your standing height, and your sitting height.
- Measure your blood pressure.
- Give you a report to keep which shows your height, weight, heart rate, and blood pressure.

Biological Specimens

We also will do the following:

- Ask you for a sample of your urine.
- Ask you to collect 3 vaginal swabs. You will do this yourself in complete privacy using cotton swabs.
- Collect less than 2 ounces of your blood using a small needle. Two ounces is approximately four tablespoons.
- Collect a small sample of your hair.
- Give you a kit with straws to collect 6 samples of your saliva over the next 2 days. We will ask you to freeze the samples, and we will collect them when we come back to pick up some equipment we will leave here.

Your urine and hair may be tested for a variety of environmental exposures. The vaginal swabs may be tested for measures of infection and inflammation. Your saliva may be measured for cortisol, a chemical your body produces when you are under stress. These measures will be done at a later time and you will not receive the results of these tests.

On the same day that we collect your blood, we will test a small sample for hemoglobin and calculate your hematocrit levels. Your hemoglobin and hematocrit results will be sent to you within a few weeks. However, if anything abnormal is found, you will be told sooner. The rest of your blood will be stored for future tests, which may include tests for environmental exposure, hormones, nutrients, and measures of infection and inflammation. You will not receive the results of the tests that may be done in the future.



OMB #: _____

Expiration Date: _____

Visit Information Card for Pregnancy Visit

Environmental Samples

We also will do the following:

- Test the air in your home for chemicals, metals, and dust using an air pump and air badges. We will leave these in your home for about a week, and then we will return to pick them up.
- Look at the environment inside and outside your home. You can walk with the study staff while they do this, but it is not required.
- Collect dust from the floor of your home that will be tested at a later time for things some people can be allergic to, as well as chemicals and pesticides. The technician will choose the rooms where the dust will be collected using Study guidelines.
- In some homes, a small amount of water will be collected and tested for chemicals.

You will not receive the results of any of these tests.

Questionnaires and Other Forms for You to Complete

If you already have had an ultrasound done or if you are scheduled to have an ultrasound done soon, you may be asked to read and sign a form before the end of the visit. By signing this form, you will give the Study permission to get a copy of the ultrasound results. If you have not had an ultrasound done and one is not scheduled to be done, we will schedule one for you. The purpose of this ultrasound is to make some measurements of your infant that will provide an estimate of your infant's age. The ultrasound will not look for anything out of the ordinary and will not be used to make any diagnoses. The ultrasound is for research purposes only and does not replace a regular visit to your health care provider. You will receive a picture from your baby's ultrasound.

We also will give you two forms to complete on your own after we leave. These include:

- A Pregnancy Diary to write down the name of medicines you take, any illness you experience, and some types of food you eat, such as fish and nuts.
- A Pregnancy Medical Care Log to keep track of doctor's visits.
- A 3-Day Time and Place Diary for you to make a note of where you spend your time during the week and on the weekend.

We will pick up the 3-Day Time and Place Diary from you when we come back to get the equipment we need to leave with you. We will not collect the Pregnancy Medical Care Log or Pregnancy Diary from you because you will be using those for the entire time you are pregnant. Also, when we return to pick up the equipment, we will ask you to complete a short form about your thoughts on all of the things we did at the visit.

Compensation

After we have completed the interview part of the visit and collected all initial environmental and biological specimens, we will give you \$80 for your time. We will also give you \$20 once we have received the environmental and biologic specimens and the questionnaires and other forms.

We would like to remind you that being in this Study is voluntary. You can decide to be in the Study or not. You have the right to not answer any question, or to ask us not to take any sample or measurement that you do not want us to take. If you decide not to participate, it will not affect any benefits which you receive now, or may receive in the future.



OMB #: _____
Expiration Date: _____

Visit Information Card for Pregnancy Visit

If you have any further questions about this Study visit, I can try to answer them, or you can call my supervisor at xxx-xxx-xxxx.



OMB #: _____

Expiration Date: _____

Visit Information Card for Pregnancy Visit

When you gave your permission to be part of the National Children's Study (NCS), we told you all about what it means to be in the study. This card tells you more details about what we would like to do at this study visit.

Physical Measures

We will do an ultrasound to collect measurements of your infant. It will provide information on your child's growth and body composition. The ultrasound will not look for anything out of the ordinary and will not be used to make any diagnoses. The ultrasound is for research purposes only and does not replace a regular visit to your health care provider. You will receive a picture from your baby's ultrasound.

Compensation

You will not receive any cash payments for your participation in this study activity.

We would like to remind you that being in this Study is voluntary. You can decide to be in the Study or not. You have the right to not answer any question, or to ask us not to take any sample or measurement that you do not want us to take. If you decide not to participate, it will not affect any benefits which you receive now or may receive in the future.

If you have any further questions about this Study visit, I can try to answer them, or you can call my supervisor at xxx-xxx-xxxx.



OMB #: _____

Expiration Date: _____

Visit Information Card for Pregnancy Visit

When you gave your permission to be part of the National Children's Study (NCS), we told you all about what it means to be in the study. This card tells you more details about what we would like to do at this study visit.

Interview

We will ask you some questions which should take about one hour. The questions will be about such things as your home, the people who live with you, any products you use, whether you have any pets, as well as about your jobs, your activities, and your health. In the last part of the interview, you will be asked to answer some questions using our computer. You can listen to the questions privately using headphones, you can listen without headphones or you can have the interviewer read the questions to you.

Physical Measures

We also will do the following:

- Measure parts of your body including your arm, and the skin on the back of your arm and upper back. You will not have to undress for us to do this.
- Measure your weight and your blood pressure.
- Give you a report to keep which shows your weight, heart rate, and blood pressure.

In addition, we will do an ultrasound to collect measurements of your infant. It will provide information on your child's growth and body composition. The ultrasound will not look for anything out of the ordinary and will not be used to make any diagnoses. The ultrasound is for research purposes only and does not replace a regular visit to your health care provider. You will receive a picture from your baby's ultrasound.

Biological Specimens

- Prior to this visit, you were given instructions on fasting (not eating or drinking) for purposes of the blood draw. Some measurements are best done on blood samples collected after fasting and we asked you to fast for 9 hours prior to this visit.
- Prior to this visit, you were given a kit with straws in it to collect 6 samples of your saliva and asked to freeze the samples and then bring them with you to this visit.

We also will do the following:

- Collect 2 ounces of your blood using a small needle. Two ounces is approximately four tablespoons. We will provide you with a snack after we have finished collecting your blood sample.
- Ask you for a urine sample.
- Collect a small sample of your hair
- Ask you to collect 3 vaginal swabs. You will do this yourself in complete privacy using cotton swabs.
- Ask you to cut or clip your toenails from all toes on both of your feet.



OMB #: _____

Expiration Date: _____

Visit Information Card for Pregnancy Visit

Your urine, hair, and toenails may be tested for a variety of environmental exposures. The vaginal swabs may be tested for measures of infection and inflammation. Your saliva may be measured for cortisol, a chemical your body produces when you are under stress. These measures will be done at a later time and you will not receive the results of these tests.

On the same day that we collect your blood, we will test a small sample for hemoglobin and calculate your hematocrit levels. Your hemoglobin and hematocrit results will be sent to you within a few weeks. However, if anything abnormal is found, you will be told sooner. The rest of your blood will be stored for future tests, which may include tests for environmental exposure, hormones, nutrients, and measures of infection and inflammation. You will not receive the results of the tests that may be done in the future.

Environmental Samples

We ask that you sample the air and settled dust in your home. We will give you instructions with the sample collection kits and ask that you mail the samples back to us. We will have a lab test the air samples for chemicals and the settled dust will be saved for additional tests later on. You will not receive the results of these tests.

Questionnaires and Other Forms for You to Complete

We will give you several forms to complete on your own after we leave. These include:

- Two forms about what you eat.
- A 3-Day Time and Place Diary for you to make a note of where you spend your time during the week and on the weekend.

We will give you a pre-paid envelope to mail these forms back to us once you are done filling them out.

At the end of this visit, we may ask you to fill out a short form with a few questions about your thoughts on the information we gave you when we asked for your permission to be in the Study. We also will ask you to complete a short form about your thoughts on all the things we did at the visit.

Compensation

After we have completed the interview part of the visit and collected all physical measurements and biological specimens, we will give you \$80 for your time. We also will give you \$20 once we have received the environmental and biologic specimens and the questionnaires and other forms.

We would like to remind you that being in this Study is voluntary. You can decide to be in the Study or not. You have the right to not answer any question, or to ask us not to take any sample or measurement that you do not want us to take. If you decide not to participate there will be no loss of benefits to which you are otherwise entitled.

If you have any further questions about this Study visit, I can try to answer them, or you can call my supervisor at xxx-xxx-xxxx.



OMB #: _____

Expiration Date: _____

Visit Information Card for Pregnancy Visit

When you gave your permission to be part of the National Children's Study (NCS), we told you all about what it means to be in the study. This card tells you more details about what we would like to do at this study visit.

Interview

We will ask you some questions which should take about one hour. The questions will be about such things as your home, the people who live with you, any products you use, whether you have any pets, as well as about your jobs, your activities, and your health. In the last part of the interview, we will ask to answer some questions using our computer. You can listen to the questions privately using headphones, you can listen without headphones, or you can have the interviewer read the questions to you.

Physical Measures

We also will do the following:

- Measure parts of your body including your arm, head, and the skin on the back of your arm and upper back. You will not have to undress for us to take these measurements.
- Measure your weight, your standing height and your sitting height.
- Measure your blood pressure.
- Give you a report to keep which shows your height, weight, heart rate, and blood pressure.

In addition, we will do an ultrasound to collect measurements of your infant. It will provide information on your child's growth and body composition. The ultrasound will not look for anything out of the ordinary and will not be used to make any diagnoses. The ultrasound is for research purposes only and does not replace a regular visit to your health care provider. You will receive a picture from your baby's ultrasound.

Biological Specimens

- Before this visit, you were asked to fast (not eat or drink) so that we could do a blood draw. Some measurements are best done on blood samples collected when you have not had anything to eat or drink for awhile and we asked you to fast for 9 hours prior to this visit.

We also will do the following:

- Ask you for a sample of your urine.
- Ask you to collect 3 vaginal swabs. You will do this yourself in complete privacy using cotton swabs.
- Collect less than 2 ounces of your blood using a small needle. Two ounces is approximately four tablespoons.
- Collect a small sample of your hair.
- Ask you to cut or clip your toenails from all toes on both of your feet.
- Give you a kit with straws in it to collect 6 samples of your saliva over the next 2 days. We will ask you to freeze the samples, and we will collect them when we come back to pick up some equipment we will leave here.

Your urine, hair and toenails may be tested for a variety of environmental exposures. The vaginal swabs may be tested for measures of infection and inflammation. Your saliva may be measured for cortisol, a chemical your body produces when you are under stress. These measures will be done at a later time and you will not receive the results of these tests.



OMB #: _____

Expiration Date: _____

Visit Information Card for Pregnancy Visit

On the same day that we collect your blood, we will test a small sample for hemoglobin and calculate your hematocrit levels. Your hemoglobin and hematocrit results will be sent to you within a few weeks. However, if anything abnormal is found, you will be told sooner. The rest of your blood will be stored for future tests, which may include tests for environmental exposure, hormones, nutrients, and measures of infection and inflammation. You will not receive the results of the tests that may be done in the future.

Environmental Samples

We also will do the following:

- Test the air in your home for chemicals, metals, and dust using an air pump and air badges. We will leave these in your home for about a week, and then we will come back to pick them up.
- Look at the environment inside and outside your home. If you want to, you can walk with us while we do this.
- Collect dust from the floor of your home that will be tested at a later time for things some people can be allergic to, as well as chemicals and pesticides. We will choose the rooms where we collect the dust using Study rules.
- In some homes, a small amount of water will be collected and tested for chemicals.

You will not receive the results of any of these tests.

Questionnaires and Other Forms for You to Complete

If you have already had an ultrasound done or if you are scheduled to have an ultrasound done soon, you may be asked to read and sign a form before the end of the visit. By signing this form, you will give the Study permission to get a copy of your ultrasound results. If you have not had an ultrasound done and one is not scheduled to be done, we will schedule one for you. The purpose of this ultrasound is to make some measurements of your infant that will provide an estimate of your infant's age.

We also will give you two forms to complete on your own after we leave. These include:

- Two forms about what you eat.
- A Pregnancy Diary to write down the name of medicines you take, any illness you experience, and some types of food you eat, such as fish and nuts.
- A Pregnancy Medical Care Log to keep track of doctor's visits.
- A 3-Day Time and Place Diary for you to make a note of where you spend your time during the week and on the weekend.

At the end of this visit, we will ask you to fill out a short form with a few questions about your thoughts on the information we gave you when we asked for your permission to be in the Study.

We will pick up most of these forms up from you when we return to get the equipment we need to leave here. We will not collect the Pregnancy Diary or the Pregnancy Medical Care Log from you because you will be using those for the entire time you are pregnant. Also, when we return to pick up the equipment, we will ask you to complete a short form about your thoughts on all of the things we did at this visit.



OMB #: _____

Expiration Date: _____

Visit Information Card for Pregnancy Visit

Compensation

After we have completed the interview part of the visit and collected all initial environmental and biological specimens, we will give you \$80 for your time. We will also give you \$20 once we have received the environmental and biologic specimens and the questionnaires and other forms.

We would like to remind you that being in this Study is voluntary. You can decide to be in the Study or not. You have the right to not answer any question, or to ask us not to take any sample or measurement that you do not want us to take. If you decide not to participate, it will not affect any benefits which you receive now, or may receive in the future.

If you have any further questions about this Study visit, I can try to answer them, or you can call my supervisor at xxx-xxx-xxxx.



OMB #: _____

Expiration Date: _____

Visit Information Card for Birth Visits

When you gave your permission to be in the National Children's Study (NCS), we told you all about what it means to be in the Study. This card tells you more details about what we would like to do during or around the time your baby is born.

When your baby is born, we will visit you in the hospital to get some information and samples from you and your baby. In order to do that, hospitals, clinics, and birthing centers are working with us, and we will let them know that you are part of the National Children's Study.

Around the Time of Delivery

Biological Specimens—Mother

We will do the following:

- Collect less than 2 ounces of blood from your arm using a small needle. Two ounces is about four tablespoons.
- Collect blood from the umbilical cord. If you have decided to store your cord blood at a cord blood bank, no cord blood will be collected.
- Collect the umbilical cord and the placenta.

Your placenta and the cord blood will be stored for future tests which may include measures of environmental exposure, hormones, nutrients, and measures of infection and inflammation. The umbilical cord and the placenta samples may be tested for chemicals and certain proteins. These measures will be done at a later time and you will not receive the results of these tests.

Before Discharge

If you and your baby go home before we can do all the physical measures or give you the forms to complete on your own, we will call you in a month to set up a time to visit you at your home.

Biological Specimens—Child

Sometime during your stay in the hospital, clinic, or birthing center, and before you leave the hospital, we will collect meconium from your child's diaper. Meconium is your child's first set of bowel movements.

We also will work with the hospital, clinic, or birthing center to collect a small portion of blood from your baby's heel. This is a routine blood collection done at birth.

Your child's meconium and blood will be stored for future tests which may include measures of environmental exposure. These measures will be done at a later time and you will not receive the results of these tests.

Biological Specimens—Mother

If you are planning to nurse, we will give you a breast milk collection kit and a breast pump before you leave and ask you to collect some of your breast milk when your baby is 1 month old. We will ask you to freeze the sample and then mail it to us. We will give you everything you need to pack up the sample and pay for the shipping.



OMB #: _____

Expiration Date: _____

Visit Information Card for Birth Visits

Your breast milk will be stored for future tests which may include measures of environmental exposures, hormones, nutrients, and measures of infection and inflammation.

Physical Measures—Child

Before your discharge, we also will do the following:

- Measure your child's length, weight and head circumference.
- Observe your child's physical condition at birth and take photographs that will later be examined to confirm your child's physical condition. You will not receive the results of this procedure.
- Conduct a developmental examination of your child that looks at newborn muscle tone and skin tone, reflexes, movement, behavior, and responses to sights and sounds. You will not receive the results of this procedure.

Questionnaires and Other Forms for You to Complete

We will update your contact information and give you an Infant Medical Provider Visit Log to keep track of your child's doctor's visits.

Other Activities

At this visit or at a later visit to the hospital, we will make notes from your medical chart about what happened during your delivery and hospital stay.

Compensation

After we have collected the visit specimens and completed the visit activities, you will receive \$20 for your time. We will also give you a small gift for you baby.

We would like to remind you that being in this Study is voluntary. You can decide to be in the Study or not. You have the right to not answer any question, or to ask us not to take any sample or measurement that you do not want us to take. If you decide not to be in the Study, it will not affect any benefits which you receive now, or may receive in the future.

If you have any further questions about these Study activities, I can try to answer them, or you may call my supervisor at xxx-xxx-xxxx.



OMB #: _____

Expiration Date: _____

Visit Information Card for Post Birth Visit

When you gave your permission to be part of the National Children's Study (NCS), we told you all about what it means to be in the study. This card tells you more details about what we would like to do at this study visit.

Interview

We will ask you some questions and give you some activities to do which should take about an hour and fifteen minutes. The questions will be about such things as how you have adjusted to having your new baby, including your stress, amount of sleep, feelings, who cares for your child, how you parent, your baby's behavior, and your family support. We also will ask about your home, the people who live with you, your jobs, your health, any pets you have, products you use around your house, and any medicines your baby takes. We'll also bring some toys with us and ask you to use them while you play with your baby. As you play, we will record you and your baby with a video camera. Finally, we will ask you to do a few activities, such as reading to us, and answering some questions about things you read.

Physical Measures

We also will ask to do the following:

- Measure parts of your baby's body including his or her head, arm, thigh, stomach, and waist, and the skin on the back of his or her arm and upper back.
- Measure your baby's weight, height, and his or her length lying down.
- Look at your baby's skin and take photos of his or her face.
- Give you a report to keep which shows your baby's length lying down and his or her weight.

Biological Specimens

We also will do the following:

- Give you a NCS diaper to collect a sample of your baby's urine during the visit.
- Give you 2 saliva sample collection kits: one for you and one for another adult who spends the most time with your baby. Each person should use only one kit. Each kit has straws in it to collect 6 samples of saliva over the next 2 days. We will ask you to freeze the samples, and we will collect all 12 of them when we come back to pick-up some equipment we will leave here.
- Give you a breast milk collection kit and ask you to collect some of your breast milk, if you are still nursing, some time during the next 5 days. We will ask you to freeze the sample, and we will collect it when we come back to pick up some equipment we will leave here.

Your baby's urine and your breast milk may be tested for a variety of environmental exposures. The saliva may be measured for cortisol, a chemical your body produces when under stress. These tests will be done at a later time and you will not receive the results of these tests.



OMB #: _____

Expiration Date: _____

Visit Information Card for Post Birth Visit

Environmental Samples

We also will do the following:

- Test the air in your home for chemicals, metals, and dust using an air pump and an air badge. We will leave these in your home for about a week, and then we will come back to pick them up.
- Look at the environment inside and outside your home. If you want to, you can walk with us while we do this.
- Collect dust from the floor of your home that will be tested for pesticides at a later time. We will choose the rooms where we collect the dust using Study rules.
- In some homes, a small amount of water will be collected and tested for chemicals.
- Collect dirt from your yard that will be stored and tested at a later time.

You will not receive the results of any of these tests.

Questionnaires and Other Forms for You to Complete

We will also give you several forms to complete on your own after we leave. These include:

- Two forms about what you are feeding your baby.
- A form about your feelings and how you and your husband or partner divide up household work.

(IF APPLICABLE: We also will leave a form for your husband or partner to do on his own after we leave. It has questions about his family background, your relationship, his jobs, his health, his feelings including how he feels about your baby and how he parents.)

We will pick up these forms from you when we return to get the equipment we need to leave here.

Compensation

After we have completed the interview part of the visit and collected all initial environmental and biological specimens, we will give you \$80 for your time. We also will give you \$20 once we have received the environmental specimens and the questionnaires and other forms.

We would like to remind you that being in this Study is voluntary. You can decide to be in the Study or not. You have the right to not answer any question, or to ask us not to take any sample or measurement that you do not want us to take. If you decide not to participate, it will not affect any benefits which you receive now, or may receive in the future.

If you have any further questions about this Study visit, I can try to answer them, or you can call my supervisor at xxx-xxx-xxxx.



OMB #: _____

Expiration Date: _____

Visit Information Card for Post Birth Visit

When you gave your permission to be part of the National Children's Study (NCS), we told you all about what it means to be in the study. This card tells you more details about what we would like to do at this study visit.

Interview

We will ask you some questions and give you and your child some activities to do which should take about an hour and a half. The questions will be about such things as your home, your jobs, any pets you have, the television programs and movies you watch, your financial situation, who cares for your child, how you parent, you and your child's health, words your child understands or says, and any medicines your child takes. We will bring some toys with us to the visit and ask you to play with your child. As you play, we will record you and your child with a video camera. We also will do a series of activities with your child to see how your child communicates, how your child can move his or her body and hold small objects, and the ways your child notices, understands, and remembers things he or she sees or hears.

Physical Measures

We also will ask to do the following:

- Measure parts of your child's body including his or her head, arm, thigh, stomach, and waist, and the skin on the back of his or her arm and upper back.
- Measure your child's weight, height, and his or her length lying down.
- Measure your child's blood pressure.
- Look at your child's skin and take photos of his or her face.
- Give you a report to keep which shows your child's length lying down, height, heart rate, and his or her blood pressure.

Biological Specimens

We also will do the following:

- Give you a NCS diaper to collect a sample your child's urine during the visit.
- Collect less than 2 ounces of your child's blood using a small needle. Two ounces is approximately four tablespoons.
- Collect a small sample of your child's hair.
- Give you a kit to collect 4 samples of your child's saliva over the next 2 days. We will ask you to freeze the samples, and we will collect them when we come back to pick up some equipment we will leave here.

Your child's urine and hair may be tested for a variety of environmental exposures. Your child's saliva may be measured for cortisol, a chemical your child's body produces when he or she is under stress. These measures will be done at a later time and you will not receive the results of these tests.



OMB #: _____

Expiration Date: _____

Visit Information Card for Post Birth Visit

Environmental Samples

We will also do the following:

- Test the air in your home for chemicals, metals, and dust using an air pump and an air badge. We will leave these in your home for about a week, and then we will come back to pick them up.
- Look at the environment inside and outside your home. If you want to, you can walk with us while they do this.
- Collect dust from the floor of your home that will be tested for pesticides at a later time. We will choose the rooms where we collect the dust using Study rules.
- In some homes, a small amount of water will be collected and tested for chemicals.
- Collect dirt from your yard that will be tested at a later time.

You will not receive the results of any of these tests.

Questionnaires and Other Forms for You to Complete

We also will give you several forms to complete on your own after we leave. These include:

- Two forms about what you are feeding your child.
- A form about your relationship with your husband or partner, your personal safety, your stress levels, and your child's feelings and behavior.
- A Child 3-Day Time and Place Diary for you to make a note of where your child spends time during the week and on the weekend.

We will pick up these forms from you when we return to get the equipment we need to leave here.

Compensation

After we have completed the interview part of the visit and collected all initial environmental and biological specimens, we will give you \$80 for your time. We also will give you \$20 once we have received the environmental specimens and the questionnaires and other forms.

We would like to remind you that being in this Study is voluntary. You can decide to be in the Study or not. You have the right to not answer any question, or to ask us not to take any sample or measurement that you do not want us to take. If you decide not to participate, it will not affect any benefits which you receive now, or may receive in the future.

If you have any further questions about this Study visit, I can try to answer them, or you can call my supervisor at xxx-xxx-xxxx.

**National Children's Study
FATHER'S CONSENT TOOL Audio Recording Script
Based on Script 06-11-2007**

T1-S1

As you know, your partner has decided to participate in an important research study to improve the health and well being of our nation's children. It's called the National Children's Study. We're hoping you will agree to join the Study, too. We'd like to give you some information about the Study, so you can decide whether or not you would like to join.

The overall purpose of the study is to help doctors and scientists learn what things in the environment may affect children's health, growth, and development, and what may cause children to develop diseases later when they are adults. To do that, the National Children's Study will be studying mothers and fathers before and during pregnancy and children from the time they are born until they are 21 years old. We will also want to follow the parents of each child because we know that parents are important to the health of their children.

Here's more on what the Study is all about:

T1-S2

The National Children's Study is being conducted as a partnership among local institutions in your community and three federal agencies. The three federal agencies are the National Institute of Child Health and Human Development, which is part of the National Institutes of Health; the Centers for Disease Control and Prevention; and the Environmental Protection Agency.

T1S3

This is the local institution in your community.

There is a Study Center with a team of community members, health professionals, and others trained to carry out the national study in your community.

T2-S1

As the future father of a child in the Study, we're hoping you will become involved. We'd like to visit you once in your home during the pregnancy to ask you some questions...

T2-S2

...to examine you to get body measurements, like height, weight and blood pressure, and to...

T2-S3

... collect blood and urine samples from you.

T2-S4

We'd like to schedule the visit, so that it would occur in the next few weeks, at a time that is good for you.

When we come to your home, we will explain exactly what we're going to do, *and* we will ask you if it's okay to do it.

If there's something you don't want to do, you can skip that part and still be in the Study.

T2-S5

In addition to this home visit, we would also like to stay in touch with you from time to time to ask some questions about your health and your relationship to your child.

We will phone or reach you by mail or computer.

If you feel uncomfortable about any questions we ask, you can skip those questions.

You will be in charge, and you can decide which questions to answer.

You are also free to stop participating in the Study at any time.

T2-S6

The information you give us will be stored with information from all the participants in the Study. Doctors and researchers will use all this information, which they call “data,” to look for patterns or relationships between children’s environments and their health.

These patterns will give researchers clues about what causes many diseases.

Written data—like your answers to questions and your height measurements—will be stored in computers and studied by researchers.

The samples we collect from you will be stored so they can be tested.

T2-S7

Some tests on your samples will be done right away. Others will be performed at a later date. Samples will be stored at least for the duration of the entire study so that we can do many other tests.

Right now we can’t tell you what all of those future tests might be because science is always improving and new tests are always being developed.

But we *can* tell you that before any new kinds of tests are done on your samples, a Committee of doctors, scientists, and community members will make sure the tests relate to child health, growth, and development and to improving our understanding of why some children are more likely to get diseases when they grow up.

If you decide to join the Study and agree to give us samples, you will be allowing us to test those samples both now and in the years ahead.

T2-S8

The Study also plans to look at DNA, or genes, the basic building blocks of our bodies. Doctors know that genes affect the health, growth, and development of children, and that the environment affects how genes work. That is why we hope to analyze the genes of all study participants. As we will explain later, if you agree to participate in the Study, you do not have to agree to this part of the study.

T3-S1

You might be wondering: “What’s in it for me?”

There may be no direct benefit to you or your family. But the Study could uncover important new medical knowledge that could benefit all of us in the years to come—maybe even your children and grandchildren. That’s something we think you might feel proud to be a part of.

As the Study unfolds, our scientists will learn a lot about children in general, and why some children are more likely than others to get certain diseases when they grow up. We might learn things like what causes asthma or what contributes to making children do well in school. We are also likely to learn about what promotes healthy pregnancies and how to reduce miscarriages and premature births.

And, as we make these discoveries, we will share them with you.

T3-S2

We will send out news through newsletters, a Web site, and other means, and we will publish this information in books and magazines.

T3-S3

In addition, if our research shows something that would be medically important for you to know about yourself, and if there is something you could do about it, we'll let you know, so that you can follow up with your doctor.

T4-S1

The risks of this study are very low. It's an observational study, which means that researchers will watch participants over time and do some routine medical exams and take some samples.

The Study does not include any experimental drugs or medicines.

Even though the risks are low, there are some things that might be a risk or discomfort to you, if you decide to join the Study.

T4-S2

People sometimes feel brief pain when blood is taken, and there's a very small risk of infection, bruising, or bleeding. The professionals who will take your blood are trained to make you feel comfortable.

T4-S3

Having us come to your home for a visit may be an inconvenience. The visit may interrupt your daily routine and other people living in your home may also be affected. To minimize this, we will set up the visit at a time that works for you, and we will be happy to change the date or time if you need to.

T4-S4

If we learn that a child is being neglected or abused, then we must report this to the proper authorities.

T4-S5

As we've said, if any of your tests or samples indicate something that is medically important for you to know about, and that you could do something about, we'll let you know. Information like that can be beneficial. But it can also be unsettling. And, because of the information we've shared with you, you might decide to spend money to undergo additional tests, which might not ultimately reveal a significant problem.

T5-S1

Giving personal information to anyone always involves some risk. Therefore this Study will make every effort to protect the identities of all participants.

To protect your personal information, we will:

- Label your samples and other information with a unique number code, so our labs will not know whose samples they are testing
- Separate your number code from your name, address, and other identifying information

T5-S2

- Store your test results and other information in a computer database protected by sophisticated security technology
- Report only group information, not individually identifiable information

T5-S3

In addition to taking all these steps to protect your privacy, we have obtained a legal document, designed to protect the privacy of people who take part in research studies. The document is called a Certificate of Confidentiality. It will help protect your information from people who are not part of the Study.

T5-S4

Certificates of Confidentiality help make sure that the Study researchers cannot be forced to tell anyone who is not connected with the Study—including the courts—about your participation, or your personal information without your written consent.

We have described the steps we will take to protect your confidentiality. We will do everything we can to ensure that your personal health information is never revealed to anyone outside the Study.

T6-S1

We understand that your time is valuable and we appreciate your helping us. The Study will pay you for your time spent during the home visit and for answering future questions. Payment for each task will be about \$50, depending on the amount of time and effort involved.

T7-S1***OTHER VOICE***

What happens to the samples and information I provide?

NARRATOR (V/O)

Data and samples will be stored for at least the duration of the Study. Some will be analyzed right away, but others may not be analyzed until a later time. If you want us to get rid of any of those stored samples, you may ask us to destroy them

T7-S2

OTHER VOICE

Will it cost me anything to take part in the Study?

NARRATOR (V/O)

No. There is no cost to you—all the tests and procedures related to the Study will be paid for by the Study. Any future tests done on your samples will also be paid for by the Study.

T7-S3

OTHER VOICE

Does the Study provide health care for me or my family?

NARRATOR (V/O)

No, the Study is not able to pay for health care. Study procedures are for research purposes only, and taking part in the Study is not a substitute for your usual visits to the doctor. The Study also does not affect your health insurance coverage.

T7-S4

OTHER VOICE

Will data from this study be used in other ways?

NARRATOR (V/O)

Yes. At certain points during the Study we will remove all personal identifiers and create what is called a public use data set—a set of totally anonymous data that scientists and researchers can use to study other things. Anyone outside the Study who uses the public use data will not be able to connect the information to any specific person.

T7-S5

OTHER VOICE

In addition to the tests the National Children’s Study will do on my samples, would these samples be used in any other way?

NARRATOR (V/O)

It is possible that scientists could create new medicines or health products based on stored samples. In agreeing to participate in this study, you are also agreeing to allow possible future use of your biological materials for these kinds of purposes.

T7-S6

OTHER VOICE

If I take part in this study, will I have to be part of other studies?

NARRATOR (V/O)

No. But you may be invited to be in other studies connected with the National Children’s Study. If so, we will ask your permission.

T8-S1

Here is some additional information for you to look over.

C1-S1

Some people feel differently about genetic information than other kinds of information. So we will be asking you specifically to agree to genetic analysis of your samples. However, if you do not agree to the genetic aspect of the Study, you can still take part in the rest of the Study.

Some of the genetic analyses we would like to do may be done right away. Others may be done in the future as the Study learns more or as new tests and techniques are developed.

Because results of individual tests can be very difficult to interpret, the National Children's Study will not give genetic information about you to you or to anyone else. In the unlikely case that the Study learns something from this genetic information that is important to your health or your family's health, *and* if there is something you could do about it, we will tell you that the information is available. In that case, we will give you the option of learning more about it.

C1-S2

Let's pause now so that you can ask the Study Representative any questions you may have.

In addition, before deciding, you may wish to discuss what you have learned about the fathers' part of the National Children's Study with your family, friends, or your doctor.

If you have more questions about the research or about your rights as a research participant, contact any of the following.

C1-S3

Please check one of the boxes below to indicate whether you would like to volunteer to participate in the fathers' part of the National Children's Study:

- I am ready to participate in the fathers' part of the National Children's Study
- I need more time to think about participation in the Study. I'd like to discuss it some more in the future.
- I do not wish to participate in the fathers' part of the National Children's Study.

Click Next when you have made your choice.

On the next screen, you will be asked for your signature. If you sign, you are agreeing to take part in a research study. This means that you have completed this informational program, and you have decided to volunteer to be in the fathers' part of the Study.

C1-S4

If you are ready to volunteer to participate in the fathers' part of the National Children's Study, you may do so now. By signing below, you are indicating the following:

- I have completed the informational program about the fathers' part of the National Children's Study.
- I understand what is involved, and what the risks and benefits are if I join.
- I understand that I may leave the Study at any time.
- I have asked and received answers to all my questions about the Study.
- I understand that I may ask further questions at any time and that I will get a paper copy of the consent form for my records.

And, please check one of these two boxes:

- I also give permission for the National Children’s Study to collect and analyze genetic information about me.
- At this time, I do not give permission for the National Children’s Study to collect and analyze genetic information about me.

I voluntarily agree to participate in the fathers’ part of the National Children’s Study.

C1- DEFER

Thank you.

We understand that you have not agreed to participate in the fathers’ part of the National Children’s Study at this time, but that you are still open to learning more about it in the future.

The Study staff person visiting with you today will talk with you about when we might contact you again.

If you like, we can leave you some materials to review yourself or with your family.

C1- DECLINE

Thank you for being willing to hear about the National Children’s Study. We’d very much like to know why you’ve chosen not to participate. Please select any or all of the choices below.

I’m not interested in participating because:

- I don’t think my wife or girlfriend will want me to do this
- I don’t think other family members will want me to do this
- I don’t want someone visiting me at my home

- I don't want the Study staff to examine me or take samples
- I just don't feel like it
- Or for another reason. Please tell the recruiter, who will record your answer

EARLY_EXIT

You clicked the EXIT button—are you sure you want to exit the program?

CLOSING_OPT-IN

Thanks you!

We are very pleased that you've agreed to participate in the father's part of the National Children's Study!

CLOSING_OPT-OUT1

Thank you for your time thinking about participation in the National Children's Study!

We look forward to talking with you again in the future.

CLOSING_OPT-OUT2

Thank you for your time thinking about participation in the National Children's Study!



OMB #: _____

Expiration Date: _____

Visit Information Card for Father Pregnancy Visit

When you gave your permission to be part of the National Children's Study (NCS), we told you all about what it means to be in the study. This card tells you more details about what we would like to do at this study visit.

Interview

We will ask you some questions which should take about 45 minutes. The questions will be about such things as your home, the people who live with you, your health and any medicines you take, and about your thoughts and feelings.

Physical Measures

We will do the following:

- Measure parts of your body including your arm, hip, and waist, and the skin on the back of your arm and upper back. You will not have to undress for us to do this.
- Measure your weight, your standing height and your sitting height.
- Measure your blood pressure.
- Give you a report to keep which shows your height, weight, body mass index, heart rate, and blood pressure.

Biological Samples

We also will do the following:

- Ask you for a sample of your urine.
- Collect less than 1 ounce of your blood using a small needle. One ounce is approximately two tablespoons.
- Collect a small sample of your hair.
- Ask you to cut or clip your toenails from all toes on both of your feet

Your blood, urine, hair, and nails will be stored and may be tested in the future for a variety of environmental exposures. These measurements will be done at a later time and you will not receive the results of these tests.

Questionnaires and Other Forms for You to Complete

We will give you a questionnaire to fill out yourself about diseases and health conditions that you or your close relatives may have had. We will give you a pre-paid envelope to mail this questionnaire back to us once you are done filling it out.



OMB #: _____

Expiration Date: _____

Visit Information Card for Father Pregnancy Visit

Compensation

After we have completed the interview part of the visit and collected the physical and biological specimens, we will give you \$80 for your time. We also will give you \$20 once we have received the questionnaire from you.

We would like to remind you that being in this Study is voluntary. You can decide to be in the Study or not. You have the right to not answer any question, or to ask us not to take any sample or measurement that you do not want us to take. If you decide not to participate, it will not affect any benefits which you receive now, or may receive in the future.

If you have any further questions about this Study visit, I can try to answer them, or you can call my supervisor at xxx-xxx-xxxx.



OMB #: _____

Expiration Date: _____

Visit Information Card for Father's Post Birth Visit

When you gave your permission to be part of the National Children's Study (NCS), we told you all about what it means to be in the study. This card tells you more details about what we would like to do at this study visit.

Interview

We will ask you some questions and ask you to do some activities. We will bring some toys with us to the visit and ask you use them while you play with your child. As you play, we will record you and your child with a video camera. We also will ask you to do a few activities, such as reading to us and answering some questions about things you read. These activities will take about a half hour. If you have not done it already, we also will ask you to complete an activity that includes answering questions about words or facts you might know, answering riddles, and finding patterns in pictures. This activity, if we do it, also will take a half hour.

Questionnaires and Other Forms for You to Complete

We also will give you a form to do on your own after we leave. The form has questions on it that ask about your relationship with your child's mother, your jobs, the television programs and movies you watch, your health, your feelings about your child, and how you parent.

We will pick up these forms from you when we return to get the equipment we need to leave here.

Compensation

After we have completed the interview part of the visit we will give you \$80 for your time. We also will give you \$20 once we have received the questionnaire we left for you.

We would like to remind you that being in this Study is voluntary. You can decide to be in the Study or not. You have the right to not answer any question, or to ask us not to take any sample or measurement that you do not want us to take. If you decide not to participate, it will not affect any benefits which you receive now, or may receive in the future.

If you have any further questions about this Study visit, I can try to answer them, or you can call my supervisor at xxx-xxx-xxxx.

**AUTHORIZATION TO OBTAIN INFORMATION FROM MEDICAL RECORDS
FOR THE NATIONAL CHILDREN’S STUDY**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE NATIONAL INSTITUTES OF HEALTH**

ULTRASOUND

A.	Provider Name: _____ Street Address: _____ City: _____ State: _____ Zip: _____ Telephone: (____) _____ - _____ <div style="margin-left: 40px; font-size: small;">Area Code</div>
B.	<p>I am voluntarily participating in the National Children’s Study (NCS), a study of the health and development of the nation’s children being conducted by the National Institutes of Health (NIH) of the U.S. Department of Health and Human Services. I authorize and request that you provide the NCS and its contractors with medical information they request about the ultrasound examination services provided to me during my current pregnancy. This authorization form covers any care I received at your facility and from any medical provider associated with your facility or who provided care to me in your facility.</p> <p>I understand that the Health Insurance Portability and Accountability Act of 1996 (HIPAA)⁽¹⁾ prohibits you from releasing my information without my authorization. This form (or a photocopy of this form) gives you my authorization. I have signed this form voluntarily, with the understanding that my decision to sign or not to sign the form will have no effect on my eligibility for treatment, payment, enrollment, or eligibility for any benefits to which I am entitled.</p> <p>I understand that the NIH and its contractors will use this information to supplement the information I have already given for NCS research on the health and development of the nation’s children. I also understand that once my information is released to the study, it is no longer covered by HIPAA but is covered by the Public Health Service Act⁽²⁾, which prohibits the release of information that would identify me or my medical providers outside the sponsoring agency and its contractors without my permission or that of my medical providers.</p> <p>I authorize the study to use information I have given in the survey to help you identify my records. I also understand that I can revoke this authorization at any time by contacting a study representative in writing or by telephone. Otherwise, this authorization expires 30 months from the date of signature.</p>
C.	1. Patient Name (first, middle, last): _____ 2. Date of Birth _____ / _____ / _____ <div style="margin-left: 40px; font-size: small;">Month Day Year</div> 3. Other Names Under Which Records May be Filed _____
D.	4. _____ <div style="margin-left: 40px; font-size: small;">Patient’s Signature—14 and over sign</div> 5. Date Signed _____ <p align="center">IF PATIENT IS AGE 14 TO 17, BOTH PATIENT AND PARENT/GUARDIAN MUST SIGN AND DATE.</p>
E.	6. _____ <div style="margin-left: 40px; font-size: small;">Parent, Guardian, Witness or Proxy’s Signature</div> 7. Date Signed _____ 8. _____ <div style="margin-left: 40px; font-size: small;">Signer’s Relationship to Patient</div> 9. Reason for Parent, Guardian, Witness or Proxy’s Signature: <input type="checkbox"/> Patient 13 or Younger <input type="checkbox"/> Patient Disabled <input type="checkbox"/> Patient 14-17 Years Old <input type="checkbox"/> Patient Deceased

FIELD USE ONLY: ID: _____ PROVID: _____ PID: _____

(1) Health Insurance Portability and Accountability Act: 42 U.S.C. 1320d-2 and 1320d-4 and the implementing regulation, 45 CFR 164.508, require a detailed authorization for your health care provider to disclose health information from your records for research purposes.
 (2) Public Health Service (PHS) Act: 42 U.S.C. 242m(d) protects the confidentiality of data collected under the research authorities of the National Institutes of Health. The National Children’s Study will be carried out in compliance with these provisions as well as those in the Children’s Health Act of 2000 (Public Law 106-310 Sec. 1004).

AUTHORIZATION TO OBTAIN BODILY FLUIDS, TISSUES, AND INFORMATION FROM MEDICAL RECORDS FOR THE NATIONAL CHILDREN'S STUDY

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE NATIONAL INSTITUTES OF HEALTH**

BIRTH

A.	Provider Name: _____ Street Address: _____ City: _____ State: _____ Zip: _____ Telephone: (____) _____ - _____ <div style="margin-left: 40px;">Area Code</div>		
B.	<p>I am voluntarily participating in the National Children's Study (NCS), a study of the health and development of the nation's children being conducted by the National Institutes of Health (NIH) of the U.S. Department of Health and Human Services. I authorize and request that you provide the NCS and its contractors with medical information they request about the labor and delivery services, and perinatal services, including treatment, testing, and test results provided to me and my child during and following my current pregnancy. I also authorize the NCS and its contractors to obtain and/or collect my urine and blood, as well as my child's blood, umbilical cord, umbilical cord blood, placenta, and meconium. This authorization form covers any care I or my child received at your facility, and from any medical provider associated with your facility or who provided care to me or my child in your facility.</p> <p>I understand that the Health Insurance Portability and Accountability Act of 1996 (HIPAA)⁽¹⁾ prohibits you from releasing my information without my authorization. This form (or a photocopy of this form) gives you my authorization. I have signed this form voluntarily, with the understanding that my decision to sign or not to sign the form will have no effect on my eligibility for treatment, payment, enrollment, or eligibility for any benefits to which I am entitled.</p> <p>I understand that the NIH and its contractors will use this information to supplement the information I have already given for NCS research on the health and development of the nation's children. I also understand that once my information is released to the study, it is no longer covered by HIPAA but is covered by the Public Health Service Act⁽²⁾, which prohibits the release of information that would identify me or my medical providers outside the sponsoring agency and its contractors without my permission or that of my medical providers.</p> <p>I authorize the study to use information I have given in the survey to help you identify my records. I also understand that I can revoke this authorization at any time by contacting a study representative in writing or by telephone. Otherwise, this authorization expires 30 months from the date of signature.</p>		
C.	1. Patient Name (first, middle, last): _____ 2. Date of Birth _____ / _____ / _____ <div style="margin-left: 40px;">Month Day Year</div> 3. Other Names Under Which Records May be Filed _____		
D.	4. _____ Patient's Signature—14 and over sign 5. Date Signed _____ <p style="text-align: center;">IF PATIENT IS AGE 14 TO 17, BOTH PATIENT AND PARENT/GUARDIAN MUST SIGN AND DATE.</p>		
E.	6. _____ Parent, Guardian, Witness or Proxy's Signature 7. Date Signed _____ 8. _____ Signer's Relationship to Patient 9. Reason for Parent, Guardian, Witness or Proxy's Signature: <input type="checkbox"/> Patient 13 or Younger <input type="checkbox"/> Patient Disabled <input type="checkbox"/> Patient 14-17 Years Old <input type="checkbox"/> Patient Deceased		

FIELD USE ONLY: ID: _____ PROVIDID: _____ PID: _____

(1) Health Insurance Portability and Accountability Act: 42 U.S.C. 1320d-2 and 1320d-4 and the implementing regulation, 45 CFR 164.508, require a detailed authorization for your health care provider to disclose health information from your records for research purposes.
 (2) Public Health Service (PHS) Act: 42 U.S.C. 242m(d) protects the confidentiality of data collected under the research authorities of the National Institutes of Health. The National Children's Study will be carried out in compliance with these provisions as well as those in the Children's Health Act of 2000 (Public Law 106-310 Sec. 1004).

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Appendix B.2

Materials for Gaining Cooperation

Household Advance Letter

Dear Neighbor,

Do you ever wonder what it takes to have a child grow up healthy? What is it about the way we live that keeps so many children from enjoying healthy lives? Many children today suffer from asthma, obesity, diabetes, and other health problems.

(LOCAL CENTER) has joined the National Institutes of Health (NIH) to conduct the largest and most ambitious research study of children's health ever to be done in the United States. The study is called the "National Children's Study," or NCS. Results from the study will improve the health and well being of children for many years to come.

Your community, along with 104 other communities across the United States, has been selected to take part. Soon, a staff member from (LOCAL CENTER) will be in your neighborhood to see if you or anyone in your household may be eligible to participate.

We really need your help. Even if there are no children living with you, or if no one is planning to become pregnant, we still would like to ask an adult in your household a few questions to see if anyone is eligible for the study. This will take only about 5 minutes. If anyone in your household is eligible, we will ask to speak with that person to get some additional information.

We hope you will join us in our effort to improve our children's health, but your participation is voluntary. If you decide not to participate, it will not affect any benefits which you receive now or may receive in the future. The information you give will be kept private and is protected by law.

If you have any questions about NCS, please call our toll-free number (xxx-xxx-xxxx) or visit the NCS website at <http://www.nationalchildrensstudy.gov>.

Thank you in advance for helping us to learn more about the health and wellbeing of our nation's children.

Sincerely,

Local investigator

Enclosure: Study Brochure

M

ost children born today grow up healthy and live longer than ever before. But the rates of asthma, diabetes, autism, and other health problems in many children are on the rise. We still have many questions about how children's environments—the air they breathe, the water they drink, and the communities they live in—affect their health and well being into adulthood.

With the help of communities and individuals like you from across the country, the National Children's Study hopes to find the answers to these questions among many others, and to use the answers to improve the health of children for years to come.

How does pollution in the environment affect our children's health?

Can asthma in children be prevented?

What is the long-term impact of playing video games on a child's development?

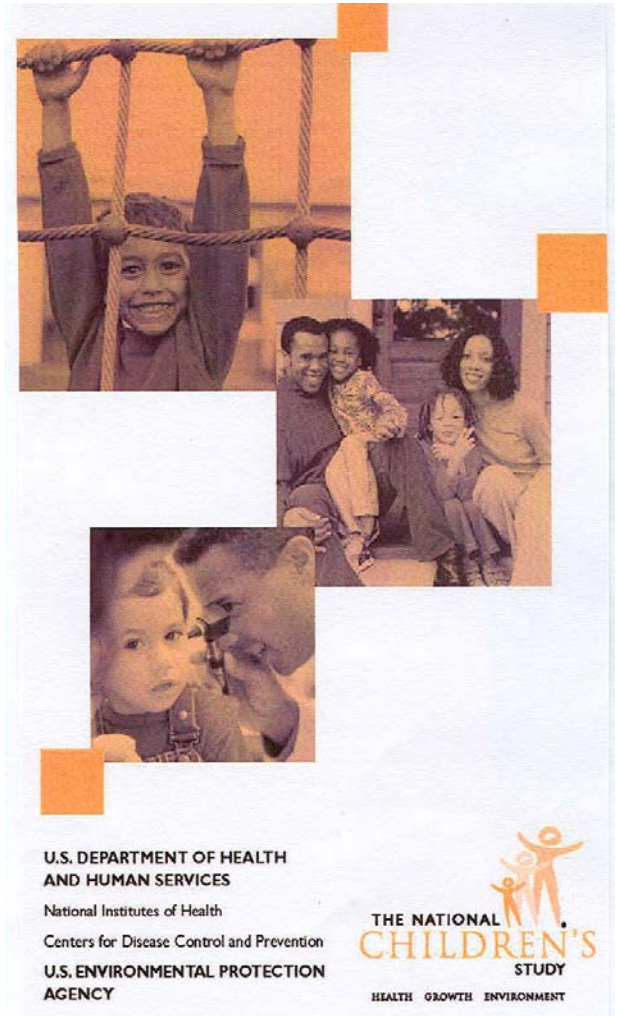
To learn more about the National Children's Study (NCS), please contact:

(CONTACT INFORMATION FOR LOCAL SITE)

or visit the NCS website at:

<http://www.nationalchildrensstudy.gov>

THE NATIONAL CHILDREN'S STUDY



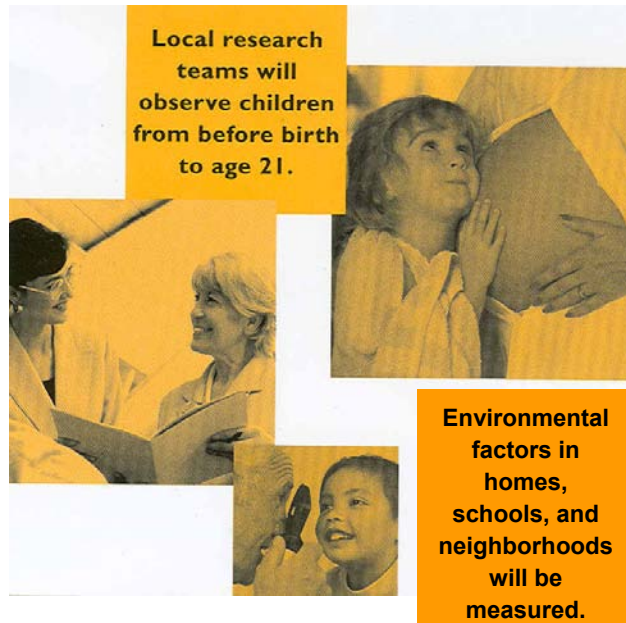
What is the National Children’s Study?

The National Children’s Study (NCS) is the largest research study ever conducted in the United States to look at the effects of the environment on children’s health and development. The Study is authorized by the Children’s Health Act of 2000, and will collect information on 100,000 children from before birth through age 21.

For the NCS, “environment” includes air, water, and soil, as well as what children eat, how they are cared for, the safety of their neighborhoods, and their health care.

The Study will look at some of the most important health issues of our time, including:

- Birth defects and other pregnancy-related problems
- Injuries
- Asthma
- Obesity and diabetes
- Behavior, learning, and mental health



How will the Study be conducted?

Across the country, selected areas in 105 counties have been scientifically chosen to represent the United States. Women in these areas who are pregnant or who may become pregnant will be eligible for enrollment in the NCS. All homes in selected neighborhoods will be visited by local Study staff to identify women who may be eligible to enroll. Study teams also will work with doctors, nurses, community leaders, and local public health workers to help recruit eligible women.

What will participants be asked to do?

Even if there are no children living with you, or if no one is planning to become pregnant, we would like to ask an adult in your household a few questions to see if anyone is eligible for the Study. This short interview should only take about 5 minutes. Then, each eligible woman will be asked to answer a few more detailed screening questions. Depending on the information that is provided, a small number of women will be invited to enroll in the Study.

During the first phase of the Study, participation will include interviews, collection of samples such as blood and urine, simple physical measures such as weight and blood pressure, and collection of samples from the environment such as air, water, dust, or soil. No medicines or treatments will be provided. When babies are



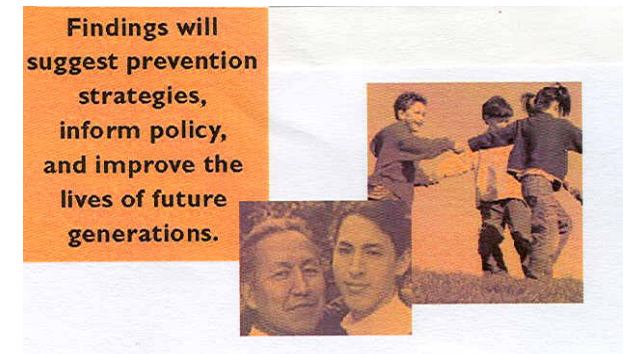
born to women enrolled in the Study, information also will be collected about the baby.

Why is participation so important?

Everyone’s cooperation will ensure that the NCS fairly represents all of America’s children. Participation is voluntary, but we hope that all women who are invited will consider joining. If anyone decides not to participate, it will not affect any benefits to which they may otherwise be entitled.

Will information be kept confidential?

All information will be kept private and confidential and used only for research purposes. NCS has obtained a Certificate of Confidentiality from the National Institutes of Health, which helps to protect privacy. The Privacy Act of 1974 (USC 552a) requires the safeguarding of individuals against invasion of privacy.



HOUSEHOLD COOPERATION LETTER

Dear Neighbor,

We recently visited your home to talk about the National Children's Study. This research study is the largest and most important research study of children's health ever to be done in the United States. Communities all across the country have been scientifically selected to be part of this study. Because of the way the research is designed, we cannot replace your household with another.

We really need your help. Even if there are no children living with you, or no one is planning to become pregnant, we still would like to ask an adult in your household a few questions to see if anyone is eligible for the study. This will take only about 5 minutes.

I have asked one of our study team members to contact your household again soon. We hope you will consider taking just a few minutes to talk to her. All information you provide will be kept private and confidential and used for research purposes only. Your participation is voluntary. If you decide not to participate, it will not affect any benefits you may be receiving.

Thanks in advance for your help with the National Children's Study. Results from the study will give us the chance to improve children's health for many years to come.

Sincerely,

Local Investigator

Pregnancy Screener Cooperation Letter

Dear Neighbor,

We recently visited your home to talk about the National Children's Study. This research study is the largest and most important study of children's health ever to be done in the United States. A carefully designed scientific process has been used to select communities across the country to be part of this study. Therefore, women living in these communities cannot be replaced with anyone else.

We really need your help. Even if you do not have any children, or if you are not planning to have children, we still would like to ask you a few questions for the study. This will take only about 5 minutes.

I have asked one of our study team members to contact you again soon. We hope you will consider taking just a few minutes to talk to her. All information you provide will be kept private and confidential, and used for research purposes only. Your participation is voluntary. If you decide not to participate, it will not affect any benefits you may receive now or in the future.

Thanks in advance for your help with the National Children's Study. Results from the study will give us the chance to improve children's health for many years to come.

Sincerely,

Local Investigator

Appointment Reminder Letter

[VC Name & Address]

[Date]

[Participant Name &
Address]

Dear [PARTICIPANT NAME]:

This is to remind you about your upcoming appointment for the National Children's Study. (You/You and your child) are scheduled for an appointment (in your home/at the [VC NAME]'s clinic:/at the [NAME OF CLINIC, HOSPITAL, DR. OFFICE]) on:

Date:

Time:

Place:

If you have any questions about this appointment, or if you need to reschedule, please call our office at (VC TELEPHONE NUMBER).

Thanks for being part of the National Children's Study! We look forward to seeing you soon.

Sincerely yours,

(VC Signature)