

Home Interview Consent

(Printed on Legal Size Paper)

#1

OMB # 0920-0237

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.

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:

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.

Exam Consent Brochure

National Health and Nutrition Examination Survey

**NHANES
Examination
Consent Brochure**



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. We use the most up-to-date methods and equipment for medical and dental exams and other lab tests.

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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. We 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.

What do I gain by taking part in the exam?

- 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?



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

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



Height and weight



Blood pressure



Breathing



Ears



Teeth



Body composition



We will collect blood and urine samples



And ask you questions about what you eat



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 2½ 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 having a blood sample taken 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 or her arm with a needle. People 12 years and older that have a morning exam will be asked to drink a sugary drink and have blood taken a second time. Although rare, the sugary 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 aged 8 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 or 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 or 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 them. 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 website, 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 a.m.-6:00 p.m. 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.



Adult/Parent Consent Form

OMB # 0920-0237

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

Consent/Assent and Parental Permission for Specimen Storage and Continuing Studies

OMB # 0920-0237

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 _____