

Attachment 1b

National Health and Nutrition Examination Survey (NHANES) Ambulatory Blood Pressure Monitoring (ABPM) Feasibility Study Screener Script

Form Approved
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Screeener

24-hour Ambulatory Blood Pressure Monitoring Feasibility Study
(Flesch-Kincaid Grade Level 9.9)

You may recall that you requested to be included in our database of research study volunteers. We are looking for people willing to meet with us for a study on blood pressure being conducted for the National Center for Health Statistics. The National Center for Health Statistics is conducting a study to evaluate three 24-hour blood pressure devices and to examine your experience using the device.

A single blood pressure measurement may not be the best way to accurately diagnose high blood pressure. This is because blood pressure changes throughout the day. An ambulatory blood pressure monitor can measure your blood pressure as you move around, living your normal daily life. It uses a small digital blood pressure machine that is attached to a belt around your body which is connected to a cuff around your upper arm. We are studying this type of blood pressure monitor that will measure your blood pressure over a 24 hour period to better understand how well the device works and your experience using it. We would like you to participate in this study. If you agree to be in this study, we will ask you to let the blood pressure device collect your blood pressure every 30 minutes for 24-hours. You will also be asked to fill out a Study Diary questionnaire that asks questions about daily activities and device removal. It is important for you to know that wearing the device may disturb your sleep, may cause some discomfort, may cause some skin irritation and you will feel tingling/pressure to your arm during cuff inflation. You will need to come to our facility for two visits. The first visit will take about 30 minutes to receive instructions with materials, fill-out questionnaires that look at how well you sleep, take a set of blood pressure measurements and fit the blood pressure cuff to your arm. You will also be asked to wear an accelerometer, or movement detector, on your wrist, which will help us assess when you are awake or asleep. After the monitor records your blood pressure for 24 hours, you will have to come back for the second visit. This visit will take about 20 minutes and you will be asked to answer two questionnaires, and return the blood pressure device, accelerometer and the study diary questionnaire that you completed at home. You will receive \$100 as a thank you for your time and effort on the second visit after returning the devices. Participation in this study is voluntary. Would you like to participate in this feasibility study?

If **No**: Thank the person and end the conversation.

If **Yes**: Great. I need to ask you a few background questions to find out if you are eligible.

VOLUNTEERS NEEDED FOR RESEARCH STUDY

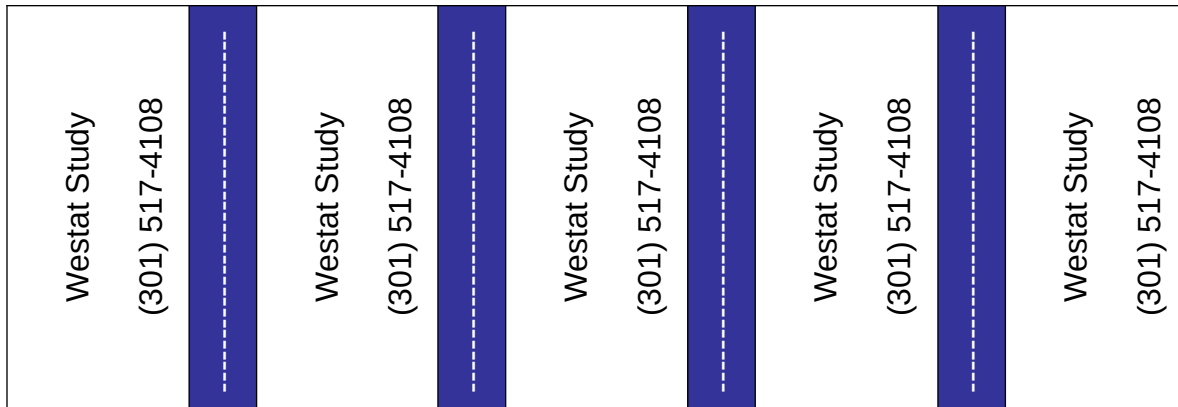
Participants Will Receive \$100

Westat, a research company in Rockville is helping the National Center for Health Statistics with a research project. We are looking for adults 18 years old and older.

Participants will be asked to collect blood pressure over a 24-hour period and answer questions on their quality of sleep and experience with the machine. You will need to come to our offices in Rockville, MD to be fitted with the machine and answer questions. Once you complete the 24-hour collection, you will come back to our office to return the machine and answer questions. We are paying people \$100 for participating.

If interested please call **(301) 517-4108** and leave a message.

TAKE ONE:



ELIGIBILITY PHONE SCREENING QUESTIONNAIRE FOR 24 HOUR AMBULATORY BLOOD PRESSURE FEASIBILITY STUDY

What is your age?

What is your gender?

Exclusion questions:

Are you pregnant (for females)? YES or NO → if yes then excluded

Do you have anything on your arms that may prevent you from having your blood pressure taken? YES or NO

If yes (to the above), does this include rashes, gauze dressings, casts, edema, paralysis, tubes, open sores or wounds, A-V shunts? YES or NO → if yes then exclude

Have you had any blood drawn from your arms within last week? YES or NO → if yes then exclude

Do you have any numbness or tingling in one or both of your arms? YES or NO → if yes then exclude

Have you had surgery on either arm or chest in the past 6 months? YES or NO → if yes then exclude

Are you able to answer questions by yourself? YES or NO → if no then exclude

Thank you for your time. Based on your answers, you are/are not eligible to participate in our study.

****Please note that if your blood pressure is too high (180/100 mmHg) when we take your initial blood pressure on the first visit, you will not be able to participate in the study for safety reasons.*

The next step is to schedule your first visit.

*****Please wear a shirt or blouse with loose fitting sleeves for your first visit.**

What is the best day and time for you to come in to our facility in the next two weeks?

Date: _____ Time: _____

APPT Time:

(Schedule the respondent)

If you have any questions or need to change your appointment, please call 1-XXX-XXX-XXXX.