

Attachment 1c

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES) 24-hour Ambulatory Blood Pressure Monitoring Feasibility Study

**Please read the following information.
If you agree to participate, sign your name at the bottom**

You are being asked to participate in a feasibility study conducted by the National Center for Health Statistics. This study will tell us if we can perform 24-hour blood pressure monitoring in a national survey. If you agree to take part in this study, you will collect your blood pressure over a 24-hour period with a machine and wear an accelerometer (movement detector). The device will take measurements every 30 minutes during the day and at night and the accelerometer will be used to better understand when you're asleep and when you're awake. We will also ask you to complete questionnaires before and after the study and keep a diary during the 24 hours. Today, a blood pressure cuff will be placed on your arm and the device will take the first blood pressure measurement of the study. You will then start collecting your blood pressure for 24 hours. Once you complete the blood pressure collection, you will come back to our office for a second visit. We will collect all the materials and give you a copy of your results.

If you take part in the study, the first visit should take 30 minutes and the second visit should take 20 minutes and you will be paid \$100 for your time and effort. The study poses minimal risks to the arms or the body. When wearing the blood pressure device, the cuff will inflate and it may feel tight and you will feel some pressure. You may also feel some discomfort, have sleep disturbance, feel tingling to the arm during inflation, and may have skin irritation during the study period. You should not get the device wet which includes showering, bathing, swimming or vigorous exercising (that makes you sweat). If for any reason, you want to take off the device, you should do so. You have the option to remove the cuff and cease participation at any time if you choose to do so during the study period.

All health data collected will be kept strictly private. We gather and protect all information as required by Federal Law: the Public Health Service Act (42 USC 242k) authorizes collection and 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) prohibit us from giving out information that can be used to identify you. Our staff are not allowed to discuss whether any person is part of this study under penalty of the above Federal laws.

Participation in this study is voluntary and you may choose to end your participation at any time without loss of benefits, and you will still receive the \$100 for your time when you return all the devices.

The results of the study will help the NHANES research team determine if 24-hour blood pressure can be performed in their Mobile Exam Units. There may be no direct benefit to you from this study except for a report of your blood pressure readings.

If you have questions about your rights as a participant, you can call the National Center for Health Statistics (NCHS) Research Ethics Review Board at 1-800-223-8118. If you have questions about the study or your results, please call Dr. Duong Nguyen, of the U.S. Public Health Service at: 1-800-452-6115. Please leave a brief message with your name and phone

number. Say that you are calling about Protocol # (to be determined). Your call will be returned as soon as possible.

If you have any complaints or questions about the device please call 1-800-xxx-xxxx. If the devices are removed, please keep them away from children or pets to avoid accidents. Please do not plug the devices into any electrical or computer cord.

I have read the information above and agree to participate in the study.

Signature: _____

Date: _____

Print Name: _____

SAMPLE ID _____