Attachment A.

Protocol for Urinary Flow Rate Pilot (ages 6+)

National Health and Nutrition Examination Survey (NHANES)
Urinary Flow Rate Pilot Study

OMB no. 0920-0237
Expires: 11/30/2009

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 1 minute 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).

Urinary Flow Rate Component Protocol:

Eligibility: Only sample persons aged 6 years or older are eligible for one or more parts of the urine flow component.

Informed Consent: Informed consent will be obtained as a part of standard NHANES consenting procedures.

Exclusion Criteria: There are no exclusions from the Urinary Flow Rate component. Collecting these urine data should not pose a risk to participants.

Study Design: Pilot 1 (Calculate Urine Flow Rate):

Specimen Collection:

Data collection for this component will be added to the current data entry of required fields by the MEC staff. The specific data collected are listed below:

Time of the current urine void;
Volume of the current void; and
Time of the previous urine void.

The time of the previous urine void will be captured at the coordinator's station. As the participant is being checked into the MEC, the coordinator will administer this question and enter the information into the coordinator application.

After being registered at the MEC, the participant will be escorted to the nearest rest room to change into paper gowns and to collect a urine sample. Currently in NHANES, this sample is a mid-stream collection, meaning that participants start the collection after they have begun to urinate. Participants continue the collection only until there is a sufficient urine sample in one cup.

Because a complete urine void (not a mid-stream collection) is required, the participant will now be given at least two urine cups and instructed to first fill one cup and depending on the volume of the urine flow, collect the urine into a second cup. Under these new procedures, participants will collect the urine sample as soon as they begin to urinate. And they will collect all the urine they are able to void, using multiple cups, if necessary.

Laboratory Testing:

The assistant coordinator will transport the urine cup(s) to the laboratory where the medical technologist (MT) will record the time of the collection. The MT will weigh the urine collection and record the weight. The urine collection application will then convert the weight of urine in grams to volume in milliliters using an approximate urine density of 1 gram per one mL.

Often, the first urine collection volume is not sufficient to aliquot into the urine testing vials. When this happens, a message will be sent from the MT to the coordinator to have the participant collect a second sample. The participant will be encouraged to drink water until they are able to provide a second sample.

The assistant coordinator will transport the second urine cup to the laboratory where the medical technologist (MT) will record the time of the second collection. The MT will weigh the urine collection and record the weight. The urine collection application will then convert the weight of urine in grams to volume in milliliters using an approximate urine density of 1 gram per one mL. Since the urine cups from the first and second collections will be combined before they are aliquoted, the urine collection application must calculate a total combined urine volume. The balance will be calibrated at each survey location using NIST weights to confirm the accuracy of the instrument.

Report of Findings:

The albumin creatinine ratio (ACR) results from this urine sample will be reported to the participant.