

Attachment 1a

NHANES Ambulatory Blood Pressure Monitoring (ABPM) Feasibility Study Description

Eligibility: Paid volunteers (non NHANES participants) ages 18 years of age and older. The maximum number of respondents would be 360.

Informed Consent: Written informed consent will be obtained.

Exclusion Criteria:

- Presence of the following on the arm: rashes, gauze dressings, casts, edema, paralysis, tubes, open sores or wounds, withered arms, A-V shunts, or if blood has been drawn on the same day.
- Pregnancy
- Sensory numbness on both arms
- Recent surgery on both arms or the chest
- Mastectomy on the side of the cuff
- Arm circumference exceeding the upper limit parameter of 50 cm
- Individuals whose initial average resting BP is $\geq 180/110$ mmHg

Data Collection: This study will be conducted at the NHANES data collection contractor's headquarters (Rockville, MD). Paid volunteers will be recruited using the contractor's recruiting database. Age eligible participants will be sent an email and asked to contact the recruiter by phone. The recruiter will explain the study requirements and answer any questions. Recruitment efforts may be supplemented by posting recruitment flyers advertising the study in suitable locations in Rockville, MD and Washington DC area. If they meet the initial criteria and are willing to participate they will come to the contractor's headquarters where written consent will be obtained. A resting blood pressure will then be taken. If this value is equal or above 180/110 mmHg they will be excluded from this study for safety reasons.

Eligible study participant will then be given an information sheet about the ABPM and be fitted with an ABPM device to wear for a period of 24 hours. This small device (approximately 12.0 x 8.0 x 4 cm) will be worn on a belt or shoulder connected to an arm cuff much like a traditional blood pressure cuff; however, it automatically inflates every 30 minutes while awake and every 30 minutes while sleeping. Participants will also wear an accelerometer on their wrist to help distinguish between night and day activities. It will be the same Actigraph GT3X-plus Activity Monitor as used previously in NHANES. The Actigraph GT3X-plus monitor measures 1.81" x 1.33" x 0.6", and weighs approximately 19 grams. The results of the physical activity monitor will not be reported to the participants, because the data from the Actigraph will be used to only identify sleep and awake periods.

During their first visit to headquarters, participants will be provided a questionnaire to evaluate quality of sleep in the last month and within the last 24 hours. While wearing the 24 hour ABPM, participants will be asked to fill out a diary questionnaire on daily activity. After the 24 hour period, participants will return to headquarters where they will turn in the devices. Participants will again be provided the same questionnaire about quality of sleep within the last 24 hours (as

administered during the first visit). They will also be asked questions about their experience with the ABPM device.

Report of Findings: Findings will be reported to participants.