

# ***Attachment 5***

## ***Informed Consent Brochures***

## **Attachment 5 - Informed Consent Brochures**

A summary of the 2011 planned consent forms follows:

1. Consent Form for Household Interview(s). If an adult household member does a proxy interview for one or more children and answers the household/family questionnaire that individual signs one interview consent form that lists all the interviews they are consenting to.
2. Consent brochures and forms for the examination.
  - a. For participants ages 7-11 there is an assent brochure (child version) and form.
  - b. For participants ages 12-17 there is an assent brochure (adult version) and form
  - c. There is a separate consent form for stored specimens where the adult participant or parent consents and the child assents
  - d. There is a separate consent form for DNA specimens for adults 20 and older
  - e. For participants 6-79, with obstructive changes on spirometry, there is a special consent form.
3. NHANES has guests participate in the examination on a regular basis. There is a consent form and health measurement list to describe the guest examination.
4. Forms signed by parents for children to get off school and/or be transported to the examination center are also in this section.

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 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.

# **Brochure on NHANES Examination and Form for Consent/Assent/Parental Permission**

## **National Health and Nutrition Examination Survey**

### **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.

### **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?**

Our health representative will ask you to make an appointment for the exam 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:

*(Picture are shown; captions a listed here:)*

Height and weight

Blood pressure

Eyes Ears

Teeth Bones

We will also 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 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 body composition tests that involve 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 behavior, 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.

### **Will you test for sexually transmitted diseases (STDs)?**

Teenagers (14 years and older) and some adults 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 exam 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.



**FORM APPROVED:**

**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

If you do not want a written report of your child's exam results, check here

**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 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:

\_\_\_\_\_

\_\_\_\_\_  
SPID

**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 agents 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



# 2011 NHANES Health Measurements

Below is a list of tests you will receive on the day of your examination.

You will only have the test if your age falls within the ages shown in parenthesis.

You will receive the results of health measures shown with a black diamond (◆). Two diamonds (◆◆) means you will receive the test result only if high or abnormal.

## Health Measurements

You will be weighed and measured (all) ◆

The doctor will take your blood pressure (8+) ◆

We will look at the condition of your teeth and gums (1+) ◆

You will have body composition tests that involve low-dosage x-rays  
Total body (8-59) ◆  
(*Pregnant women will not have bone density tests*)

You will have a taste and smell test (40+) ◆

You will have a hearing test (20-69) ◆

You will have breathing tests (6-79)  
Exhaled nitric oxide test using the NIOX-MINO™ device

Lung function test measuring the volume of air you can breathe out after taking a deep breath in ◆

- If the test shows abnormal results, you will be asked to visit our doctor and give permission to do another breathing test
- The doctor will talk to you about breathing a medication that opens up your breathing tubes before doing the test again

## Private Interviews

You will be asked questions about your eating habits (all)

You will be asked to answer questions about:

Weight history (8-15)

Reproductive history (females 12+)

Drug use (12-69), alcohol and tobacco use (12-19), self-identified stage of puberty (8-19), and sexual history (14-69)\*

*\*(You will do this by yourself and using a private touch-screen computer)*

You will be asked to take short tests to assess your learning and memory (60+)

## Lab Tests on Urine (6+)

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 (all) [arsenic ◆◆]

Kidney function tests (all) ◆

Sexually transmitted diseases: Chlamydia (14-39) ◆

*(Urine is not tested for drug use)*



Please turn over to see the next page.

# 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.

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.**

## **Brochure on NHANES Examination and Form for Assent for Participants 7-11 Years Old**

### *Text for Informational Brochure for Participants 7-11 Years of Age*

The National Health and Nutrition Examination Survey (NHANES) studies the health and diet of people in this country.

The survey will look at how young people grow and develop. We will ask questions about what your body looks like. We will look at special health problems that may affect kids.

We go all over the United States in these vans.

Our survey wants you to come to this exam center. The exam is like going to the doctor. Your exam will help us find out more about the health of children your age.

We will ask questions about what you eat and drink.

You will change into special exam clothes at the exam center.

Our doctor will take your pulse.

We will take your blood pressure.

We will see how much you weigh and how tall you are.

We will look at your teeth.

We will test your breathing.

We will check your blood and urine in our lab.

We will send you and your parents a report on your exam.

We will give you money to thank you for helping us with our survey.

Our staff will answer any questions you have.

We would like you to go to our mobile exam center vans for an exam. You will help us learn more about all children in the United States.

**National Health and Nutrition Examination Survey (NHANES)**

Your parents say that you can take part in this special survey. You have just read about the survey in this book. The survey tells us about the health of people. We will ask you to have an exam at our vans that are here in your town. This exam is a little like going to the doctor. Other kids and their families will be at the center. You do not have to do this if you do not want to. If you take part, you will learn some things about yourself. You will help us learn a lot about other kids in the United States.

If you want to take part in the survey, write your name below.

---

Signature of participant 7-11 years old

---

Print name of participant

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 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** 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

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

I disagree

\_\_\_\_\_  
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 \_\_\_\_\_





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 National Center for Health Statistics, part of 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)