Attachment B.

National Health and Nutrition Examination Survey (NHANES)
Blood Pressure Cuff Comparability Study

OMB no. 0920-0950
Expires: 11/30/2015

Assurance of confidentiality – All information which would permit identification of an individual, a practice, or an establishment will be held confidential, will be used for statistical purposes only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons 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 (PL-107-347).

Public reporting burden of this collection of information is estimated to average 35 minutes per response, 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 a 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).

Blood Pressure Cuff Comparability Study (adults):
Eligibility: Adult sample persons are eligible for this study. The maximum number of respondents would be 136.

Informed Consent: Written informed consent will be obtained at the study site.

Exclusion Criteria: The exclusions for this study are as follows.

- Presence of the following on both arms: rashes, gauze dressings, casts, edema, paralysis, tubes, open sores or wounds, withered arms, a-v shunts, or if blood has been drawn from arm within last week.
- Being pregnant or being diabetic
- Arm circumference exceeding the upper limit parameter of 50 cm.
- Not being able to perform blood pressure on both arms

Data Collection: This study will be conducted by NHANES staff using the Johns Hopkins University ProHealth facility located in Baltimore, MD. NHANES has partnered with this organization because they have existing examination space and a pool of volunteers to recruit from. While NHANES staff will conduct the study, Johns Hopkins Pro Health staff will do the recruiting and informed consent participants. Participants will be volunteers who are not part of the regular NHANES sample.

Participants will take part in two separate scenarios for the study. In one scenario of the study, two identical Omron HEM-907 XL machines will be used to take blood pressure using the standard Omron cuff. Three measurements per machine will be taken. In the other scenario,

two Omron machines will also be used. However, one Omron HEM-907 XL will be connected to the standard Omron cuff. The other Omron HEM-907 XL will be connected to a Baumanometer cuff. Again three measurements will be taken per device.

Because we are evaluating 4 cuff sizes we need 34 subjects per cuff size. The sample size calculation was based on a power of 0.8, Type I error of 0.5, standard deviation of 2 to detect a 1 mm Hg difference in BP. This would be a sample size of 34 per cuff yielding 136 participants total.

Report of Findings: Blood pressure results from this feasibility study will be reported to participants.