Attachment 12c

Blood Pressure Methodology Phase 2

Form Approved OMB No. 0920-0950 Exp. Date xx/xx/20xx

Assurance of Confidentiality – All information which would permit identification of an individual, a practice, or an establishment will be held confidential, will be used 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). By law, every employee as well as every agent has taken an oath and is subject to a jail term of up to five years, a fine of up to \$250,000, or both if he or she willfully discloses ANY identifiable information about you.

NOTICE-Public reporting burden of this collection of information is estimated to average 30 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 Methodology Phase 2

<u>Eligibility</u>: All NHANES participants ages 8 and older who participate in the mobile examination center (MEC) blood pressure measurements component are eligible. The maximum number of respondents would be 2,500.

<u>Informed Consent</u>: We will obtain written informed consent as part of the regular NHANES consent process for the examination in the MEC.

<u>Exclusion Criteria</u>: There are no exclusion criteria except those already in place for the regular NHANES Blood Pressure MEC component.

<u>Data Collection</u>: There is no intention of replacing the current NHANES physician obtained BP components. All NHANES 2018 participants aged 8 years and older will be eligible to participate in the study.

This phase of the study will require the following randomization schema: the individual survey participant will randomly be assign to have their BP taken by the mercury device first or the Omron device first. That is all eligible survey participants will have their BP taken twice once by mercury and once by Omron. The BP obtained by mercury will be done by the physician according to NHANES protocol and will be the "official BP reading" whereas the BP obtain by Omron will be done by trained technicians and will follow the Omron protocol including double keying the results. The two BP determinations will not be taken sequentially but will follow the MEC components flow. For example, an individual may be assigned first to have their BP taken with Omron by the health technicians and half an hour later with mercury obtained by the physicians.

Report of Findings: Findings from the blood pressure methodology study will not be reported to participants. Participants will receive blood pressure results from their regular NHANES blood pressure measurements.