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.

Due to 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 January 2009 for the first group of PSUs in the pilot, and in April 2009 for the second group 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
- 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 booklet 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 multi-page consent booklet.

However, the video may also 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 over 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 review the booklet with respondents. (If the respondent indicates a preference for reading the consent booklet on her own, the interviewer does not have to review it 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 multi-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.

Upon arrival, the interviewer who conducts the consent process will reintroduce herself, if necessary, answer any questions the respondent may have and then get verbal consent to continue 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. In both conditions, the detailed information about each component of data collection for the visit is given on the "Visit Information Card" or VIC at the time of the first interview.

General Study Design

The consent study only includes English and Spanish speaking women in their first trimester of pregnancy as identified in the pregnancy screener. Under the current protocol for the first few months of the enrollment period, the consent process will either occur at the same visit as the pregnancy screener or as its own visit. The TI interview component will initiate about 3 months after enrollment begins, so at that point the consent process may be coupled with the pregnancy screener, the T1 visit, or occur as its own visit. The evaluation does not include women who are not pregnant at the time of the screening interview since they complete slightly different consent materials.

Table 1 shows the estimated number of consent opportunities anticipated by February through September 2009 in the pilot areas for women identified as in their first trimester in the screening interview. Analysis will be completed by February 2010, and decisions on the method of consent for the Main Study will be available in April 2010.

Table 1: The estimated number of consent opportunities in each condition, cumulating across months in 2009.

Month (in 2009)	Total Video Consent	Total Booklet Consent
February	18	18
March	40	40
April	105	105
May	175	175
June	235	235
July	300	300
August	345	345
September	375	375

Analysis of the consent methods will use all data collected through September in order to maximize the amount of data available for analysis, about 375 cases in each condition. Table two 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 90% confidence interval will ultimately be larger when reflecting the impact of clustering. Thus, the small number of cases will only result 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
July	50%	38.3%	11.7%
August	50%	39.1%	10.9%
September	50%	39.6%	10.4%

As indicated above, respondents will be randomly assigned to condition, though assignment occurs at an address level rather than a person level. Thus all women eligible for a T1-first interview living in the same household will receive the same treatment.

In addition to measuring whether the two consent conditions impact enrollment differentially, the study will also 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.

Women who complete the consent process and decide to enroll receive a two part evaluation questionnaire. The first part includes questions that collect feedback on format and presentation of the consent materials, as well as general attitude information about the study. We refer to this as the Part 1 Consent questionnaire. Interviewers ask respondents to complete the Part 1 questionnaire at the same visit they complete the consent process. The Part 2 questionnaire includes a short set of questions to assess comprehension in regards to several critical components of informed consent (i.e., scientific purpose of the research, voluntary nature, risks with participating, benefits of participating). Interviewers will ask respondents to complete the Part 2 questionnaire at the end of the portion of the T1 visit during which the interview occurred. We separated the evaluation into two components with the intention of delaying the amount of time between the actual administration of consent and the assessment of comprehension. The delay should diminish the chance that the women in the video condition respond to the evaluation questions based on memory of the questions in the video rather than an actual understanding of the study to which they are providing consent. We take this precaution because even though the wording of the evaluation questions is not the exact same as the wording used in the questions embedded within the video, the questions are similar.

The IMS will keep track of the dates on which the respondent completes each questionnaire so the analysis can account for differences in time between the actual consent visit and when the respondent completed the questionnaires. The questionnaires contain essentially the same questions for both the video and booklet conditions, with only slight wording differences necessary to reflect the appropriate video or booklet mode of administration. (Appendices A.2.1.g, pages 1-4).

Respondents who decide not to enroll in the study after reviewing at least some portion of the consent materials will also complete an evaluation questionnaire for their condition, but the questionnaires for non-enrolled women are shorter, and there is only one part. Rather than asking details about the consent materials she reviewed, the non-enrolled version includes questions to assess how much of the consent process she completed, why she chose not to participate in the study as well as an additional opinion question about the study in general. Women who enroll in the study also answer the same general opinion question about the study but not as part of the consent evaluation questionnaires. (Appendices A.2.1.g, pages 5-8).

In general, regardless of the consent condition, all respondents will complete a self-administered paper questionnaire collecting feedback on their consent process and for those who enroll, their understanding of the consent information. 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. *Answers collected at the T1 visit will assess initial comprehension. Answers collected at the end of the T3 visit will assess knowledge retention.* (Statistical) comparison of mean score for comprehension by consent group.
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.
6.	Do the respondents' attitudes about the survey topic and objective provide a mediating influence on any observed differences in enrollment by method of consent?	By condition, measure correlation between enrollment and responses to attitude questions

The evaluation may also 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/difficulty of implementing the two different consent processes.

Video script to follow.

Video Script for General Consent content will be based on the Hard-Copy General Consent booklet.

OMB #: 0925-xxxx
Expiration Date: xx/xxxx

THE NATIONAL CHILDREN'S STUDY

HEALTH GROWTH ENVIRONMENT

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 by chance 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 need both pregnant women, and women who are not pregnant, to volunteer to be part of this study. Things around you now, like the air you breathe and the water you drink, might influence the health and development of your children or future children, if you get pregnant. We are asking you to join thousands of women from across the United States to learn things that may help many people. This information may help in the future, although it may not help you or your family, right now.

Joining the study is your choice. You can decide not to join. If you do join, you can leave for any reason at any time. And you can refuse to answer any question.

Sponsors:

The National Children's Study is a partnership between local organizations in your community, and four Federal agencies. The Federal agencies are the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the National Institute of Environmental Health Sciences (both are part of the National Institutes of Health), the U.S. Environmental Protection Agency (EPA), and the Centers for Disease Control and Prevention (CDC).

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 will help researchers understand how the social and physical environment affects children's health, growth, and development. The study is also interested in how the environment acts together 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 National Children's Study is an observational study. Observational studies do not involve asking you to change what you normally do. We will be collecting information about you, and if you are or become pregnant, your child and your child's environment. We will not be asking you or your child to take any medicines or drugs.

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. The study will learn what things in the social and physical environment affect whether or not children will develop diseases, both while they are young and also later, when they become adults. Finally, there are medical conditions in children that weren't around 30 or 40 years ago, or were not at the levels we see now. These include obesity, diabetes, autism, learning disabilities, and cardiovascular disease to name just a few. The National Children's Study will help us understand why this is happening and what we can do about these conditions and others like infant morality and injuries.

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.

How long will the National Children's Study last?

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.

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

If you decide to join the study, we will come to your home to collect information about you, your health and your environment**.** We will also contact you from time to time by phone, mail or computer to ask you a few questions. If it is okay with you, we will ask the child's father to participate in the study, too.

How will the National Children's Study collect information?

There are several ways the study will collect information. We will ask you questions and ask you to complete forms. We will do physical exams and collect biological and environmental samples. We may also ask you to keep track of certain things, like what you eat. We will ask you to collect some samples yourself.

What kinds of information will be collected?

If you decide to join the study, we will come to your home to collect information about you, your health, and your environment. During the visit, we'd also like to examine you to get body measurements, like height, weight and blood pressure.

We will collect samples from you like blood, hair and saliva, and ask you to collect a sample of your urine and your vaginal fluid. We will also collect samples from your home like air, dust, and water.

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.

How many visits should I expect?

If you are not pregnant, we will visit you once. We will also contact you from time to time by phone, mail or computer to ask you a few questions.

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.

And if you are or become pregnant, we will visit you more often. Altogether, there are about 15 visits spread out over the 21 years of the study. There will be a few visits while you are pregnant, and a visit when you give birth. There will be a few visits after you give birth, and then, as your child grows older, there will be one visit about every two years.

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

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 can change your mind and withdraw your permission at any time. Then, no new information from your medical records 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 the other women in the study. Doctors and researchers will use all this information to look for patterns or relationships between environment and health. These patterns will help researchers better understand the causes for many diseases.

Some tests on your samples will be done right away. If we know the results from tests done during a visit, we will give them to you during that same visit. But there are other tests that we will conduct that we cannot interpret right away. And, most of the samples we collect from you will be tested some time in the future using state-of-the-art technologies. Many of those tests may help us understand more about science someday, but won't be able to tell us about people's health right now. This is why some test results will not be given to you. But we will always tell you during a visit which results we will give you and which results we will not.

Samples will be stored for at least the duration of the study, so we can do many other tests. Right now, we don't know what all of those future tests might be, because science is always improving and new tests are always being developed. But we do know 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 are young and 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.

How will my privacy be protected?

The potential loss of confidentiality is a risk to being in the study. We have taken steps 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.
- Separate your number code from your name and address after your responses are collected and processed. Researchers will study data with the number code but not your name and address.
- Store your test results and other electronic information in a computer database protected by advanced security technology and statistical procedures.
- Store your biologic, environmental and other forms of information in a secure research facility. Access to this facility will be monitored.
- Require researchers to ask permission to examine highly confidential study information. Applications will be reviewed by experts to determine if researchers can protect your data.
- Monitor researchers studying sensitive information to make sure that they are protecting your data in the way they promised.
- Require researchers using your data to sign affidavits of nondisclosure. This means that researchers must promise to use the information you provide for scientific

purposes only, and to not give information to anyone else who has not made this promise.
- Require researchers to report only group information, not individually-identifiable information, from the data you provide.
- Review these steps over time to improve the ways in which we protect information that could be used to identify you.

We have obtained a legal document from the U.S. Department of Health and Human Services (DHHS) that is 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.

With this Certificate, we cannot be forced, for example by court order or subpoena, to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. But if there is an audit or evaluation of the study by staff of the DHHS, it may be necessary to disclose information to those staff. You should understand that a Certificate of Confidentiality does not prevent you, as provider of permission for yourself to participate in the Study, from voluntarily releasing information about yourself or your involvement in this study. So if an insurer, employer, or another party learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that in addition to our efforts, you and your family must also actively protect your own privacy.

Also, you should understand that we will take actions necessary under federal or local law, including reporting to authorities, to prevent serious harm to yourself, your child or others such as in cases of child abuse or neglect that we find out about or observe. The Certificate of Confidentiality does not stop the reporting of child abuse or neglect.

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

Yes, your genetic information comes from your family history and some samples, like blood. The study plans to look at DNA, or genes, the basic building blocks of our bodies, because doctors know that genes affect the health and development of children, and that the social and physical environment affects how genes work. That is why we hope to study the genes of all people in the study.

Some people have concerns about use of their genetic information. As a result, the National Children's Study will take the steps I described earlier to protect all of your information, including your genetic information.

Also, some people are sensitive about genetic information for cultural or religious reasons. If you don't want to be in the genetics part of the study, you should let us know, and you can still be in the rest of the study.

Sometimes doctors and scientists cannot interpret the meaning of new research results. As a result, the National Children's Study will not give genetic results to you.

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 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 are young and when they grow up. We might learn things like what causes asthma or what helps children do well in school. We are also likely to learn about what promotes healthy pregnancies and how to reduce miscarriages and premature births. As we make these discoveries, we will share them with you.

We will send out news through newsletters, a web site, and other ways. We will also put this information in books and magazines.

In addition to general health news, we will also give you some specific information about you. We will give you reports about some of the information we are collecting, like height, weight and blood pressure.

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 give you names of people and 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. The study does not include taking any medicines or drugs. There are some things that might be a risk or discomfort to you, if you decide to join the study.

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.

The potential loss of confidentiality is a risk to being in the study. We will take many steps to protect the information you provide that could be used to identify you. We will continue to review these procedures to improve the ways we protect your data over time.

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.

The home visit is likely to take two to three hours at a time convenient to you. But having us come to your home may interrupt your daily routine. 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.

If you tell us or we see that a child is being abused or neglected, or we learn that you 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 understand that your time is valuable and we appreciate your helping us. The study will pay you in appreciation of your time spent during the home visit when someone from the Study Center comes to ask you questions and take samples. Payment for visits will be about $25 to $100, depending on the amount of time and effort involved.

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.

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

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 or any other benefits you may be receiving. 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, 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.

What if I move?

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.

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

No. There is no cost to you. All 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.

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 procedures are for research purposes only, and taking part in the study is not a substitute for your usual visits to the doctor.

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

Yes. After removing your name and address, we will create a computer file of data collected in the study. Researchers will use this data file to study other things about children's health.

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 biological samples we collect and store for this study. By agreeing to be in this study, you are also agreeing to allow possible future use of your biological materials for these purposes.

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

No. However, you may be invited to be in other studies that are connected with the National Children's Study. If so, we will ask your permission and you can always say "no thanks."

Who can I contact if I have further questions?

If you have questions, feel free to ask the Study Representative who has talked to you about being in the study.

If you have any other questions about your or your child's rights as a research participant, now or in the future, you may contact the persons listed on the page we will ask you to sign.

> ***After reading this booklet, we hope you will choose to be in the National Children's Study. We will ask you to sign a form that says you decided to be in the study. If you decide to be in the study, you can leave at any time. You can decide to answer some questions and not others. And you can decide to participate in some study collections and not others. Either way, you can still be in the study. Before you sign the form, you may want to talk with your family, friends, or your doctor about the National Children's Study. Thank you for taking the time to learn about this important study.***

NATIONAL CHILDREN'S STUDY
General Consent for Study Participation

- I have received information about "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 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.
- I understand that I may leave the study at any time.
- I understand that at any time in the study, if there is a question I don't want to answer or part of the study I don't want to do, I don't have to do it, and I can still be in the study.
- 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 choose to join the National Children's Study.

National contact:

Participant

Printed Legal Name of Participant: _____

Signature of Participant: _____

Date: _____/_____/_____

Parent/Legal Guardian (if participant is a non-emancipated minor)

I have received information about "Making an Informed Choice About Being in the National Children's Study" which explains the nature and purpose of the National Children's Study. I give my permission for _____ to take part in the study if she agrees to be part of it. (name)

Printed Legal Name of Parent/Legal Guardian: _____

Signature of Parent/Legal Guardian: _____

Date: _____/_____/_____

Witness (if required)

I observed the interviewer explain "Making an Informed Choice About Being in the National Children's Study" to the participant and she signed or marked this form.

_____ _____/_____/_____

Signature of Witness Date

Printed Name of Person Obtaining Consent: _____

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

OMB #: 0925-xxxx
Expiration Date: xx/xxxx

JOINING THE BIOLOGICAL SPECIMEN AND ENVIRONMENTAL SAMPLE COLLECTION IN THE NATIONAL CHILDREN'S STUDY

You have agreed to participate in the National Children's Study. Thank you!

You have joined thousands of women across the United States to help researchers better understand how the social environment, like your neighborhood, and the physical environment, like the air you breathe and the water you drink, might influence the health and development of your children or future children, if you get pregnant.

We are now asking you to participate in the biological specimen and environmental sample collection part of this study. Biological specimens include things like hair, saliva, blood, and toenail clippings. Environmental samples include things like dust, air, and water. Biological samples and environmental samples are extremely important to the kinds of things we can learn about how the environment may influence children's health.

Each time we ask you for a specimen or sample, we will tell you up front how much, how it would be collected, and how we would store and protect it. We will also tell you if there are any risks from giving the specimen or sample.

You can decide if you want to be part of the biological specimen and environmental sample collection for the National Children's Study. You can decide not to be part of this collection and still be in the rest of the study. You can decide to give some specimens and samples, but not others. And you can decide if the biological specimens you give can be used for genetic research. Either way, you can still participate. And, if you do join this part of the study, you can leave for any reason and at any time.

Sponsors: The National Children's Study is a partnership between local organizations in your community, and four Federal agencies. The Federal agencies are the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the National Institute of Environmental Health Sciences (both are part of the National Institutes of Health), the U.S. Environmental Protection Agency (EPA), and the Centers for Disease Control and Prevention (CDC).

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 will help researchers understand how the social and physical environment affects children's health, growth, and development. The study is also interested in how the environment acts together with a person's characteristics, such as their genes, to prevent disease and promote health.

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

The National Children's Study is an observational study. Observational studies do not involve asking you to change what you normally do. We will be collecting information about you, and if you are or become pregnant, your child and your child's environment. We will not be asking you or your child to take any medicines or drugs.

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. The study will learn what things in the social and physical environment affect whether or not children will develop diseases, both while they are young and also later, when they become adults. Finally, there are medical conditions in children that weren't around 30 or 40 years ago, or were not at the levels we see now. These include obesity, diabetes, autism, learning disabilities, and cardiovascular disease to name just a few. The National Children's Study will help us understand why this is happening and what we can do about these conditions and others like infant morality and injuries.

How will the National Children's Study collect information?

There are several ways the study will collect information. We will ask you questions and ask you to complete forms. We will do physical exams and collect biological and environmental samples. We may also ask you to keep track of certain things, like what you eat. We will ask you to collect some samples yourself.

What kinds of information will be collected?

If you decide to join the study, we will come to your home to collect information about you, your health, and your environment. During the visit, we'd also like to examine you to get body measurements, like height, weight and blood pressure.

Over the course of the study, we will ask to collect biological specimens from you. The kind and amount of these biological specimens will depend on when we contact you. But we will always explain exactly which specimens we would like to collect, how much, and how we would like to collect them. For example, if we ask to collect your blood, our specially-trained study center employees will use a needle from a vein in your arm, and collect about 3-4 tablespoonfuls. A trained employee may also ask to cut a small sample of hair (about 20 strands) from the back of your head. We may ask you to collect some specimens yourself. For example, we may ask you to collect your urine in a cup (about 3 tablespoonfuls), and to collect three vaginal swab samples. We may also ask you to use a straw to collect about ½ teaspoon of saliva 3 times a day for 2 days. You may also be asked to clip your toenails and provide us the clippings. We expect to analyze your specimens in the future for hormones, nutrients, pesticides and other chemicals, heavy metals, and genetic material, among others, but not all measurements will be made on all specimens.

We will also ask to collect environmental samples from your home, like air, dust, and water, over the course of the study. The kind and amount of these samples will depend on when we contact you, too. Just like with your personal biological specimens, we will always explain exactly which samples we would like to collect, how much, and how we would like to do it. For example, if we ask to collect dust from your home, our specially-trained study center employees will use a vacuum and several wipes. We may also ask to collect drinking water. Sometimes, we may ask you to collect air or dust samples using simple kits, and to keep a diary for a week. We expect to analyze your environmental samples in the future for metals, pesticides and other chemicals, and substances that may cause allergies, but not all measurements will be made on all samples.

If you are or become pregnant, we will ask you questions about your pregnancy. We may also ask for a copy of your baby's ultrasound, if you have one. We will ask to schedule ultrasounds for you from time to time during your pregnancy, and we will pay for them. Each time, we will give you a copy of your baby's ultrasound picture.

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.

What will happen to all this information?

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 to look for patterns or relationships between environment and health. These patterns will help researchers better understand the causes for many diseases.

Some tests on your samples will be done right away. If we know the results from tests done during a visit, we will give them to you during that same visit. But there are other tests that we will conduct that we cannot interpret right away. And, most of the samples we collect from you will be tested some time in the future using state-of-the-art technologies. Many of those tests may help us understand more about science someday, but won't be able to tell us about people's health right now. This is why some test results will not be given to you. But we will always tell you during a visit which results we will give you and which results we will not.

Samples will be stored for at least the duration of the study, so we can do many other tests. Right now, we don't know what all of those future tests might be, because science is always improving and new tests are always being developed. But we do know that before any new kinds of tests are done on your specimens and 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 are young and when they grow up. If you decide to join this part of the study and agree to give us specimens and samples, you will be allowing us to test those specimens and samples both now and in the years ahead.

How will my privacy be protected?

The potential loss of confidentiality is a risk to being in the study. We have taken steps 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.
- Separate your number code from your name and address after your responses are collected and processed. Researchers will study data with the number code but not your name and address.
- Store your test results and other electronic information in a computer database protected by advanced security technology and statistical procedures.
- Store your biologic, environmental and other forms of information in a secure research facility. Access to this facility will be monitored.
- Require researchers to ask permission to examine highly confidential study information. Applications will be reviewed by experts to determine if researchers can protect your data.
- Monitor researchers studying sensitive information to make sure that they are protecting your data in the way they promised.
- Require researchers using your data to sign affidavits of nondisclosure. This means that researchers must promise to use the information you provide for scientific purposes only, and to not give information to anyone else who has not made this promise.
- Require researchers to report only group information, not individually-identifiable information, from the data you provide.
- Review these steps over time to improve the ways in which we protect information that could be used to identify you.

We have obtained a legal document from the U.S. Department of Health and Human Services (DHHS) that is 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.

With this Certificate, we cannot be forced, for example by court order or subpoena, to disclose information that may identify you in any Federal, state, or local civil, criminal, administrative, legislative, or other proceedings. But if there is an audit or evaluation of the study by staff of the DHHS, it may be necessary to disclose information to those staff. You should understand that a

Certificate of Confidentiality does not prevent you, as provider of permission for yourself to participate in the Study, from voluntarily releasing information about yourself or your involvement in this study. So if an insurer, employer, or another party learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that in addition to our efforts, you and your family must also actively protect your own privacy.

Also, you should understand that we will take actions necessary under federal or local law, including reporting to authorities, to prevent serious harm to yourself, your child or others such as in cases of child abuse or neglect that we find out about or observe. The Certificate of Confidentiality does not stop the reporting of child abuse or neglect.

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

Yes, your genetic information comes from your family history and some samples, like blood. The study plans to look at DNA, or genes, the basic building blocks of our bodies, because doctors know that genes affect the health and development of children, and that the social and physical environment affects how genes work. That is why we hope to study the genes of all people in the study.

Some people have concerns about use of their genetic information. As a result, the National Children's Study will take the steps I described earlier to protect all of your information, including your genetic information.

Also, some people are sensitive about genetic information for cultural or religious reasons. If you don't want to be in the genetics part of the study, you should let us know, and you can still be in the rest of the study.

Sometimes doctors and scientists cannot interpret the meaning of new research results. As a result, the National Children's Study will not give genetic results to you.

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 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 are young and when they grow up. We might learn things like what causes asthma or what helps children do well in school. We are also likely to learn about what promotes healthy pregnancies and how to reduce miscarriages and premature births. As we make these discoveries, we will share them with you.

We will send out news through newsletters, a web site, and other ways. We will also put this information in books and magazines.

In addition to general health news, we will also give you some specific information about you. We will give you reports about some of the information we are collecting, like height, weight and blood pressure.

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 give you names of people and 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. The study does not include taking any medicines or drugs. There are some things that might be a risk or discomfort to you, if you decide to join the study.

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.

The potential loss of confidentiality is a risk to being in the study. We will take many steps to protect the information you provide that could be used to identify you. We will continue to review these procedures to improve the ways we protect your data over time.

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.

The home visit is likely to take two to three hours at a time convenient to you. But having us come to your home may interrupt your daily routine. 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.

If you tell us or we see that a child is being abused or neglected, or we learn that you are a danger to yourselves or others, then we must report this to the proper authorities.

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

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 or any other benefits you may be receiving. 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, 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.

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 biological samples we collect and store for this study. By agreeing to be in this study, you are also agreeing to allow possible future use of your biological materials for these purposes.

Who can I contact if I have further questions?

If you have questions, feel free to ask the Study Representative who has talked to you about being in the study.

If you have any other questions about your or your child's rights as a research participant, now or in the future, you may contact the persons listed on the page we will ask you to sign.

After reading this booklet, we hope you will choose to be part of the biological specimen and environmental sample collection for the National Children's Study. We will ask you to sign a form that says you decided to be part of this collection for the study. You can decide to give some specimens and samples and not others. If you choose to be part of this collection, you can change your mind later and leave at any time. Either way, you can still be in the study. Before you sign the form, you may want to talk with your family, friends, or your doctor about the National Children's Study. Thank you for taking the time to learn about this important study.

NATIONAL CHILDREN'S STUDY

Biological Specimen and Environmental Sample Collection

Consent Signature Form

- I have received information about "Joining the Biological Specimen and Environmental Sample Collection in the National Children's Study."
- I understand what is involved, and what the risks and benefits are, if I join this part of the study.
- I understand that my biological specimens and environmental samples will be stored in a secure research facility, and that NCS will protect access to my specimens and samples.
- I understand that test results from my specimens and samples will not be given to me.
- I understand that at any time in the study, if there is a question I don't want to answer, a biological specimen or an environmental sample I don't want to give, or part of the study I don't want to do, I don't have to do it, and I can still be in the study.
- I understand that my biological specimens may be used for a variety of future tests, including chemical, genetic and nutritional tests. I agree to allow my biological specimens to be used for future NCS tests.
- 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 receive a copy of this consent form for my records.

I choose to join the biological specimen and environmental sample collection of the National Children's Study.

☐ At this time, I do NOT want genetic information to be collected from my biological specimens. I understand that I can still be in the study and other types of tests will be performed on my biological specimens.

National contact:

Participant

Printed Legal Name of Participant: _____

Signature of Participant: _____ Date: _____/_____/_____

Parent/Legal Guardian (if participant is a non-emancipated minor)

I have received information about "Making an Informed Choice About Being in the National Children's Study" which explains the nature and purpose of the National Children's Study. I give my permission for _____ to take part in the study if she agrees to be part of it. (name)

Printed Legal Name of Parent/Legal Guardian: _____

Signature of Parent/Legal Guardian: _____ Date: _____/_____/_____

Witness (if required)

I observed the interviewer explain "Making and Informed Choice About being in the National Children's Study" to the participant and she signed or marked this form.

_____ _____/_____/_____

Signature of Witness Date

Printed Name of Person Obtaining Consent: _____

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

OMB #: 0925-xxxx
Expiration Date: xx/xxxx

National Children's Study

Visit Information Sheet
Pre-Pregnancy Visit

Thank you for agreeing to participate in the National Children's Study, we told you what it means to be in the study. The last time we visited with you, we described what the study was about in general. Today, we'd like to tell you more about the kinds of information that we will ask to collect from you during this particular visit.

Being in this study is your choice. You can skip any question you don't want to answer. If there is a part of the study you don't want to do, you can skip that, too. Either way, you can still be part of the study if you want to.

And you can decide to be in the study or not at any time. If you leave the study, you can rejoin it later. If you decide later that you do not want us to keep your information, you can tell us and we will destroy data we have not yet begun to study. You can also tell us if you don't want your samples to be used for genetic, chemical or nutritional tests. But we will not be able to destroy data already given to researchers or cancel tests already performed.

We also would like to remind you that if you tell us, or if we see, that a child is being abused or neglected, or if we learn from our visit that you are a danger to yourself or others, then we must report this to the proper authorities.

Interview

We would like to ask you some questions about such things as your home, the people who live with you, your jobs, your activities, your health, and any medicines you take. The interview should take about half an hour.

You might feel uncomfortable about some of the questions we ask. If so, you can skip those questions. You can decide which questions to answer. However, we 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.

Questionnaires and Other Forms for You to Complete

We will give you two questionnaires to complete on your own after we leave. These forms ask questions about what you eat.

At the end of the visit, we also will ask for your thoughts about all of the things we did at this visit.

We will pick up these items from you or, if you prefer, we will give you instructions and provide materials for you to return them by mail.

Biological Specimens

At this visit, we would like you to:

- Collect a sample of your urine in a cup we provide (about 3 tablespoonfuls).
- Collect three vaginal swabs using swabs we provide. You would do this yourself in complete privacy using a specially designed kit.

Your urine may be tested for a variety of environmental exposures. The vaginal swabs may be tested for measures of infection and inflammation. These tests will be done in the future using state-of-the-art technologies. Many of the tests may help us understand more about science someday, but won't

be able to tell us about people's health right now. This is why the results we collect will not be given to you. Taking part in the study is not a substitute for your usual visits to the doctor.

We also would like to:

- Cut a small sample of your hair (about 20 strands) from the back of your head.
- Collect about 3 tablespoons of your blood by using a small needle.

We are medical professionals specially trained to do this safely. We are also trained to make you feel comfortable when we take your blood, but people sometimes feel brief pain when blood is taken, and there is a very small risk of infection, bruising, or bleeding.

Your blood may be tested for a variety of environmental exposures, hormones, nutrients, and measures of infection and inflammation. These tests will be done in the future using state-of-the-art technologies. Many of the tests may help us understand more about science someday, but won't be able to tell us about people's health right now. This is why the results we collect will not be given to you. Taking part in the study is not a substitute for your usual visits to the doctor.

Physical Measures

We would like to:

- Measure your arm and the skin on the back of your arm and upper back.
- Measure your weight.
- Measure your blood pressure.

We will give you your weight and blood pressure during this visit. But we will not give you medical advice. Taking part in the study is not a substitute for your usual visits to the doctor.

Environmental Samples

We would like to:

- Look at the physical environment inside and outside your home. You can walk with us while we do this. We will not enter any rooms inside your home or spaces outside of your home that do you do not want us to enter.
- Collect dust from the floor of your home. The dust will be tested in the future for pesticides. We will collect the dust from the rooms where you spend the most time. We will not enter any rooms inside your home that do you do not want us to enter.
- Set up an air monitor in the room where you spend the most time. The monitor collects air that will be tested for particles and airborne chemicals found in household environments. The monitor measures what is in the air and does not release anything into the air. Because your activities may change from day to day, we will monitor the air for about 7 days. We will work with you to find an appropriate place for the air monitor. The air monitor is very stable. However, if you have safety concerns, we can provide a baby gate to enclose the air monitor. We will return in about a week to pick the monitor up. We will give you a brochure that can help answer any questions you may have about the air monitor.

Just as with biospecimen tests, we will not give environmental test results to you. These tests will be done in the future using state-of-the-art technologies. Many of the tests may help us understand more about science someday, but won't be able to tell us about people's health right now. This is why the results we collect will not be given to you. Taking part in this study is not a substitute for any other environmental testing of your home.

Thank you

To thank you for your time spent completing this visit, we will give you $100 in appreciation of your time.

If you have any questions about this study visit, I can try to answer them, or I will provide you with contact information for you to call the local office.

T1 Visit Information Sheet

The Visit-specific Visit Information Sheet is pending.
It will follow the format of the exemplar document of B.1.2.d.

T2 Visit Information Sheet

The Visit-specific Visit Information Sheet is pending.
It will follow the format of the exemplar document of B.1.2.d.

T3 Visit Information Sheet

The Visit-specific Visit Information Sheet is pending.
It will follow the format of the exemplar document of B.1.2.d.

Birth Visit Information Sheet

The Visit-specific Visit Information Sheet is pending.
It will follow the format of the exemplar document of B.1.2.d.

6-Month Visit Information Sheet

The Visit-specific Visit Information Sheet is pending.
It will follow the format of the exemplar document of B.1.2.d.

12-Month Visit Information Sheet

The Visit-specific Visit Information Sheet is pending.
It will follow the format of the exemplar document of B.1.2.d.

Video script to follow.

Video Script for General Consent content will be the same as the hard-copy General Consent booklet.

OMB #: 0925-xxxx
Expiration Date: xx/xxxx

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

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.

Fathers play an important part in the lives their children. That's why we're hoping you will agree to join the study, too. We are asking you to join thousands of fathers from across the United States to learn things that may help many people. This information may help in the future, although it may not help you or your family, right now.

Joining the study is your choice. You can decide not to join. If you do join, you can leave for any reason at any time. And you can refuse to answer any question.

Sponsors:

The National Children's Study is a partnership between local organizations in your community, and four Federal agencies. The Federal agencies are the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the National Institute of Environmental Health Sciences (both are part of the National Institutes of Health), the U.S. Environmental Protection Agency (EPA), and the Centers for Disease Control and Prevention (CDC).

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 our nation's children. The study will help researchers understand how the social and physical environment affects children's health, growth, and development. The study is also interested in how the environment acts together 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 National Children's Study is an observational study. Observational studies do not involve asking you to change what you normally do. We will be collecting information about you and your child, and your child's environment. We will not be asking you or your child to take any medicines or drugs.
We want to involve both parents of each child because we know that parents are important to the health of their children.

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. The study will learn what things in the social and physical environment affect whether or not children will develop diseases, both while they are young and also later, when they become adults. Finally, there are medical conditions in children that weren't around 30 or 40 years ago, or were not at the levels we see now. These include obesity, diabetes, autism, learning disabilities, and cardiovascular disease to name just a few. The National Children's Study will help us understand why this is happening and what we can do about these conditions and others like infant morality and injuries.

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

The study will include about 100,000 mothers, fathers, and their babies from all over the United States.

How long will the National Children's Study last?

The National Children's Study will be studying women before and during pregnancy, fathers, and children from the time they are born until they are 21 years old.

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

If you decide to join the study, we will come to your home to collect information about you, your health and your environment**.** We will also contact you from time to time by phone, mail or computer to ask you a few questions.

How will the National Children's Study collect information?

There are several ways the study will collect information. We will ask you questions and ask you to complete forms. We will do physical exams and collect biological specimens. We will ask you to collect some samples yourself.

What kinds of information will be collected?

If you decide to join the study, we will come to your home to collect information about you and your health. During the visit, we'd also like to examine you to get body measurements, like height, weight and blood pressure.

We will collect samples from you like blood, hair and saliva, and ask you to collect a sample of your urine.

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.

How many visits should I expect?

There will be one home visit during the pregnancy, and we may ask to visit you at home again later. In addition, 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.

What will happen to all this information?

The information you give us will be stored with information from all the other fathers in the study. Doctors and researchers will use all this information to look for patterns or relationships between environment and health. These patterns will help researchers better understand the causes for many diseases.

Some tests on your samples will be done right away. If we know the results from tests done during a visit, we will give them to you during that same visit. But there are other tests that we will conduct that we cannot interpret right away. And, most of the samples we collect from you will be tested some time in the future using state-of-the-art technologies. Many of those tests may help us understand more about science someday, but won't be able to tell us about people's health right now. This is why some test results will not be given to you. But we will always tell you during a visit which results we will give you and which results we will not.

Samples will be stored for at least the duration of the study, so we can do many other tests. Right now, we don't know what all of those future tests might be, because science is always improving and new tests are always being developed. But we do know 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 are young and 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.

How will my privacy be protected?

The potential loss of confidentiality is a risk to being in the study. We have taken steps 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.
- Separate your number code from your name and address after your responses are collected and processed. Researchers will study data with the number code but not your name and address.
- Store your test results and other electronic information in a computer database protected by advanced security technology and statistical procedures.
- Store your biologic, environmental and other forms of information in a secure research facility. Access to this facility will be monitored.
- Require researchers to ask permission to examine highly confidential study information. Applications will be reviewed by experts to determine if researchers can protect your data.
- Monitor researchers studying sensitive information to make sure that they are protecting your data in the way they promised.
- Require researchers using your data to sign affidavits of nondisclosure. This means that researchers must promise to use the information you provide for scientific purposes only, and to not give information to anyone else who has not made this promise.
- Require researchers to report only group information, not individually-identifiable information, from the data you provide.
- Review these steps over time to improve the ways in which we protect information that could be used to identify you.

We have obtained a legal document from the U.S. Department of Health and Human Services (DHHS) that is 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.

With this Certificate, we cannot be forced, for example by court order or subpoena, to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. But if there is an audit or evaluation of the study by staff of the DHHS, it may be necessary to disclose information to those staff. You should understand that a Certificate of Confidentiality does not prevent you, as provider of permission for yourself to participate in the Study, from voluntarily releasing information about yourself or your involvement in this study. So if an insurer, employer, or another party learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that in addition to our efforts, you and your family must also actively protect your own privacy.

Also, you should understand that we will take actions necessary under federal or local law, including reporting to authorities, to prevent serious harm to yourself, your child or others such as in cases of child abuse or neglect that we find out about or observe. The Certificate of Confidentiality does not stop the reporting of child abuse or neglect.

Will you be obtaining genetic information about me?

Yes, your genetic information comes from your family history and some samples, like blood. The study plans to look at DNA, or genes, the basic building blocks of our bodies, because doctors know that genes affect the health and development of children, and that the social and physical environment affects how genes work. That is why we hope to study the genes of all people in the study.

Some people have concerns about use of their genetic information. As a result, the National Children's Study will take the steps I described earlier to protect all of your information, including your genetic information.

Also, some people are sensitive about genetic information for cultural or religious reasons. If you don't want to be in the genetics part of the study, you should let us know, and you can still be in the rest of the study.

Sometimes doctors and scientists cannot interpret the meaning of new research results. As a result, the National Children's Study will not give genetic results to you.

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 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 are young and when they grow up. We might learn things like what causes asthma or what helps children do well in school. We are also likely to learn about what promotes healthy pregnancies and how to reduce miscarriages and premature births. As we make these discoveries, we will share them with you.

We will send out news through newsletters, a web site, and other ways. We will also put this information in books and magazines.

In addition to general health news, we will also give you some specific information about you. We will give you reports about some of the information we are collecting, like height, weight and blood pressure.

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 give you names of people and agencies that can help you.

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

The risks of this study are very low. The study does not include taking any medicines or drugs. There are some things that might be a risk or discomfort to you, if you decide to join the study.

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.

The potential loss of confidentiality is a risk to being in the study. We will take many steps to protect the information you provide that could be used to identify you. We will continue to review these procedures to improve the ways we protect your data over time.

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.

The home visit will be scheduled for a time convenient to you. But having us come to your home may interrupt your daily routine. 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.

If you tell us or we see that a child is being abused or neglected, or we learn that you 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 understand that your time is valuable, and we appreciate your helping us. The Study will pay you in appreciation of your time spent in study-related activities, like a home visit, and for answering questions. Payment for each task will be about $25 to $100, depending on the amount of time and effort involved.

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

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 or any other benefits you may be receiving. 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, 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.

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

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.

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

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

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

Yes. After removing your name and address, we will create a computer file of data collected in the study. Researchers will use this data file to study other things about children's health.

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

It is possible that scientists could create new medicines or health products in the future based on biological samples we collect and store for this study. By agreeing to be in this study, you are also agreeing to allow possible future use of your biological materials for these purposes.

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

No. However, you may be invited to be in other studies that are connected with the National Children's Study. If so, we will ask your permission and you can always say "no thanks."

Who can I contact if I have further questions?

If you have questions, feel free to ask the Study Representative who has talked to you about being in the study.

If you have any other questions about your or your child's rights as a research participant, now or in the future, you may contact the persons listed on the page we will ask you to sign.

> ***After reading this booklet, we hope you will choose to be in the National Children's Study. We will ask you to sign a form that says you decided to be in the study. If you decide to be in the study, you can leave at any time. You can decide to answer some questions and not others. And you can decide to participate in some study collections and not others. Either way, you can still be in the study. Before you sign the form, you may want to talk with your family, friends, or your doctor about the National Children's Study. Thank you for taking the time to learn about this important study.***

NATIONAL CHILDREN'S STUDY
General Consent for Study Participation

- I have received information about "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 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.
- I understand that I may leave the study at any time.
- I understand that at any time in the study, if there is a question I don't want to answer or part of the study I don't want to do, I don't have to do it, and I can still be in the study.
- 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 choose to join the National Children's Study.

National contact:

Participant

Printed Legal Name of Participant: _____

Signature of Participant: _____

Date: _____/_____/_____

Parent/Legal Guardian (if participant is a non-emancipated minor)

I have received information about "Making an Informed Choice About Being in the National Children's Study" which explains the nature and purpose of the National Children's Study. I give my permission for _____ to take part in the study if he agrees to be part of it. (name)

Printed Legal Name of Parent/Legal Guardian: _____

Signature of Parent/Legal Guardian: _____

Date: _____/_____/_____

Witness (if required)

I observed the interviewer explain "Making an Informed Choice About Being in the National Children's Study" to the participant and he signed or marked this form.

_____ _____/_____/_____

Signature of Witness Date

Printed Name of Person Obtaining Consent: _____

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

OMB #: 0925-xxxx
Expiration Date: xx/xxxx

THE NATIONAL CHILDREN'S STUDY

HEALTH GROWTH ENVIRONMENT

JOINING THE BIOLOGICAL SPECIMEN COLLECTION IN THE NATIONAL CHILDREN'S STUDY

You have agreed to participate in the National Children's Study. Thank you!

You have joined thousands of fathers across the United States to help researchers better understand how the social environment, like your neighborhood, and the physical environment, like the air you breathe and the water you drink, might influence the health and development of your children.

We are now asking you to participate in the biological specimen collection part of this study. Biological specimens include things like hair, saliva, blood, and toenail clippings. Biological samples are extremely important to the kinds of things we can learn about how the environment may influence children's health.

Each time we ask you for a specimen, we will tell you up front how much, how it would be collected, and how we would store and protect it. We will also tell you if there are any risks from giving the specimen.

You can decide if you want to be part of the biological specimen collection for the National Children's Study. You can decide not to be part of this collection and still be in the rest of the study. You can decide to give some specimens, but not others. And you can decide if the biological specimens you give can be used for genetic research. Either way, you can still participate. And, if you do join this part of the study, you can leave for any reason and at any time.

Sponsors: The National Children's Study is a partnership between local organizations in your community, and four Federal agencies. The Federal agencies are the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the National Institute of

Environmental Health Sciences (both are part of the National Institutes of Health), the U.S. Environmental Protection Agency (EPA), and the Centers for Disease Control and Prevention (CDC).

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 will help researchers understand how the social and physical environment affects children's health, growth, and development. The study is also interested in how the environment acts together with a person's characteristics, such as their genes, to prevent disease and promote health.

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

The National Children's Study is an observational study. Observational studies do not involve asking you to change what you normally do. We will be collecting information about you, your child and your child's environment. We will not be asking you or your child to take any medicines or drugs.

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. The study will learn what things in the social and physical environment affect whether or not children will develop diseases, both while they are young and also later, when they become adults. Finally, there are medical conditions in children that weren't around 30 or 40 years ago, or were not at the levels we see now. These include obesity, diabetes, autism, learning disabilities, and cardiovascular disease to name just a few. The National Children's Study will help us understand why this is happening and what we can do about these conditions and others like infant morality and injuries.

How will the National Children's Study collect information?

There are several ways the study will collect information. We will ask you questions and ask you to complete forms. We will do physical exams and collect biological specimens. We may also ask you to keep track of certain things, like what you eat. We will ask you to collect some samples yourself.

What kinds of information will be collected?

If you decide to join the study, we will come to your home to collect information about you, your health, and your environment. During the visit, we'd also like to examine you to get body measurements, like height, weight and blood pressure.

Over the course of the study, we will ask to collect biological specimens from you. The kind and amount of these biological specimens will depend on when we contact you. But we will always explain exactly which specimens we would like to collect, how much, and how we would like to collect them. For example, if we ask to collect your blood, our specially-trained study center employees will use a needle from a vein in your arm, and collect about 3-4 tablespoonfuls. A trained employee may also ask to cut a small sample of hair (about 20 strands) from the back of your head.

We may ask you to collect some specimens yourself. For example, we may ask you to collect your urine in a cup (about 3 tablespoonfuls). We may also ask you to use a straw to collect about ½ teaspoon of saliva 3 times a day for 2 days. You may also be asked to clip your toenails and provide us the clippings. We expect to analyze your specimens in the future for hormones, nutrients, pesticides and other chemicals, heavy metals, and genetic material, among others, but not all measurements will be made on all specimens.

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.

What will happen to all this information?

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 to look for patterns or relationships between environment and health. These patterns will help researchers better understand the causes for many diseases.

Some tests on your samples will be done right away. If we know the results from tests done during a visit, we will give them to you during that same visit. But there are other tests that we will conduct that we cannot interpret right away. And, most of the samples we collect from you will be tested some time in the future using state-of-the-art technologies. Many of those tests may help us understand more about science someday, but won't be able to tell us about people's health right now. This is why some test results will not be given to you. But we will always tell you during a visit which results we will give you and which results we will not.

Samples will be stored for at least the duration of the study, so we can do many other tests. Right now, we don't know what all of those future tests might be, because science is always improving and new tests are always being developed. But we do know that before any new kinds of tests are done on your specimens, 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 are young and when they grow up. If you decide to join this part of the study and agree to give us specimens, you will be allowing us to test those specimens both now and in the years ahead.

How will my privacy be protected?

The potential loss of confidentiality is a risk to being in the study. We have taken steps 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.
- Separate your number code from your name and address after your responses are collected and processed. Researchers will study data with the number code but not your name and address.

- Store your test results and other electronic information in a computer database protected by advanced security technology and statistical procedures.
- Store your biologic and other forms of information in a secure research facility. Access to this facility will be monitored.
- Require researchers to ask permission to examine highly confidential study information. Applications will be reviewed by experts to determine if researchers can protect your data.
- Monitor researchers studying sensitive information to make sure that they are protecting your data in the way they promised.
- Require researchers using your data to sign affidavits of nondisclosure. This means that researchers must promise to use the information you provide for scientific purposes only, and to not give information to anyone else who has not made this promise.
- Require researchers to report only group information, not individually-identifiable information, from the data you provide.
- Review these steps over time to improve the ways in which we protect information that could be used to identify you.

We have obtained a legal document from the U.S. Department of Health and Human Services (DHHS) that is 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.

With this Certificate, we cannot be forced, for example by court order or subpoena, to disclose information that may identify you in any Federal, state, or local civil, criminal, administrative, legislative, or other proceedings. But if there is an audit or evaluation of the study by staff of the DHHS, it may be necessary to disclose information to those staff. You should understand that a Certificate of Confidentiality does not prevent you, as provider of permission for yourself to participate in the Study, from voluntarily releasing information about yourself or your involvement in this study. So if an insurer, employer, or another party learns about your participation, and obtains your consent to receive research information, then we may not use the Certificate of Confidentiality to withhold this information. This means that in addition to our efforts, you and your family must also actively protect your own privacy.

Also, you should understand that we will take actions necessary under federal or local law, including reporting to authorities, to prevent serious harm to yourself, your child or others such as in cases of child abuse or neglect that we find out about or observe. The Certificate of Confidentiality does not stop the reporting of child abuse or neglect.

Will you be obtaining genetic information about me?

Yes, your genetic information comes from your family history and some samples, like blood. The study plans to look at DNA, or genes, the basic building blocks of our bodies, because doctors know that genes affect the health and development of children, and that the social and physical environment affects how genes work. That is why we hope to study the genes of all people in the study.

Some people have concerns about use of their genetic information. As a result, the National Children's Study will take the steps I described earlier to protect all of your information, including your genetic information.

Also, some people are sensitive about genetic information for cultural or religious reasons. If you don't want to be in the genetics part of the study, you should let us know, and you can still be in the rest of the study.

Sometimes doctors and scientists cannot interpret the meaning of new research results. As a result, the National Children's Study will not give genetic results to you.

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 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 are young and when they grow up. We might learn things like what causes asthma or what helps children do well in school. We are also likely to learn about what promotes healthy pregnancies and how to reduce miscarriages and premature births. As we make these discoveries, we will share them with you.

We will send out news through newsletters, a web site, and other ways. We will also put this information in books and magazines.

In addition to general health news, we will also give you some specific information about you. We will give you reports about some of the information we are collecting, like height, weight and blood pressure.

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 give you names of people and 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. The study does not include taking any medicines or drugs. There are some things that might be a risk or discomfort to you, if you decide to join the study.

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.

The potential loss of confidentiality is a risk to being in the study. We will take many steps to protect the information you provide that could be used to identify you. We will continue to review these procedures to improve the ways we protect your data over time.

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.

The home visit will be scheduled for a time convenient to you. But having us come to your home may interrupt your daily routine. 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.

If you tell us or we see that a child is being abused or neglected, or we learn that you are a danger to yourselves or others, then we must report this to the proper authorities.

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

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 or any other benefits you may be receiving. 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, 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.

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 biological samples we collect and store for this study. By agreeing to be in this study, you are also agreeing to allow possible future use of your biological materials for these purposes.

Who can I contact if I have further questions?

If you have questions, feel free to ask the Study Representative who has talked to you about being in the study.

If you have any other questions about your or your child's rights as a research participant, now or in the future, you may contact the persons listed on the page we will ask you to sign.

> ***After reading this booklet, we hope you will choose to be part of the biological specimen collection for the National Children's Study. We will ask you to sign a form that says you decided to be part of this collection for the study. You can decide to give some specimens and not others. If you choose to be part of this collection, you can change your mind later and leave at any time. Either way, you can still be in the study. Before you sign the form, you may want to talk with your family, friends, or your doctor about the National Children's Study. Thank you for taking the time to learn about this important study.***

NATIONAL CHILDREN'S STUDY

Biological Specimen Collection

Consent Signature Form

- I have received information about "Joining the Biological Specimen Collection in the National Children's Study."
- I understand what is involved, and what the risks and benefits are, if I join this part of the study.
- I understand that my biological specimens will be stored in a secure research facility, and that NCS will protect access to my specimens.
- I understand that test results from my specimens will not be given to me.
- I understand that at any time in the study, if there is a question I don't want to answer, a biological specimen I don't want to give, or part of the study I don't want to do, I don't have to do it, and I can still be in the study.
- I understand that my biological specimens may be used for a variety of future tests, including chemical, genetic and nutritional tests. I agree to allow my biological specimens to be used for future NCS tests.
- 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 receive a copy of this consent form for my records.

I choose to join the biological specimen collection part of the National Children's Study.

☐ At this time, I do NOT want genetic information to be collected from my biological specimens. I understand that I can still be in the study and other types of tests will be performed on my biological specimens.

National contact:

Participant

Printed Legal Name of Participant: _____

Signature of Participant: _____ Date: _____/_____/_____

Parent/Legal Guardian (if participant is a non-emancipated minor)

I have received information about "Making an Informed Choice About Being in the National Children's Study" which explains the nature and purpose of the National Children's Study. I give my permission for _____ to take part in the study if he agrees to be part of it. (name)

Printed Legal Name of Parent/Legal Guardian: _____

Signature of Parent/Legal Guardian: _____ Date: _____/_____/_____

Witness (if required)

I observed the interviewer explain "Making and Informed Choice About being in the National Children's Study" to the participant and he signed or marked this form.

_____ _____/_____/_____

Signature of Witness Date

Printed Name of Person Obtaining Consent: _____

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

OMB #: 0925-xxxx
Expiration Date: xx/xxxx

National Children's Study

Visit Information Sheet
Father Visit

Thank you for agreeing to participate in the National Children's Study, we told you what it means to be in the study. The last time we visited with you, we described what the study was about in general. Today, we'd like to tell you more about the kinds of information that we will ask to collect from you during this particular visit.

Being in this study is your choice. You can skip any question you don't want to answer. If there is a part of the study you don't want to do, you can skip that, too. Either way, you can still be part of the study if you want to.

And you can decide to be in the study or not at any time. If you leave the study, you can rejoin it later. If you decide later that you do not want us to keep your information, you can tell us and we will destroy data we have not yet begun to study. You can also tell us if you don't want your samples to be used for genetic, chemical or nutritional tests. But we will not be able to destroy data already given to researchers or cancel tests already performed.

We also would like to remind you that if you tell us, or if we see, that a child is being abused or neglected, or if we learn from our visit that you are a danger to yourself or others, then we must report this to the proper authorities.

Interview

We would like to ask you some questions 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. We will also ask you to answer some questions about words you might know, things you might have seen in the world around you, and to do some activities that show the different ways you think about and solve problems. The interview should take about an hour.

You might feel uncomfortable about some of the questions we ask. If so, you can skip those questions. You can decide which questions to answer. However, we 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.

Questionnaires and Other Forms for You to Complete

We will give you a questionnaire to fill out about health conditions that 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.

Biological Samples

At this visit, we would like you to

- Collect a sample of your urine in a cup we provide (about 3 tablespoonfuls).
- Cut or clip your toenails from all toes on both of your feet.

Your urine may be tested for a variety of environmental exposures. These tests will be done in the future using state-of-the-art technologies. Many of the tests may help us understand more about science someday, but won't be able to tell us about people's health right now. This is why the results

we collect will not be given to you. Taking part in the study is not a substitute for your usual visits to the doctor.

We also would like to

- Cut a small sample of your hair (about 20 strands) from the back of your head.
- Collect about 2 tablespoons of your blood using a small needle.

We are medical professionals specially trained to do this safely. We are also trained to make you feel comfortable when we take your blood, but people sometimes feel brief pain when blood is taken, and there is a very small risk of infection, bruising, or bleeding.

Your blood may be tested for a variety of environmental exposures, hormones, nutrients, and measures of infection and inflammation. These tests will be done in the future using state-of-the-art technologies. Many of the tests may help us understand more about science someday, but won't be able to tell us about people's health right now. This is why the results we collect will not be given to you. Taking part in the study is not a substitute for your usual visits to the doctor.

Physical Measures

We would like 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.
- Measure your weight and your height.
- Measure your blood pressure.

We will give you your weight, height and blood pressure during this visit. But we will not give you medical advice. Taking part in the study is not a substitute for your usual visits to the doctor.

Thank you

To thank you for your time spent completing this visit, we will give you $100 in appreciation of your time.

If you have any questions about this study visit, I can try to answer them, or I will provide you with contact information for you to call the local office.

12-Month Visit Information Sheet

The Visit-specific Visit Information Sheet is pending.
It will follow the format of the exemplar document of B.1.3.d.

OMB #: 0925-xxxx
Expiration Date: xx/xxxx

National Children's Study
Authorization to Obtain Medical Data (Ultrasound)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE NATIONAL INSTITUTES OF HEALTH, THE CENTERS FOR DISEASE CONTROL AND PREVENTION, AND THE ENVIRONMENTAL PROTECTION AGENCY

_____ ___ ___ ___ - ___ ___ ___ - ___ ___ ___ __
Provider name Phone number

_____
Street address

_____ ___ ___ ___ ___ ___ ___ ___ ___
City State Zip

I am participating in the National Children's Study (NCS), a study of the health and development of the nation's children being led by the U.S. Department of Health and Human Services-through the National Institutes of Health and the Centers for Disease Control and Prevention-and the U.S. Environmental Protection Agency. I authorize and request that you provide the National Children's Study staff and its contractors with medical information they request about the ultrasound examination services provided to me during my current pregnancy. This authorization covers any ultrasound exams and related medical follow-up I received at your facility and from any medical provider associated with your facility or who provided care to me in your facility.

I understand that the Health Insurance Portability and Accountability Act of 1996 (HIPAA)(1) prohibits you from releasing my medical information without my authorization. This form (or a photocopy of this form) gives you my authorization. I have signed this form voluntarily. 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.

I understand that the National Institute of Health and its contractors will use this information to supplement the information I have already given to National Children's Study for 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.

I authorize study staff 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. This authorization expires 30 months from the date of signature.

_____ _____
Patient name (first, middle, last): Other names under which medical records may be filed

_____ ___ ___ /___ ___ /___ ___ ___ ___
Patient's signature 14 and over sign Date signed

If Patient Is Age 14 - 17, Both Patient and Parent/Guardian Must Sign and Date.

_____ ___ ___ /___ ___ /___ ___ ___ ___
Parent, guardian, witness or proxy's signature Date signed

_____
Signer's relationship to patient

Reason for parent, guardian, witness or proxy's signature:
☐ Patient 13 or younger ☐ Patient disabled
☐ Patient 14-17 years old ☐ Patient deceased

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).

Place Label here

OMB #: 0925-xxxx
Expiration Date: xx/xxxx

National Children's Study

Authorization to Release Medical Data (Ultrasound)

As part of your participation in the National Children's Study led by the U.S. Department of Health and Human Services-through the National Institutes of Health and the Centers for Disease Control and Prevention-and the U.S. Environmental Protection Agency **an** ultrasound was performed today. **The ultrasound will obtain specific measurements of your baby. This ultrasound is not considered a substitute for an ultrasound your health care provider may do. No attempt has been made to diagnose or treat any of your medical conditions.**

Your health care provider may be interested in seeing a copy of your ultrasound scan. With your permission, we will send a copy of the ultrasound scan to your health care provider. If you agree and give us the name and address of your health care provider, we will send him or her a copy of your ultrasound scan along with a letter about the National Children's Study.

Permission to Send Ultrasound Scan to Your Health Care Provider:

☐ I agree that you may send a copy of my ultrasound scan to my health care provider named below.
☐ I do not agree to send a copy of my ultrasound scan taken to my health care provider.
☐ I do not have a health care provider.

Name of participant: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Birth date: ☐☐/☐☐/☐☐☐☐

Signature of participant: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Date: ☐☐/☐☐/ 20 ☐☐

Health Care Provider's Contact Information:

Name: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Address: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

City, State, Zip code: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Phone: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Name of data collector: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Staff ID: ☐☐☐☐☐☐☐

Place Label here

OMB #: 0925-xxxx
Expiration Date: xx/xxxx

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: ( ) _____ - _____
Area Code

B. 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.

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.

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.

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.

C. 1. Patient Name (first, middle, last): _____

2. Date of Birth ____ / ____ / ____
Month **Day** **Year**

3. Other Names Under Which Records May be Filed _____

D. 4. _____
Patient's Signature—14 and over sign

5. Date Signed _____

IF PATIENT IS AGE 14 TO 17, BOTH PATIENT AND PARENT/GUARDIAN MUST SIGN AND DATE.

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:
- ☐ Patient 13 or Younger
- ☐ Patient 14-17 Years Old
- ☐ Patient Disabled
- ☐ 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).

Revised 9/8/08

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 to conduct the largest research study of children's health ever to be done in the United States. The study is called the National Children's Study. Results from the study may 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, 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.

Your participation is voluntary, but we hope you will join us in our effort to improve our children's health. The information you give will be kept private and is protected by law.

If you have any questions about the study, please call our toll-free number (xxx-xxx-xxxx) or visit the National Children's Study website at http://www.nationalchildrensstudy.gov.

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

Sincerely,

Local Investigator

Enclosure: Study Brochure

The National Children's Study

Study Brochure

Most 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 many pressing health concerns.

What is the National Children's Study?

The National Children's Study is the largest research study of children's health ever conducted in the United States. Its purpose is to look at the effects of the environment on children's health and development. By recruiting women of child-bearing age, information will be collected on 100,000 children beginning before they are born. The study will continue to collect information on these children until they reach 21 years of age.

Who will be in the study?

Across the country, selected areas within 105 different counties have been scientifically chosen to represent the United States. We will be recruiting women in these areas to join the study if they are pregnant or may become pregnant. Study teams will also work with doctors, nurses, community leaders, and local public health workers to help make the study successful. Local study staff will visit all homes in selected neighborhoods to talk to the men and women who live

there. This will tell us whether anyone living there may be eligible to take part in the full study.

What will you be asked to do?

First, we would like to talk to an adult in your household. It will only take about 5 minutes for this interview. Even if you do not have any children living with you, or if you do not plan to have children, it's still important that we get some basic information. After that, if any women of child-bearing age live in your household, we will ask them to answer a few questions. Depending on the answers to these questions, some women will then be invited to enroll in the full study.

If you are a woman who is invited to enroll in the full study, you will be given more details about what you will be asked to do. Study staff will meet with you to complete a variety of data collection activities. As babies are born to women who are enrolled in the full study, information will be collected about their babies as they grow. Fathers of these babies will also be asked to take part in certain activities.

Why is your cooperation so important?

Everyone's cooperation will ensure that the National Children's Study fairly represents all of America's children. You can decide to participate or not. That is your choice. However, we hope that you will decide to join us in this important effort. If you decide not to participate, it will not affect any benefits to which you or your family may be entitled.

Will information be kept confidential?

All information will be kept private and confidential and used only for research purposes. The 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 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, 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 our team member. All information you provide will be kept private and confidential and used for research purposes only. Your participation is voluntary.

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 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, 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 our team member. All information you provide will be kept private and confidential, and used for research purposes only. Your participation is voluntary.

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 letter is meant to remind you about your upcoming appointment for the National Children's Study. You are scheduled for an appointment in your home on:

Date:

Time:

At that time, [DATA COLLECTOR'S NAME] will ask you to answer some questions about your health and your home.

- If any pesticide products have been used in your home or yard in the past 6 months, please gather the containers, letters from building maintenance about pesticide application, or receipts from the exterminator that list which products were used. These products would have been used to control for ants, termites, cockroaches, bees, wasps, moths, or other insects. Our staff would like to look at the labels during the visit.

- If any products were used on your pets to control fleas, ticks, or mites ***in the past 6 months***, ***please gather the containers for all of those products have been applied.*** Products include flea collars; flea and tick powders; shampoos; or other flea, tick, and mite control products. Our staff would like to look at the labels during the visit

- Our staff also would like to look at the labels for any prescription and non-prescription medicines, as well as any vitamins, minerals, herbals, and other dietary supplements you have taken since you became pregnant. Please gather the containers and have them available during the visit.

- If you have any ***personal record or calendar***, such as the Medical Care Log, that helps you remember the dates of any doctor or health care provider visits you had ***since you became pregnant***, please have it available during the interview.

You are scheduled for another appointment in your home on:

Date:

Time:

At the end of the first visit, [DATA COLLECTOR'S NAME] will give you $100 to thank you for completing *both* visits.

If you have any questions about either of these appointments, or if you need to reschedule, please call our office at [VC TELEPHONE NUMBER].

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

Sincerely yours,

(VC Signature)

Post Enumeration Letter

_____/_____/_____
Date

Dear _____,
Name

You may be eligible to participate in the National Children's Study. A member of our staff will be stopping by in the next few days to ask you a few questions to find out if you can be part of the National Children's Study. This will only take a few minutes of your time.

Attached is a copy of the National Children's Study brochure. Please call {NAME} at (XXX)-(XXX)-(XXXX) if you have any questions or to schedule a visit.

Thank you,

_____
Data collector name

Enclosure: Study Brochure

High Pregnancy Group (No Visit) Letter

_____/_____/_____
Date

Dear _____,
Participant name

Thank you for speaking with me today about the National Children's Study. We will call you again in about 4 weeks to see how you are doing and to ask you a few questions. The questions will be similar to the ones you answered today, and will only take a few minutes of your time.

Your participation is voluntary. If you decide to participate, the information you give will be kept private and is protected by law.

Please call us if anything changes, for example if you move, change your name or get pregnant. Please call {NAME} at (XXX)-(XXX)-(XXXX) if you have need to contact us or have any questions.

Thank you,

_____
Data collector name

Moderate and Low Pregnancy Group Letter

_____/_____/_____
Date

Dear _____,
Participant name

Thank you for speaking with me today about the National Children's Study. We will call you again in a few months to see how you are doing and to ask you some questions. The questions will be similar to the ones you answered today, and will only take a few minutes of your time.

Your participation is voluntary. If you decide to participate, the information you give will be kept private and is protected by law.

Please call us if anything changes, for example if you move, change your name or get pregnant. Please call {NAME} at (XXX)-(XXX)-(XXXX) if you have need to contact us or have any questions.

Thank you,

_____
Data collector name

Post Consent Letter

_____/_____/_____
Date

Dear _____,
Participant name

Thank you for agreeing to be part of the National Children's Study. We are planning to begin pregnancy visits in the near future.

Your first pregnancy visit will be in your home and include:

- Asking you some questions,
- Taking some measures such as your blood pressure and weight,
- Collecting some environmental samples such as dust and water, and
- Asking you for samples of your blood, urine and hair.

We will also be leaving some brief questionnaires for you to complete, and we will come back a week or so later to pick these up and to complete the visit activities.

We will call you to schedule your visit at your convenience. At that time, we will explain more about the visit and answer any questions you may have.

Please call {NAME} at (XXX)-(XXX)-(XXXX) if you have any questions.

Thank you,

Incentive "Thank You" Letter

_____/_____/_____
Date

Dear _____,
Participant name

Thank you for your time today. Your participation in the National Children's Study is very important and we appreciate your part in making it a success.

Please accept the enclosed reimbursement for your time and your assistance with this very important research study.

We look forward to your on-going participation in the National Children's Study. Before your next scheduled study activity, if you have any questions or need to update any of your information, please call {NAME} at XXX-XXX-XXXX.

Thank you,

_____
Data collector name

Study Withdrawal letter

{DATE)

Name
Address
City, State, Zip

Dear _____,

We have received your request to no longer be part of the National Children's Study. The researchers and staff want to thank you for your help with our study. You have been an important part of the largest and most ambitious research study of children's health ever done in the United States.

If you would like to continue to receive the study newsletter, or if you would like to re-join the study again at any time in the future, please call (PI NAME) at (XXX) XXX-XXXX or the Study Coordinator at (XXX) XXX-XXXX.

Sincerely,