

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY
HOME INTERVIEW CONSENT

Print name of person questioned _____
First Middle Last

You have been chosen to take part in the National Health and Nutrition Examination Survey (NHANES), conducted by the National Center for Health Statistics, part of the Centers for Disease Control and Prevention (CDC). This research tells us about the health and nutrition of people in the United States. It combines an interview with a health exam. Our interviewer will ask questions about you and your family. Some questions are about your work and general health. Others are about health problems and other health topics. Health research using NHANES can be enhanced by combining your survey records with other data sources. The data gathered are used to link your answers to vital statistics, health, nutrition, and other related records. The questions today will take about one hour. We may contact you to check the work of your interviewer. We may contact you again for further studies.

Data gathered in this survey are used to study many health issues. We are required by law (read box below) to use your information for statistical research only and to keep it confidential. The law prohibits us from giving anyone any information that may identify you or your family without your consent.

You may take part in this survey or not. The choice is yours. You will not lose any benefits if you say no. If you choose to take part, you don't have to answer every question.

We can do additional health research by linking your interview and exam data to vital statistics, health, nutrition, and other related records. May we try to link your survey records with other records?

Yes No

Do you have more questions about the survey? You can make a toll-free call to Dr. Kathryn Porter at the U.S. Public Health Service at 1-800-452-6115, Monday-Friday, 8:30 AM-6:00 PM EST. If you have questions about your rights about being in the survey, call the Research Ethics Review Board at the National Center for Health Statistics, toll free, at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol # 2005-06. Your call will be returned as soon as possible.

SIGNATURE OF PERSON ANSWERING QUESTIONS:

I have read the information above. I agree to proceed with the interview.

Date
IF PERSON ABOVE IS 16 OR 17 YEARS OLD, A PARENT/GUARDIAN MUST ALSO SIGN BELOW:
(Unless participant is an emancipated minor)

Signature of parent/guardian Date

I observed the interviewer read this form to the person named above and he/she agreed to participate by signing or marking this form.

Witness (if required) Date
Name of staff member present when this form was signed: _____

HOUSEHOLD ID _____ FAMILY # _____
Which questionnaire(s) did person respond to? FAMILY SP (IF CHECKED, PRINT BELOW)
SP NAME SP ID SP NAME SP ID

Assurance of Confidentiality - All information which would permit identification of an individual, a practice, or an establishment will be held confidential, will be used only by NCHS staff, contractors, and other agents authorized by NCHS to perform statistical activities, only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347). By law, every employee as well as every agent has taken an oath and is su to a jail term of up to five years, a fine of up to \$250,000, or both if he or she willfully discloses ANY identifiable information about you.

Public reporting burden of this collection of information may take up to 6.7 hours per response for total participation, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-0237). 01/11

National Health and Nutrition Examination Survey

Examination Consent Brochure 2011

Overview

The National Health and Nutrition Examination Survey (NHANES) is a survey conducted by the National Center for Health Statistics, part of the Centers for Disease Control and Prevention. We have designed the survey to learn about the health and diet of people in the United States.

Our survey is unique. It combines a home interview with health measurements, which we do in mobile units. These special mobile centers travel across the country with a highly trained medical team. Our team looks at special health topics. They use the most up-to-date methods and equipment for medical and dental exams and other lab tests.

Why is this health survey important?

We will use the data gathered in this survey to find out the number of people with certain health problems — for example, diabetes and high blood pressure. We will look at diet and other habits that affect health, such as smoking and exercise. NHANES data will tell us the health and nutrition of people of all ages. It will also help design health programs and services, and expand our knowledge about the health of people in the United States.

Why is this health survey important?

- Free health test results
- The chance to help learn more about the health of the Nation
- A token of thanks for your time and effort

You may choose to be in the survey and you may allow your child to be in it, too. That is your choice. There is no penalty if you refuse. You may refuse any part of the exam and are free to drop out anytime. Also, during the interviews you may choose not to answer every question.

What will I be asked to do at the mobile center?

<photo of MEC>

Upon arriving at the mobile center, you will be asked to change into a two-piece examination outfit.

<photo of outfit>

Our medical team will then guide you to private rooms where we will check you:

Height and weight <photo of child having his height measured>

Blood pressure <photo of blood pressure measurement>

Ears <photo of an adult male in the audiometry booth>

Teeth <photo of dentist and child>

Body Composition <photo of the dual x-ray absorptiometry machine>

We will also collect blood and urine samples <photo of the phlebotomist and a senior>

And ask you questions about what you eat <photo of dietary interview and woman>

If your appointment is scheduled in the morning, we will ask you not to eat or drink anything overnight. The health tests may take from 2 ½ to 4 hours for those 12 and older and 1-3 hours for younger children. The time spent in the mobile center and the tests you receive will be based on your age and current medical condition. (For a full list of exams you may receive, see the Health Measurements List.)

Are the tests safe?

The tests are safe. Some tests may cause you slight discomfort. Examples are taking a blood sample or not eating for 9 hours. For the blood sample, a person will have a small amount of blood drawn from a vein in his/her arm with a needle. People 12 years and older that have a morning exam will be asked to drink a sugar drink and have blood taken a second time. Although rare, the sugar drink can cause nausea, vomiting, bloating, or headache. We will not ask you to have any test that is wrong for you because of a health problem you have. We will give a *body composition* test that involves low-dosage x-rays to persons 8-years-old and older. Radiation exposure during this test is equal to a cross-country airline flight or a few days of natural background radiation. But because the *body composition* scan

involves x-rays, no one who is pregnant should get this exam. We will get information about periods from girls and women, and those who have started their periods will have a urine pregnancy test. Those with a positive test will not have the *body composition* scan.

Will you ask personal questions?

At the mobile center you will be asked some personal questions. A trained interviewer will ask some of these questions. Other questions, like those about stages of body development for children and teens, sexual behaviors and drug use, will be asked in complete privacy. The interviewer will leave the room. The questions will be on a computer screen. You answer by touching an answer on the screen. Like all of the other data we collect, the answers you give us are kept strictly private. If you are under 18 years of age, we may notify your parents if we have reason to believe you may harm yourself because of sad feelings.

Will I get my results?

Yes, you will get a report of your results. If the exam shows urgent health problems, we will notify you at once and refer you for treatment. If some urgent problem is found through your lab tests, we will immediately send that information in a letter to your home address. If you wish, we will mail the routine results to you about 3-4 months after the exam. In general, we give results only to the person examined or to the parents/guardians of children. Some results, like those for sexually transmitted disease (STD) tests and pregnancy tests, are not put in writing. We report positive pregnancy test results only to the person tested if she is 14 years or older and doesn't already know she is pregnant. If a girl is younger than 14 and has a positive pregnancy test, we will inform both her and her parent/guardian. How we report STD test results is explained in the next section. Some tests are not reported because they will be used only for research and are not used for medical care. Better ways to look at some of the tests may be developed in the future. Some of the tests may be read again. We will not report the results of future tests to you. NHANES does not cover the cost of any health care you may decide to get after the exam. *If you have questions about getting your results, please call 1-800-452-6115.*

Will you test for sexually transmitted diseases (STDs)?

Teenagers (14 years and older) and adults under 60 years will have tests for STDs. We will not put these results in writing, but you can get STD test results a few weeks after the exam. Before you leave the mobile center, you will be given a toll-free number, a password, and the dates to call for your results. Only you will get your test results by calling in and telling us your password. Parents will not be told their child's STD test results. If your test results show that you have a current health problem, we will talk with you about the results and tell you how to get treatment. We will keep all STD test results

completely private, just like all other test results. If you do not want to be tested, you can tell a staff member. For details on the tests, please see the Health Measurements List.

Will my information be kept private?

We respect your privacy. Public laws keep all information you give private. These laws do not allow us to give out data that identifies you or your family without your permission. This means that we cannot give out any facts about you, even if a court of law asks for it. However, if we find signs of child abuse during an exam, we will report it to the local department of social services or the police.

We will keep all survey data safe and secure. When we share data with our partners, we do so in a way that protects your privacy as required and guaranteed by law. Our interviewer can provide you a list of our partners if you wish to learn more.

How are NHANES data used?

What you tell us, your exam results, and samples you give are a good resource for health science. Many Federal agencies, universities, and other public and private groups use NHANES data. They use it to help find new cures and treatments for diseases and disabilities. The aim is to make the health of all people better. Results of this survey may be reported in journals, at major scientific meetings, or through other news media. None of these reports will ever name or use data that can point to any person who took part in the survey. NHANES has been used in important national reports. One of these highlights the food we eat. Another tells us about the exposures we have to chemicals in the environment. The survey has also been used to track the number of people who are overweight or obese. Research using NHANES can be found on our Web site, listed on the back of this brochure. Health research using NHANES can be enhanced by combining your survey records with other data sources. An example is linking your survey results with vital statistics and Medicare claims. To do this, we will ask your permission to collect your Social Security and Medicare numbers. As we told you before, we keep this information safe and secure.

Also, we may need to contact you in the future. To do this we will ask public or private agencies, such as the Post Office, to give us changes to your address. In the past, we have had the chance to call or revisit people who took part in this survey. We may contact you in the future to ask you to be part of other research projects. Your participation in future studies is voluntary.

More questions?

Our survey representative can discuss other questions or concerns you might have or give you printed material that can help you. She or he can give you a phone number in your area that you can call for more facts about the survey. Also, you can make a free call to Dr. Kathryn Porter of the U.S. Public Health Service to discuss any aspect of the survey. She can be reached at 1-800-452-6115, Monday-Friday, 8:30 AM-6:00 PM EST. You may also contact her regarding any harm to you resulting from this survey. You can also get answers to your questions by mail (Room 4322, 3311 Toledo Rd., Hyattsville, MD 20782). You may have questions about your rights as a participant in this research study. If so, please call the Research Ethics Review Board at the National Center for Health Statistics, toll-free, at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol # 2005-06. Your call will be returned as soon as possible.

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

CONSENT/ASSENT AND PARENTAL PERMISSION FOR EXAMINATION AT THE MOBILE EXAMINATION CENTER

Print name of participant _____
First Middle Last

PARENT OR GUARDIAN OF SURVEY PARTICIPANT WHO IS UNDER 18 YEARS OLD:

For the Parent or Guardian of the Survey Participant who is a minor (unless the participant is an emancipated minor):

I have read the Examination Brochure and the Health Measurements List which explain the nature and purpose of the survey. I freely choose to let my child take part in the survey.

Signature of parent/guardian Date

SURVEY PARTICIPANT WHO IS 12 YEARS OLD OR OLDER:

I have read the Examination Brochure and the Health Measurements List which explain the nature and purpose of the survey. I freely choose to take part in the survey.

Signature of participant Date

If you are 18 and older, and do not want a written report of your exam results, check here

I observed the interviewer read this form to the person named above and he/she agreed to participate by signing or marking this form.

Witness (if required) Date

Name of staff member present when this form was signed:

Assurance of Confidentiality – All information which would permit identification of an individual, a practice, or an establishment will be held confidential, will be used only by NCHS staff, contractors, and other agents authorized by NCHS to perform statistical activities, only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347). By law, every employee as well as every agent has taken an oath and is subject to a jail term of up to five years, a fine of up to \$250,000, or both if he or she willfully discloses ANY identifiable information about you.

SP ID

2011 NHANES Health Measurements List, continued

Lab Tests on Blood (1+)

You will have your blood drawn. The blood will be tested for:

- Anemia (all) ♦
- Nutrition status (all) ♦
- Exposures to environmental metals: lead, cadmium, and mercury (all) ♦
- Infectious diseases (2+) ♦♦
- Total Cholesterol/HDL (6+) ♦
- Triglycerides/LDL (Morning session participants only, 12+) ♦
- Exposure to environmental chemicals (selected participants 6+)
- Kidney and liver function (12+) ♦
- Thyroid function (selected participants 12+) ♦
- Markers of celiac disease (6+) ♦
- Marker of muscle damage (12+) ♦
- Markers of immunization status (6-49) ♦♦
- Caffeine (6+)
- Sexually transmitted diseases (STD):
 - Genital herpes (14-49) ♦
 - Human immunodeficiency virus (HIV) (18-59) ♦
 - Human Papillomavirus (HPV) (14-59)
- Glucose (12+) ♦
 - Persons examined in the morning will have their blood drawn a second time to check for prediabetes

Lab Tests on Saliva

- Human Papillomavirus (HPV) (14-69)

Women and girls only:

You will be asked to self-administer a vaginal swab in complete privacy. The swab will be tested for the presence of Human Papillomavirus (14-59) ♦

Females 12 years and older will have a urine pregnancy test, as well as girls 8-11 who have started their periods. Our physician will tell you if you are pregnant if you did not already know it. Parents of girls younger than 14 years of age who are pregnant will also be informed of the test result ♦♦

After your visit to the NHANES mobile center:

If you had a dietary interview as part of your exam, you will get a phone call 3-10 days after the exam to be asked similar questions.

You will be asked to provide another urine sample (ages 6 years and older). Before leaving the center, you will be given instructions, a clean empty cup, and a prepaid, addressed box for shipment to our lab.

You will be asked to wear a physical activity monitor for 7 days after your exam (ages 6 years and older). A prepaid envelope will be provided for mailing the monitor back to our headquarters.

People who test positive for hepatitis C will be called and asked to be in a brief phone interview 6 months after the exam.

Taking part in these interviews and health measures after your visit to the mobile center is voluntary.

If you have questions about getting your results, please call 1-800-452-6115.

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES)
Consent/Assent and Parental Permission for Specimen Storage and Continuing Studies

Print name of participant _____
First Middle Last

Q Why will a sample of blood and urine be kept for future health studies?

A We will store some of the blood and urine from persons who are examined in NHANES for future health studies. These samples will be frozen and kept in a specimen bank for as long as they last. Your participation is voluntary and no loss of benefits will result if you refuse.

Q What studies will be done with the samples?

A At this time, no specific studies are planned besides the tests included in the NHANES exam. As scientists learn more about health and diseases, other studies will be conducted that may include stored samples. There can be many additional studies on these samples.

We will keep strictly confidential all health data and samples that we collect in NHANES as required by Federal law. By confidential we mean that the information that we release to the public can not be used to identify you. Our staff is not allowed to discuss that any person is part of this survey under penalty of Federal laws: Section 308(d) of the Public Health Service Act (42 USC 242m), the Privacy Act of 1974 (5 USC 552A), and the Confidential Information Protection and Statistical Efficiency Act (PL 107-347).

Q Who can use the stored samples for further study?

A Researchers from Federal agencies, universities, and other scientific centers can submit proposals to use the stored specimens. These proposals will be reviewed for scientific merit and then by a separate board that determines if the study proposed is ethical. The NHANES program will always know which

samples belong to you or your child, but we will not give other researchers any information that could identify you or your child.

Q Will I receive results from any future testing of my specimens?

A Science and medicine are continually advancing. New tests and new ways of looking at results will be developed in the future. We can't predict what tests will be done or what the results will mean for your health. The NHANES program will not contact you or your family with results from these future studies. We will describe the completed studies on our website. If you are interested in your results from any of these studies, you may call our toll-free number, 1-800 452-6115 to request your specific results as they come available.

Q What are the benefits and risks for allowing my blood or urine sample to be used for future studies?

A You will not directly benefit but these studies may eventually help the health of people in the future. The risk of giving a sample includes the minor risk associated with taking the blood sample. There may also be a risk that some people may use the information from these studies to exaggerate or downplay differences among people. The ethics board that will review all studies using these samples will attempt to prevent any misuse of the information gained from the NHANES samples.

Q How can I remove blood or urine samples from the specimen bank?

A In the future, if you want samples removed from the specimen bank, call us toll-free at 1-800-452-6115.

The results of continuing studies of your stored specimens may help find new ways to prevent, treat, and cure many diseases.

For persons ages 7 and over, check a box

- Yes, my blood and urine may be kept for future health studies, and I understand that I will not be contacted with the results from these studies
No, my blood and urine cannot be kept for future health studies

For parent/guardian of a child under the age of 18, check a box

- Yes, my child's blood and urine may be kept for future health studies, and I understand that I will not be contacted with the results from these studies
No, my child's blood and urine cannot be kept for future health studies

Signature of participant age 7 or over Date

Signature of parent/guardian of participant under 18 Date
(Unless the participant is an emancipated minor)

I observed the interviewer read this form to the person named above and he/she agreed to participate by signing or marking this form.

Witness (if required) Date

Name of staff member present when this form was signed:

SP ID

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES)**Consent for Specimen Storage and Continuing Studies Using DNA**

Print name of participant _____
 First Middle Last

Q Why will a sample of my DNA be kept for future health studies?

A Genes are the “instruction book” for people. Genes are made out of DNA. The DNA of a person is about 99.9% the same as the DNA of another person, but no two people have the same DNA except identical twins. Differences in DNA are called genetic variations and explain differences such as eye color and partly explain why some people get certain diseases. To look at these variations many genetic tests may be done on your blood sample. We will keep the DNA for an unlimited time. Studies of human genes are helping us learn about many diseases and health conditions. The information from people who are part of NHANES could help that effort.

We will store part of the blood sample that we collect in the exam center for future genetic studies. These samples will be frozen and kept in a specimen bank for as long as they last. Your participation is voluntary and no loss of benefits will result if you refuse.

Q What genetic studies will be done with the samples?

A Science and medicine are continually advancing. New tests and new ways of looking at results will be developed in the future. We can't predict what test will be done or what the results will mean for your health

Q Who can use the stored DNA samples for further study?

A Researchers from Federal agencies, universities, and other scientific centers can submit proposals to use the stored specimens. These proposals will be reviewed for scientific merit and then by a separate board that determines if the study proposed is ethical. The NHANES program will always know which samples belong to you, but we will not give other researchers any information that could identify you.

We will keep strictly confidential all health data and samples that we collect in NHANES, as required by Federal law. By

confidential we mean that the information that we release to the public can not be used to identify you. Our staff is not allowed to discuss that any person is part of this survey under penalty of Federal laws: Section 308(d) of the Public Health Service Act (42 USC 242m), the Privacy Act of 1974 (5 USC 552A), and the Confidential Information Protection and Statistical Efficiency Act (PL 107-347).

Q Will I receive results from any future testing of my specimens?

A The NHANES program will not contact you or your family with results from these future studies. We will describe the completed studies on our website. If you are interested in your results from any of these studies, you may call our toll-free number, 1-800-452-6115, to request your specific results as they become available.

Q What are the benefits and risks for giving a blood sample for future genetic studies?

A You will not directly benefit but these studies may eventually help the health of people in the future. The risk of giving a sample includes the minor risk associated with taking the blood sample. There may also be a risk that some people may use the information from the genetic studies to exaggerate or downplay differences among people. The ethics board that will review all studies using these samples will attempt to prevent any misuse of the information gained from the NHANES DNA samples.

Q How can I remove my DNA samples from the specimen bank?

A In the future, if you want samples removed from the specimen bank, call us toll-free at 1-800-452-6115.

The results of continuing studies of your stored specimens may help find new ways to prevent, treat, and cure many diseases.

Only for **persons ages 20 and over**, check a box

- Yes, my blood may be kept for future health studies using my genes to help understand genetic links to medical conditions, and I understand that I will not be contacted with the results from these studies

- No, my blood cannot be kept for future health studies using my genes

Signature of participant age 20 or over

Date

I observed the interviewer read this form to the person named above and he/she agreed to participate by signing or marking this form.

Witness (if required)

Date

Name of staff member present when this form was signed:

SP ID

Bronchodilator and Repeat Spirometry Informed Consent
National Health and Nutrition Examination Survey
Lung Function Testing with Medication

Your lung function test results were outside the normal range. The amount of air you breathed out in one second was less than expected for someone your age and sex. One reason could be narrowing of the small breathing tubes leading to your lungs.

The NHANES survey is asking you to take a medicine and do another breathing test. The results will show if you have a reversible breathing problem like asthma.

- You will be given medicine called albuterol to inhale that works to open your lungs.
- Although rare, the medication can briefly cause a fast heart beat, chest pain, nervousness or tremor; very rarely, an allergic reaction can occur.
- The Food and Drug Administration (FDA) could review your personal survey data since they monitor the safety of all medications. The FDA has approved the use of this medication for people aged 4 years and older.
- You will be asked to do another breathing test.
- The doctor will ask you questions about your health. The breathing medicine will not be given to people with certain types of health problems. If you have any of these health problems, you will not be asked to take the medicine or have another breathing test.
- Participation is voluntary.

I have read the information above. I freely choose /permit my child/ to have the medication and another lung function test.

Signature of the participant (ages 6 years and over) _____
Date

Signature of the parent or guardian
(Required if the participant is a minor) _____
Date

Print the name
of the participant _____ _____ _____
First Middle Last

Name of staff member present when this form was signed: _____

DEPARTMENT OF HEALTH & HUMAN SERVICES
National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

Dear Principal:

Please excuse the below named student from class to participate in a national health survey conducted by the Centers for Disease Control and Prevention. The date and arrangements we have made for transportation are indicated below.

NAME _____

DATE _____

- Parent will pick up.
- Taxi will pick up.
- One of our representatives will pick up.
- Student will leave from home.

Thank you for your cooperation and your appreciation of the valuable contribution this student is making to our study. If you need to contact us, please call _____.

Sincerely,

Stand Manager

As parent/guardian of the above named child, I consent to the arrangements indicated.

Signed (Parent/Guardian)

NATIONAL HEALTH SURVEY
AUTHORIZATION FOR TRANSPORTATION ARRANGEMENTS FOR
PERSONS UNDER 16 YEARS OF AGE

NAME OF CHILD: _____ AGE: _____

- I consent to transportation of my child to and from the Mobile Exam Center/Field Office by members of the CDC health survey staff.
- I consent to transportation of my child to and from the Mobile Exam Center/Field Office in a taxi arranged and paid for by the CDC health survey.
- I will drive.

Children under 12 must come to the Mobile Exam Center accompanied by someone aged 12 and over. Please complete the subsequent section with this in mind. Children under 12 who arrive alone will not be examined.

- Mother will accompany.
- Father will accompany.
- Other person 12 and over will accompany _____
Specify
- Will come alone (only for children ages 12 - 16).

(Date)

(Signature of Parent or Guardian)

(Witness)