



National Health and Nutrition Examination Survey (NHANES)

Informed Consent and Outreach

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Chief Medical Officer
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Division of Health and Nutrition Examination Surveys
National Center for Health Statistics

Chief Medical Officer (CMO)

- Primary contact for participants and their medical providers for any medical questions from the Report of Findings (ROF)
 - Provide medical interpretation of results and recommendations
- Acting Human Subjects Officer for NHANES
- Assist with Operations Activities to include Outreach

Obtaining Consent

- NHANES consents are obtained for each phase of the survey
 - Household interview
 - Mobile Examination Center (MEC)

Obtaining Consent

- Participants are provided with a packet of consent materials
- To fulfill the requirement of informed consent, the field staff administering the consent must review the following documents with participants:
 - Confidentiality Brochure
 - Mobile Examination Center (MEC) Consent/Assent Brochures
 - Consent/Assent Forms
 - Health Measurements List
- Participants provide verbal consent prior to beginning home interview

Confidentiality Brochure

- Outlines the confidentiality laws and privacy protections for NHANES participants

Our promise to you

- Your health exam will be free. We will share the results with you and give you a token of appreciation for your time.
- Taking part in NHANES will not affect your benefits like Medicare, Medicaid, Social Security, food stamps, or disability.
- We will provide free transportation to our mobile health center or help cover the cost of getting there.
- We will keep your information confidential. We will never give any information to state or federal agencies, including the police or immigration services.
- We will remove all information that could show your identity, like your name, address, or phone numbers.

NATIONAL CENTER FOR HEALTH STATISTICS



How the National Health and Nutrition Examination Survey Keeps Your Information

CONFIDENTIAL



Centers for Disease
Control and Prevention
National Center for
Health Statistics

2021 Confidentiality Brochure

Consent Brochure

- Provides a brief overview about the survey, who sponsors it, and how it is conducted
 - The benefits of participation are discussed as well as what to expect at the MEC
 - Emphasize that all information will be kept confidential and how all data collected on this survey will be used



Centers for Disease Control and Prevention
National Center for Health Statistics



nhanes



on Survey
for nation's health

National Health and Nutrition Examination Survey

Overview

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

Our survey is unique. It combines interviews with health measurements that are done in special mobile exam centers. These centers travel across the country, each with its own highly trained medical team. The team looks at special health topics. We use the most up-to-date methods and equipment for medical exams and lab tests.

Why is this health survey important?

We 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 look at diet and other habits that affect health, such as smoking and exercise.

NHANES provides health and nutrition information on people of all ages. It is also used by those who design health programs and services, and the survey expands 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 you are free to drop out at any time. 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 your height and weight, blood pressure, and body composition. We will collect blood and urine samples.

If your appointment is scheduled in the morning, we will ask you not to eat or drink anything except water overnight. The health tests may take up to 2 ½ hours. 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.

After your visit to the NHANES mobile center

You will be asked to participate in two dietary interviews by phone 3-7 days after your visit to the mobile center. All survey participants will be asked to take part in the interviews. An adult will answer questions for children less than 5 years old and will assist children 6-11 years old. Participants 12 years and older will respond for themselves.

You, or an adult in your family (if you are between 1-15 years old), will also be asked about food shopping habits in a separate interview.

For each of these interviews, you will receive a token of thanks for your time and effort.



January 2022 MEC Exam Consent/Assent Brochure

Consent Brochure

- CDC-recommended COVID-19 precautions are discussed
- Provides CMO and Ethics Review Board contact information for any questions after participation

Safety precautions

The mobile center and medical team will follow CDC guidelines for COVID-19 precautions. Participants will be asked to follow all CDC safety recommendations. Staff will wear masks, gloves, and other personal protective equipment as needed. The number of participants and staff at the mobile center will be limited to ensure proper social distancing. Special care will be taken to clean surfaces and equipment with CDC recommended disinfectants after each participant exam. Upon arrival at the mobile center you will be asked questions about your health on that day and over the past 2 weeks.



More questions?

Visit the NHANES participant website at <https://www.cdc.gov/nchs/nhanes/participant.htm>.

Our survey representatives can discuss other questions or concerns you might have or give you printed material that can help you. They can also give you a phone number in your area that you can call for more facts about the survey.

You can call our Chief Medical Officer, Dr. Duong Nguyen of the U.S. Public Health Service, to discuss any aspect of the survey. He can be reached at 1-800-452-6115, Monday-Friday, 7:30 a.m.-4:30 p.m. ET. You may contact him regarding any harm to you resulting from this survey. You can also get answers to your questions by writing to Dr. Nguyen at MS P08, 3311 Toledo Rd., Hyattsville, MD 20782-2064.

If you have questions about your rights as a participant in this study, please call the 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, and say that you are calling about Protocol (#2021-05) for NHANES 2021-2022. Your call will be returned as soon as possible.



Consent/Assent Forms

- Consent/Assent and Parental Permission for Examination at the MEC

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY CONSENT/ASSENT AND PARENTAL PERMISSION FOR EXAMINATION AT THE MOBILE EXAMINATION CENTER		OMB # 0920-0950
Print name of participant _____		
First	Middle	Last
PARENT OR GUARDIAN OF SURVEY PARTICIPANT WHO IS UNDER 18 YEARS OLD:		SURVEY PARTICIPANT WHO IS 12 YEARS OLD OR OLDER:
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 take part in the survey.
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 or guardian		Date
FOR PARENT OR GUARDIAN OF SURVEY PARTICIPANT 12-17 YEARS (check the box):		SURVEY PARTICIPANT WHO IS 7-11 YEARS:
I agree to have my child's interview about his/her current health status, diet, and health behaviors recorded for quality control. ☐		Your parents say you can take part in this special survey. You have just read about the survey in this booklet.
I do not agree to have my child's interview about his/her current health status, diet, and health behaviors recorded for quality control. ☐		If you want to take part in the survey, write your name below.
_____		Signature of participant
_____		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 – We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors, and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m) and the Confidential Information Protection and Statistical Efficiency Act of 2018 (Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)). In accordance with CIPSEA, every NCHS employee, contractor, and 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.		
2021		
SP ID _____		

Specimen Storage & Continuing Studies Consent Form

- Participants are must choose to either to allow or not allow NHANES to keep/store blood and urine samples.
- No samples collected will be stored for future research unless participants provide documented consent

OMB # 0920-0950

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

The results of continuing studies of your stored specimens may help find new ways to prevent, treat, and cure many diseases. Please turn to the back of this form for answers to commonly asked questions.

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
(Unless the participant is an emancipated minor ☐) 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: _____

SPID _____

Assurance of Confidentiality – We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors, and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m) and the Confidential Information Protection and Statistical Efficiency Act of 2018 (Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)). In accordance with CIPSEA, every NCHS employee, contractor, and 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.

Future Studies Consent FAQ

- Participant Confidentiality protected by Section 308(d) of the Public Health Service Act (42 USC 242m) and the Privacy Act of 1974 (5 USC 552A)
- Participants are informed that NHANES will not contact regarding any results from future testing

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES) Consent and Parental Permission 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 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 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.

People conducting these studies will not contact NHANES participants for any additional information.

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) and the Privacy Act of 1974 (5 USC 552A).

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.

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

A Most studies using DNA samples will simply add to our knowledge of health and disease. Therefore, we do not plan to contact you with individual results from these studies. Periodically we will announce on our web site general results from the studies being conducted, (<http://www.cdc.gov/nchs/nhanes.htm>). To get more general information about a particular study, you can call our toll-free number, 1-800 452-6115.

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.

Health Measurements List

- Provides participants a list of the health exams that are conducted.



2021 NHANES Health Measurements

Below is a list of tests you may receive on the day of your examination. You will only have the test if your age falls within the ages shown in parentheses. You will receive the results of health measures shown with a black diamond (♦). Two diamonds (♦♦) means you will receive a result only if positive, or abnormal.

Before you enter the NHANES Mobile Examination Center

Health Measurements

You will be weighed and measured (all) ♦
We will take your blood pressure (8+) ♦
You will have a body composition test that involves low-dosage x-rays
(*Pregnant women will not have this test*)
Total body scan (8-59) ♦
You will have a liver ultrasound transient elastography test (12+) ♦
(*Pregnant women will not have this test*)
You will have your balance tested (20-69)♦

Private Interviews

You will be asked to answer questions about:
Reproductive history (females 12+)
Drug use (12-59)
Alcohol and tobacco use (12+)
Sexual history (14-69)

(*You will do these by yourself using a touch screen computer for privacy*)

Lab Tests on Urine

You will be given a clean empty cup when you arrive at the exam center. When you change into the exam clothes in a private rest room, you will provide a urine sample. The urine will be tested for:

Exposure to environmental chemicals and metals

Arsenic (3+) ♦♦
Nickel (3+) ♦

Kidney function tests: (3+)
Albumin/ creatinine ratio ♦

Sexually transmitted diseases:
Chlamydia (14-39) ♦
Trichomonas (14-59)

(*NHANES does not test for illicit drug use*)

Please turn over to see the next page

Health Measurements List

- Provides participants a list of the health exams that are conducted.
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Environmental Health Profile

- Acetylcholinesterase (6+)
- Butyrylcholinesterase (6+) ◆◆
- Acrylonitrile (1/3 participants 6+)
- Aromatic amines (urine) (3-5, 1/3 participants 6+)
- Flame retardant metabolites (blood – 12+, urine – 3-5, 1/3 participants 6+)
- Insecticides, pesticides, herbicides, fungicides and metabolites (blood - 1/3 participants 12+, urine – 3-5, 1/3 participants 6+)
- Metals/elements in blood
 - Cadmium (1+) ◆
 - Lead (1+) ◆
 - Manganese (all) ◆
 - Mercury/mercury speciation (1+)◆
 - Selenium (1+) ◆
- Trace metals/elements in urine (3-5, 1/3 participants 6+)

Consent at MEC

- Documents presented by MEC staff again for any final questions prior to obtaining consent signatures



National Health and Nutrition Examination Survey

2021 NHANES Health Measurements

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Centers for Disease Control and Prevention
National Center for Health Statistics



nhanes
The Nation's Mobile Health Survey



National Health and Nutrition Examination Survey

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NHANES Outreach



Purpose of Outreach

- Encourage participation in the NHANES by:
 - Underscoring the importance of the study
 - Demonstrating the benefits and relevance of participation
 - Addressing suspicion and fear

Local Health Department

- Months before starting at a location, NHANES meets with the local health departments to inform them that the survey is coming
- During the meeting, agenda items include inquiring for important community leaders
- Request assistance from Public Affairs staff for media contacts



NHANES Outreach

- Elected officials, City Councils
- Influential community leaders (religious, universities, cultural)
- Invited to NHANES media day

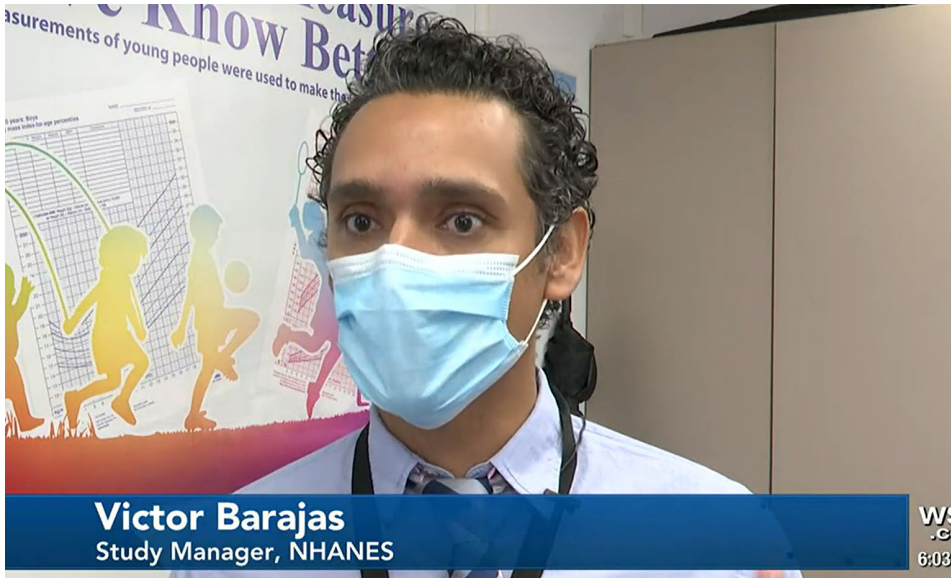


NHANES Community Outreach

- Community presentations
- Partner with local academic institutions for support and endorsement



Media outreach



Thank you

