

Attachment C.

**Protocol 24 Hour Urine Sodium Calibration Study (ages 20 and older)**

**National Health and Nutrition Examination Survey (NHANES)  
24 Hour Urine Sodium Calibration Study**

OMB no. 0920-0237  
Expires: 11/30/2012

Notice - Information contained on this form which would permit identification of any individual or establishment has been collected with a guarantee that it will be held in strict confidence, will be used only for purposes stated for this study, and will not be disclosed or released to others without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m). Public reporting burden of this collection of information is estimated to average 2.5 hours 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 (0920-0214).

24 Hour Urine Sodium Calibration Study Protocol:

Eligibility: Paid volunteers 20 years or older are eligible.

Informed Consent: Informed consent will be obtained (see page 2).

Exclusion Criteria: Pregnant women, individuals currently taking a loop diuretic and participants who have started treatment for hypertension within the past two weeks.

Study Design:

Specimen Collection:

Paid volunteers will be recruited to collect urine for 24 hours and provide a corresponding dietary recall. Initial recruitment will occur via telephone. Four hundred volunteers will be recruited. To provide comparability to the current NHANES urine collection protocols, the participants will need to collect each individual void in a separate container and label that container with the time of urine collection. During the initial visit to be instructed on urine collection the participant's height, weight and blood pressure will also be measured. From among the 400 volunteers, 133 will be asked to collect a second 24 hour urine (and corresponding dietary recall) 4-10 days after

the first. It is anticipated that to get volunteers to adhere to this demanding protocol that a remuneration of \$125 per urine collection will be required.

Laboratory Testing:

The 24 urine and three selected individual voids collected during the 24 hours will be tested for sodium, potassium and creatinine.

Report of Findings:

The participant's height, weight and blood pressure will be reported during the initial visit,

Informed consent:

**NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES)  
24 Hour Urine Sodium Calibration Study**

*CONSENT FORM*

**Please read the following information.**

**If you agree to participate, sign your name at the bottom**

Thank you for agreeing to participate in this health research sponsored by the Centers for Disease Control (CDC). Your participation will help improve assessment of salt intake in the NHANES. Your participation will include height, weight, blood pressure measurement, the collection of all your urine for a 24 hour period, and an interview about what you eat. All procedures are done by trained staff, who will explain procedures in more detail as you go along. If your blood pressure is outside the normal range our staff will talk to you about it and provide the results and recommendations for follow up with a health care provider. The CDC cannot provide treatment or medication, nor pay for follow-up you may require.

You are asked to participate in the NHANES 24 Hour Urine Sodium Calibration Study. This will take about 2.5 hours of your time and you will be paid \$125.00 for your time and effort.

**You may refuse to answer a question at any time. You may also choose to end your participation. There is no penalty for withdrawing from the study.**

If you have any questions, feel free to speak to any member of the staff. You may also contact Dr. Kathryn Porter of the U.S. Public Health Service at 1-800-452-6115.

I HAVE READ THE INFORMATION PRESENTED ABOVE, AND CONSENT TO PARTICIPATE IN THE EXAMINATION.

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Print first, middle, last name of volunteer

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Signature of adult volunteer

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Date

**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 other agents authorized by NCHS to perform statistical activities, 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.