

Attachment A.

**National Health and Nutrition Examination Survey (NHANES)  
Health Measures at Home Study (ages 18+)**

OMB no. 0920-0237

Expires: 11/30/2012

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**Health Measures and Home Pilot Study Assessment Protocol:**

Eligibility: Sample persons aged 18 years or older are eligible for this study.

Informed Consent: Informed consent will be obtained during the National Health and Nutrition Examination Survey (NHANES) Mobile Examination Center (MEC) exam.

Exclusion Criteria: Participants who are unable to respond for themselves, are unable to complete the study in English without the assistance of an interpreter, are pregnant, or have a physical condition which precludes them from the collection of accurate physical measures and bio-specimen collection will be excluded. Participants who refused the finger stick or are excluded from the phlebotomy, anthropometry (height, weight, arm circumference), and physician (blood pressure) component in the MEC will also be excluded.

Health Measures:

Height, weight, and blood pressure will be measured in the MEC and in the home. Both in the MEC and in the home, height will be measured once and weight will be measured twice using two scale models. One blood pressure (BP) measurement will be collected in the MEC. Up to three BP measurements will be collected in the home. If a respondent who wears a sleeve is unwilling or unable to roll up their sleeve, the blood pressure measurements will be taken over the sleeve and it will be noted that it was taken over clothing. Respondents who rolled up their sleeve for the first two blood pressure measurements will be asked to roll down their sleeve for a third BP reading.

### Specimen Collection:

Dried blood spots (DBS) will be collected in the MEC by a trained phlebotomist. Up to two finger sticks will be collected per respondent. DBS assessments include CRP, HbA1c, HDL, and TC. DBS will be compared to the MEC venous blood specimens.

Dried blood spots (DBS) will also be collected in the home. The DBS will be collected twice, once by a lay interviewer and once by a trained health technician. Both the interviewer and health technician will perform the collection on the same visit to the respondent's home.

### Report of Findings:

Blood pressure findings on bare arms will be reported to participants. All other measures done are for methodological study purposes.

## **Scripts & Talking Points**

### **Suggested Script for Recruitment at the MEC**

#### **Health Measures at Home Study**

We are conducting a special study to determine if some of the measurements done here at the exam center can be done at home. This study has two parts. First, we would like to measure your height and weight, and take your blood pressure with the same equipment we will use in the home. We also ask for your permission to do a finger stick test with a sterile lancet. This is very similar to a finger stick someone with diabetes does to check their blood sugar. These measurements will be done today, before you leave the exam center.

The second part of the study will be done in your home. At your home these measurements and the finger stick will be collected separately by a health technician and by an interviewer.

The measurements we collect today will take about 25 minutes or less. Then we will set up an appointment to do the same measurements in your home. Results from these measurements will not be reported to you because you will receive results from your exam earlier today. During your home exam, we will tell you your blood pressure reading. The home exam measurements will not be part of the information collected for national statistics.

Participation is voluntary. You will receive a check for \$60 for your time at the conclusion of the home exam. Are you willing to participate in this special study?

#### **Reminder Calls Script**

Hello, I am \_\_\_\_, with the NHANES program. I'm calling to remind you of your appointment {tomorrow/date} at {time} for the Health Measures at Home Study. {Name of interviewer and health technician} will be at your home to conduct the study. They will measure your height, weight, blood pressure and do a finger stick. Do you have any questions? Thank you for participating in our study.

## **Consent (obtained at the MEC)**

### **Consent to Participate in the Health Measures at Home Study**

The Centers for Disease Control and Prevention is conducting research to determine how measurements done here at the exam center compare to those taken at your home. This study has two parts. The first part takes place in the examination center today, and the second part will take place in your home in the next few days.

#### **In the Mobile Examination Center:**

Today, we will repeat some of the measurements already taken, this time with different equipment. You will not miss any of your NHANES components. We will fit in these extra measures while you are waiting for your other exams and you will still not be here more than 4 hours. We will measure your height, weight, and blood pressure. We will also prick your finger with a sterile lancet to get drops of blood for laboratory testing. Results from these tests will not be reported to you because you will receive results from your exam earlier today. Also, your data will not be part of the information collected for national statistics.

**In your home:** For the second part of the study, we will make an appointment to visit your home and two examiners will do these measurements and finger stick again. We want to know how results will compare when done by two people. At your home, one person will measure your weight twice, height, and blood pressure, and perform a finger stick. Once he/she is finished, a second person will do all of the measurements again, including the finger stick. If your sleeve needs to be rolled up for the blood pressure measurement, we will ask you to roll down your sleeve for a third blood pressure reading over your sleeve. The exam at your home will take approximately 1 hour. The technician will tell you your blood pressure reading that day. You will not receive any other results.

#### **Other information**

The examinations pose no more harm than a usual visit to a doctor.

All data collected will be kept strictly confidential and will be used only for research. By law, the information you provide cannot be used for any other purpose without your permission.

Participation in this study is voluntary. You will not lose any benefits if you refuse to participate.

If you have questions about your rights as a participant, you may call the Chair of the Ethics Review Board at the National Center for Health Statistics at (1-800-223-8118). If you have other questions about the study or your results, please do not hesitate to call Dr. Kathryn Porter of the U.S. Public Health Service at: 1-800-452-6115.

You will receive a copy of this form, which you should keep for your records. Please sign on the laptop if you understand this information and voluntarily agree to participate.

Signature: \_\_\_\_\_ *electronic*  
Print Name: \_\_\_\_\_ *electronic*

Date: \_\_\_\_\_

## Report of Findings

*These measurements were obtained as part of a study and do not represent a medical diagnosis. Interpretation of these measurements must be made by a physician.*

Date of Examination: \_\_\_\_\_

Participant Name: \_\_\_\_\_

### Blood Pressure

	Your Measurements	Normal
Systolic Blood Pressure:	_____ mm Hg	< 120
Diastolic Blood Pressure:	_____ mm Hg	< 80

- 1) Your blood pressure today is **within the normal range**. We suggest you see your doctor within the next year to have your blood pressure rechecked.
- 2) Your blood pressure today is **above normal** and is in the pre-hypertensive range. We suggest you see your doctor within the next six months to have your blood pressure rechecked.
- 3) Your blood pressure today is **high**. We suggest you see your doctor within the next two months to have your blood pressure rechecked.
- 4) Your blood pressure today is **very high**. We suggest you see your doctor within the next two weeks to have your blood pressure rechecked.
- 5) Your blood pressure today is **severely high**. We suggest you see your doctor today or as soon as possible to have your high blood pressure treated.

Items 1 – 4 are from the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003. Item #5 is based on a recommendation from the American Heart Association.