

Attachment K.

Protocol for 24 Hour Urine Sodium Validation Study (ages 20-79)

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

OMB no. 0920-0237
Expires: 12/31/2011

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24 Hour Urine Sodium Validation Study Protocol:

Eligibility: Ages 20-79 (with 1/3 in each of these age groups—20-39-40-59, 60-79), equal numbers of both genders, and including non-Hispanic Blacks and the Hispanic population.

Informed Consent: Written informed consent will be obtained.

Exclusion Criteria: Pregnant women, persons who take diuretics, medicine for high blood pressure, ACE inhibitors, or angiotensin receptor blockers and those with renal disease will be excluded from this study.

Study Design: Paid volunteers will be recruited and initially screened for inclusion and exclusion criteria via telephone. If they meet the criteria and are willing to participate they will come to a central location, the NHANES home office. At the home office, participants will receive instructions and supplies, and venipuncture, height, weight and blood pressure measurements and a dietary recall will be obtained. After leaving the home office, participants will collect their urine for 24 hours, during the course of a normal day. They will be asked to use a separate container for each collection. After urine collection, participants will return their specimens to the NHANES home office and a dietary recall will be obtained for the 24 hours that their urine was collected.

Data Collection: Venipuncture, height, weight and blood pressure measurements, before the urine collection, and both dietary recalls will be obtained at the NHANES home office. Participants will do urine collections on their own, during the normal course of their day.

Report of Findings: The participants will be given their blood pressure measurement and the results of the venipuncture.