

Attachment 5

Consent Materials

- Consent Brochure Text
- Consent Form for Living Participant

NHANES Longitudinal Study

Consent Brochure Text

Reading Level: 10.1

Overview

Welcome back to the National Health and Nutrition Examination Survey (NHANES)! As a participant of the survey, you have been chosen to take part in a follow-up study that will cover topics such as heart disease, diabetes, and other health conditions.

The NHANES Longitudinal Study is conducted by the National Center for Health Statistics (NCHS), part of the Centers for Disease Control and Prevention (CDC). This study will combine an interview and brief exam in your home during a single visit.

Why is this health study important?

The data we collected from you in the past was used to study the health and nutrition of people in the United States. This study will help us understand how health changes over time.

This study is being done on a small group of 800 persons from across the country to see if we can find, interview, and examine prior NHANES participants. The information gathered will help us move forward toward launching a full-scale study of all adults previously examined in NHANES. We may contact you in the future to collect more information.

What do I gain by taking part in the study?

- The chance to help us keep learning more about the health of the nation.
- Health test results.
- A token of thanks for your continued time and participation.

Taking part in the survey is voluntary. There is no penalty if you refuse. During the interview you may choose not to answer every question. You may also refuse any part of the exam.

What will I be asked to do?

An interview and a health exam will be conducted in your home. Together, this visit is expected to take about one hour.

The Interview includes:

Questions about your health habits, health problems, and your doctor and hospital visits.

The Health Exam includes:

- Weight and waist measurement
- Blood pressure measurement
- Testing the feeling in your feet (Monofilament test)
- Collecting a blood sample from your finger to test for diabetes

After the exam, we will ask you to:

- Collect and mail a urine sample to test for kidney disease.

Are the tests safe?

The tests are safe. Some tests may cause you slight discomfort. For example, the blood sample is collected using a finger stick.

We will not do any test that is unsafe for you because of a health problem or health condition you have.

Will I get my results?

Yes, you will get two reports with your results. At the end of the exam, the Health Representative will provide you with a written report with your weight, waist measurement, and blood pressure findings. A second report will be mailed to you several weeks after the exam and will include additional results from the diabetes, kidney, and foot sensation tests if they were successfully performed. If the exam shows urgent health problems, we will call and notify you at once, and advise you as to where you may get this finding evaluated. We give results to the person examined or to a legal guardian when prior consent is given.

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 my information be kept private?

We take your privacy very seriously. The information you give us will be used for statistical research only. This means that your information will be combined with other people's information in a way that protects everyone's identity. As required by federal law, only those NCHS employees, our contractors, and our specially designated agents who must use your personal information for a specific reason can see it. Otherwise, your data will only be shared after all information that could identify you and/or your family has been removed.

Strict laws prevent us from releasing information that could identify you or your family to anyone else without your consent. A number of federal laws require that all information we collect be kept confidential: Section 308(d) of the Public Health Service Act (42 United States Code 242m(d)), the Confidential Information Protection and Statistical Efficiency Act (CIPSEA, Title 5 of Public Law 107-347), and the Privacy Act of 1974, 5 U.S.C. § 552a. Every NCHS employee, contractor, research partner, and agent has taken an oath to keep your information private. If he or she willfully discloses ANY identifiable information, he/she could get a jail term of up to five years, a fine of up to \$250,000, or both.

In addition, NCHS complies with the Federal Cybersecurity Enhancement Act of 2015. This law requires the federal government to protect federal computer networks by using computer security programs to identify cybersecurity risks like hacking, internet attacks, and other security weaknesses. The Act allows software programs to scan information that is sent, stored on, or processed through government networks in order to protect the networks. If any cybersecurity risk is detected, the information system may be reviewed for specific threats by computer network experts working for the government (or contractors or agents who have governmental authority to do so). Only information directly related to government network security is monitored. The Act requires any personal information that identifies you or your family to be removed from suspicious files before they are shared.

More questions?

Our Health Representative can discuss other questions or concerns you might have or give you printed material. Also, you can make a free call to Dr. Duong T. Nguyen of the U.S. Public Health Service to discuss any aspect of the study. He can be reached at 1-800-452-6115, Monday-Friday, 7:30 a.m.-4:30 p.m. EST. You may also contact him regarding any harm to you resulting from this survey. You can also get answers to your questions by writing to him at MS P08, 3311 Toledo Road, Hyattsville, MD 20782.

You may have questions about your rights as a participant in this 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 # 20XX-XX. Your call will be returned as soon as possible.

NHANES Longitudinal Study

INTERVIEW AND HOME EXAM CONSENT

Reading Level: 9.1

OMB # 0920-NEW

You have been chosen to take part in the National Health and Nutrition Examination Survey (NHANES) Longitudinal Study, conducted by the National Center for Health Statistics (NCHS), part of the Centers for Disease Control and Prevention (CDC). This research study will help us design future studies to understand how health changes over time. Our Health Representative will ask you questions about your health status, medical conditions, health care services, and health behaviors. A brief in-home exam will follow the interview and will include weight and waist measures, a foot sensation test, and a blood pressure reading. A blood sample will be obtained, and you will be asked to collect and mail a urine sample. The questions and in-home exam today will take about one hour. We may contact you to check the work of our staff. We may also contact you again for further studies.

We are required by law to use your information for statistical research only and to keep it confidential. Please refer to the box below for more detailed information on federal laws that protect your privacy.

Taking part in this survey is voluntary. You will not lose any benefits if you chose not to take part. If you choose to take part, you don't have to answer every question and you can stop the interview or exam at any time.

Do you have more questions about the survey? You can make a toll-free call to Dr. Duong T. Nguyen of the U.S. Public Health Service at 1-800-452-6115, Monday-Friday, 7:30 AM-4:30 PM ET. If you have questions about taking part 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 # XXXX-XX. Your call will be returned as soon as possible.

SIGNATURE OF PERSON ANSWERING QUESTIONS AND PARTICIPATING IN THE EXAM:

I have read the information above and the consent brochure. I agree to proceed with the interview and exam.

Date

SIGNATURE OF CARETAKER / GUARDIAN IF SELECTED PARTICIPANT IS UNABLE TO PROVIDE WRITTEN CONSENT:

Signature of Caretaker / Guardian

Date

I observed the Health Representative read this form and the consent brochure to the person named below as the selected participant and he/she agreed to participate by signing or marking this form.

Witness or Interpreter (if required)

Date

Name of staff member present when this form was signed:

RECORD PARTICIPANT INFORMATION:

SP NAME _____

SP ID _____

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 USC 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, Title 5 of Public Law 107-347). 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. In addition, NCHS complies with the Cybersecurity Enhancement Act of 2015. This law requires the Federal government to protect its information by using computer security programs to identify cybersecurity risks against federal computer networks.

The Cybersecurity Act of 2015 permits monitoring information systems for the purpose of protecting a network from hacking, denial of service attacks and other security vulnerabilities.¹ The software used for monitoring may scan information that is transiting, stored on, or processed by the system. If the information triggers a cyber threat indicator, the information may be intercepted and reviewed for cyber threats. The Cybersecurity Act specifies that the cyber threat indicator or defensive measure taken to remove the threat may be shared with others only after any information not directly related to a cybersecurity threat has been removed, including removal of personal information of a specific individual or information that identifies a specific individual. Monitoring under the Cybersecurity Act may be done by a system owner or another entity the system owner allows to monitor its network and operate defensive measures on its behalf.

¹ "Monitor" means "to acquire, identify, or scan, or to possess, information that is stored on, processed by, or transiting an information system"; "information system" means "a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination or disposition of information"; "cyber threat indicator" means "information that is necessary to describe or identify security vulnerabilities of an information system, enable the exploitation of a security vulnerability, or unauthorized remote access or use of an information system".

Medical errors and injuries are very rare. The NHANES program cannot provide money or other compensation if they occur. However, if you believe you have been harmed as a result of your participation in NHANES, we want to know about it. Please call us at 1-800-452-6115. You also have a right to file a claim under the Federal Tort Claims Act with the Centers for Disease Control and Prevention. We can provide you with information about how to do so. You must file the claim within two years after the date you became aware of the personal injury, loss of property, or other damage.

Public reporting burden of this collection of information may take up to 1.5 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 (0920-0950).