Attachment 9a Consents

#1 OMB # 0920-0950

**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.

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 and you can stop the interview at any time.

We can do additional health research by linking the interview and exam data of everyone listed under “SP NAME” in the gray box below to vital statistics, health, nutrition, and other related records. May we try to link these survey records with other records?

Yes No N/A

Do you have more questions about the survey? You can make a toll-free call to the Senior Medical Officer at 1-800-452-6115, Monday-Friday, 8:30 AM-5:30 PM ET. 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 # 2011-17. 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.

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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

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**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) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, Title 5 of Public Law l 07-347). In accordance with CIPSEA every NCHS employee, contractor and agent have 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.

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 (0920-0950). **01/17**

**National Health and Nutrition Examination Survey**

**Examination Consent Brochure 2016 (see Attachment 9b)**

**Child Assent Brochure 2016 (see Attachment 9c)**

OMB # 0920-0950

###### 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.

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Signature of parent/guardian Date

**FOR PARENT OR GUARDIAN OF SURVEY PARTICIPANT 12-17 YEARS:**

 I agree to have my child’s interview about his/her current health status, diet, and health behaviors recorded for quality control.

 I do not agree to have my child’s interview about his/her current health status, diet, and health behaviors recorded for quality control.

**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.

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Witness (if required) Date

Name of staff member present when this form was signed:

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| **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) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, Title 5 of Public Law l 07-347). In accordance with CIPSEA every NCHS employee, contractor and agent have 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. |

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SP ID

OMB # 0920-0950

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

**2016 MEC Assent**

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. You can also stop at any time and you do not have to do any tests that 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.

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Signature of participant 7-11 years old

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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.

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Witness (if required) Date

Name of staff member present when this form was signed:

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

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

SP ID

 

U.S DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics

**2017 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 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+) ♦

Dental imaging for fluorosis (12-29)

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) ♦

Hip and spine bone density scans (50+) ♦

You will have a liver elastography test (12+)♦

You will have a hearing test (children/adolescents 6-19 and adults 70+) ♦

**Private Interviews**

You will be asked to answer questions about:

Eating habits (all)

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 these by yourself using a touch-screen computer in privacy)*

**Lab Tests on Urine (3+)**

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+ ♦♦]

Kidney function tests (3+) ♦

Sexually transmitted diseases:

Chlamydia (14-39) ♦

Trichomonas (14-59) ♦

(*Urine is not tested for drug use*)

**Lab Tests on Water:**

The interviewer will collect a sample of household tap water if participants are under 20 years of age. The water will be tested for fluoride. ♦

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**Please turn over to see the next page.**

**2017 NHANES Health Measurements, cont.**

**Lab Tests on Blood (1+)**

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

Anemia (all) ♦

Nutrition status (all) ♦

High-sensitivity C-Reactive Protein (hs- CRP) (all tested) (1+) ♦

Exposures to environmental metals:

Lead, cadmium, mercury, manganese (all participants 1+) ♦

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+) ♦

Cytomegalovirus (CMV) (1-5) ♦♦

Sexually transmitted diseases (STDs):

Herpes simplex virus type-2 (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

Fluoride (6-19) ♦

**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 12-59 years old 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. ♦♦

**Men and boys only:**

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

**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.

**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.**

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**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. You can request that your samples be removed at any time. 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. 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) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, Title 5 of Public Law l 07-347). In accordance with CIPSEA every NCHS employee, contractor and agent have 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.

***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

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Signature of participant age 7 or over Date

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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.

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Witness (if required) Date

Name of staff member present when this form was signed:

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SP ID