

Attachment 20a

National Health and Nutrition Examination Survey (NHANES) Dual X-ray Absorptiometry (DXA) Crossover Study Description

Eligibility: Adults volunteers (15 men and 15 women) between the ages of 20-70 will be eligible for this crossover study

Informed Consent: Written informed consent will be obtained using the form below

Exclusion Criteria: Exclusion Criteria:

Volunteers who meet any of the following criteria are not eligible for the study:

- Females who are pregnant
- Those who had an X-ray or test with the use of contrast material, such as barium, in the past 7 days
- Those who weigh over 450 pounds (limitation for examination table)

Data Collection:

This pilot is a crossover study, similar to one conducted in 2010 when the DXA machines were last replaced. The study will be conducted on 30 volunteers aged 20-70 years old. They will be recruited by recruiting agency based on gender and age. Volunteers will not be related in anyway to an NHANES primary sampling unit or samples household. A set of screening questions will be asked over the telephone with interested participants. The screening questions include questions on age, gender, primary language and exclusion questions to ensure they will be able to complete whole body, spine and femur scans (attachment 20b).

All adult volunteers will complete three DXA scans (whole body, spine and femur) on Hologic Discovery A Fan Beam Bone Densitometer (current NHANES DXA model). Then the same three scans will be conducted on Hologic Horizon A Fan Beam Bone Densitometer (new DXA model). All scans will be taken in the supine position. All scans will be administered by NHANES radiology technicians. All radiology technicians are experienced and have certification from the American Registry of Radiologic Technologists (ARRT), which is recognized in all 50 states. The technicians are trained on the current DXA model and will be trained in acquisition of the whole body, spine and femur scans on the new DXA model by staff from Hologic, the manufacturer of the NHANES bone densitometers. Training will occur before the start of the cross over study.

Women of childbearing age are excluded from the DXA component if their urine pregnancy test is positive or if they say they are pregnant. Participants who have had x-rays or tests with contrast materials in the past 7 days are also excluded.

For this Dual X-ray Absorptiometry (DXA) Crossover Study Genic, we consulted with internal NCHS staff and external subject matter experts, Dr. John Shepherd and Hologic Inc.staff.

Report of Findings:

Percent body fat and bone mineral density will be reported to volunteers. The results will be mailed in approximately 12 weeks.

Variables reported:

- Percent total body fat.
- Hip and spine bone mineral density (BMD) with interpretations using T-scores.

Informed Consent

National Health and Nutrition Examination Survey (NHANES) Dual X-ray Absorptiometry (DXA) Crossover Study

**Please read the following information.
If you agree to participate, sign your name at the bottom**

You are being asked to participate in a crossover study conducted by the National Center for Health Statistics. This study will help us keep monitoring osteoporosis and body composition changes in the US population. If you agree to take part in this study, you will complete three DXA scans (whole body, spine and femur) on Hologic Discovery A Bone Densitometer and three DXA scans on Hologic Horizon A Bone Densitometer. The scans are administered by trained, certified and licensed health professionals.

The whole body scan will measure how much body fat you have. The spine and femur scans will measure how strong your bones are.

All health data collected will be kept strictly private. We gather and protect all information as required by Federal Law: the Public Health Service Act (42 USC 242k) authorizes collection and Section 308(d) of the Public Health Service Act (42 USC 242m), the Privacy Act of 1974 (5 USC 552A), and the Confidential Information Protection and Statistical Efficiency Act (PL 107-347) prohibit us from giving out information that can be used to identify you. Our staff are not allowed to discuss whether any person is part of this study under penalty of the above Federal laws.

Participation in this study is voluntary and you may choose to end your participation at any time without loss of benefits, and you will still receive the \$100 for your time.

If you have questions about your rights as a participant, you can call the National Center for Health Statistics (NCHS) Research Ethics Review Board at 1-800-223-8118. If you have questions about the study or your results, please call Dr. Duong Nguyen, of the U.S. Public Health Service at: 1-800-452-6115. Please leave a brief message with your name and phone number. Say that you are calling about Protocol # (to be determined). Your call will be returned as soon as possible.

I have read and understand the information presented above and agree to participate in the study.

Print first, middle, and last name of volunteer

Signature of adult volunteers

Date