Attachment 12

National Health and Nutrition Examination Survey (NHANES) Waist Circumference Methodology Study – NHANES 2016

OMB no. 0920-0950 Expires: XX/XX/XXXX

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 8 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).

NHANES Comparison Study of Waist Circumference Measurements

<u>Eligibility</u>: All NHANES participants 20 years and older who participate in the mobile examination center (MEC) body measurements component are eligible. The maximum number of respondents would be 3000.

<u>Informed Consent</u>: Written informed consent will be obtained as part of the regular NHANES consent process for the examination in the MEC.

Exclusion Criteria: Individuals with cognitive impairments or in a wheelchair will be excluded.

<u>Data Collection</u>: The study will take place in the MEC. NHANES measures waist circumference (WC) at the level of the iliac crest as recommended by the National Heart, Lung, and Blood Institute (NHLBI). Other major studies use different anatomic landmarks to measure WC. The World Health Organization (WHO) measures WC at the mid-point between the highest point of the iliac crest and the lowest rib. The NHLBI sponsored Multi-Ethnic Study of Atherosclerosis (MESA) measures WC at the level of the umbilicus.

The WHO–WC and MESA–WC measurements will be added to the current anthropometry component (body measurements), and performed when the current NHANES–WC measurement is done. The NHANES-WC, WHO-WC, and MESA-WC will be randomized and measurements will be taken directly on the skin. The MESA-WC obtained on the skin will be taken twice in a random order, once using a Lufkin tape and once using Gulick II Plus tape measure. The

NHANES automated data collection system will be updated with prompts to ensure that the health technician and the recorder are performing the correct protocol with the correct data entry screen in the order the randomization process assigns.

An additional measurement is done when the participant is in street clothes (either before changing into the exam gown at the beginning of the appointment, or at the end of exam after changing back into street clothes). The health technician (HT) will give the participant a brief explanation and a demonstration of doing a self-measured MESA–WC measurement using a Gulick II Plus tape. HTs will first measure the thickness of clothing with a caliper and record the measurement to the nearest millimeter. This measurement will allow investigators to account for thickness of the clothing. The participant will then be asked to put the tape measure around his/her waist at the level of the umbilicus to obtain a coached self-measured MESA–WC. The self-measurement will be observed (i.e., coached) by the HT to ensure it is done correctly. The HT will then record the result from the tape measurement to the nearest 0.1 cm. If the participant could not conduct the measurement correctly because he/she could not understand the verbal instructions, the HT will code "Not done" for the self-measured MESA-WC.

<u>Report of Findings:</u> Findings from the NHBLI-WC measurement are already provided to participants as part of the regular NHANES study. Findings from the WHO-WC and MESA-WC measurements will not be reported to participants.

Script

Body measurements (BM), specifically waist circumference measurements, are part of the usual NHANES examination. Health technicians will use the following script to introduce the waist circumference measurement over street clothes.

"We would like you to take a measurement of your waist over your clothes as part of your body measurements exam. First, I'll measure the thickness of your clothes. Second, I'll ask you to put a tape measure around your waist like a belt at the level of your belly button. I will coach you how to apply the tape correctly and will ask you to make the corrections by yourself. Lastly, I'll record the results of the measurement."

There will be text for the additional WC measurements in the BM component. "For this part of your exam, we usually take 1 waist circumference measurement. Today, however, we'd like to take additional waist circumference measurements for our study." The participant will have the option of declining the additional WC measurements.

Waist Circumference Pilot Study Report

A pilot study was conducted from 05/30/2015 to 06/29/2015 on NHANES participant ages 20 years and older. The response rate was 97% for coached self-measurement and 94% for all other measurements done as part of the body measurement component (NHANES-WC, WHO-WC, and MESA_WC). Additional details are provided below.

NHANES Body Measurements (all) = 177 (11 partial, 2 not done)

Completion rate by WC measurement:

	Total	Completed	Not Done
NHANES-WC	177	168 (95%)	9 (5%)
WHO-WC	177	165 (93%)	12 (7%)
MESA-WC (G/L)	177	166 (94%)	11 (6%)
Self-measurement (coached)-MESA-WC (G)	177	171 (97%)	6 (3%)

Reasons for Not Done:

	NHANES – WC	MESA-WC (G and L)**	WHO	Self-Collected WC
SP Refusal*	7	7	7	1
SP Pregnant		2	2	3
Physical limitation	1	1	2	
Came late/left	1	1	1	1

early		
Other (full body spanx)		1

^{*}Participant refusals = 6 participants refused to change into examination gowns and 1 refused all WC measurements including sagittal abdominal diameter (SAD).

^{**} G=Gulick II tape; L=Lufkin tape.