

## **Attachment 2b – Informed Consent Both Studies**

National Health and Nutrition Examination Survey Crossover Studies

**Please read the following information.**

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

You are being asked to participate in a National Health and Nutrition Examination Survey (NHANES) crossover study conducted by the National Center for Health Statistics. NHANES data are used to measure the overall health of the U.S., develop health programs, and improve the quality of medical care. A crossover study is routinely used to simultaneously compare changes in how a laboratory study is run (like comparing results from old and new lab machines, tests, or supplies like blood tubes), and to find out if the results of the old and new tests are the same or different because of that change.

This study has two parts. One part is the Dual Energy X-Ray Absorptiometry or DXA crossover, which monitors osteoporosis and body composition changes in the U.S. population. This study compares the results of the same test on a new machine to those obtained on the machines we recently used. If you agree to the DXA study, you will complete six DXA scans (whole body, spine or backbone, and femur or thigh bone) on two different Hologic Horizon A Bone Densitometers. The whole-body scan will measure how much body fat you have. The spine and femur scans will measure the strength of your bones. The scans are administered by trained, certified, and licensed health professionals. The DXA study will take about 40 minutes. You will receive the reading from the new Bone Densitometer machine before leaving today. You may decline to receive results if you wish.

The DXA scans involve low-dosage x-rays. Radiation exposure during these scans is equal to a cross-country airline flight or a few days of natural background radiation. However, because the bone density scan involves x-rays, those who are pregnant will not be scanned. Therefore, women who wish to participate in the crossover study will require a urine pregnancy test prior to the scans. Those who test positive or decline to take the test will not be eligible to participate.

The second part of the study is the Hematology Analyzer and Blood Tube crossover study. This study compares the results of the same blood test on a new machine to those obtained on the machines we recently used. The tests will also compare blood tubes; and the tests being run measure nutritional biomarkers, biomarkers for diabetes, kidney, liver and heart diseases, thyroid hormones, infectious diseases, and tobacco biomarkers. If you agree to take part in this study, you will undergo a blood draw of approximately 1.8 tablespoons or 4 tubes. The whole blood draw process will take approximately 10 minutes. You will receive some results before leaving today in addition to mailed results in approximately 4 weeks. You will be asked to provide a mailing address if you wish to receive the mailed results. You may decline to receive any results.

It is important to know that the results from these crossover studies are intended to validate and compare laboratory and medical equipment. They are not to be used to make any clinical diagnoses. Interpretation of these results must be made by an appropriately licensed healthcare provider.

You can choose to share the results with your healthcare providers. If you take your results to them, they may recommend other tests that may or may not identify health a concern. You will be responsible for any costs associated with these additional tests.

Participation in both parts of this study is voluntary. You may choose to end your participation at any time without any loss of benefits. We take your privacy very seriously. Federal law requires that we keep all information that we obtain from these crossover studies confidential; and your information will only be used for statistical purposes.

For your participation, you will receive \$100 for the DXA scan and \$30 for the Hematology study for a total of \$130 on a debit/gift card.

If you have questions about your rights as a participant, you can call the National Center for Health Statistics (NCHS) Ethics Review Board at 1-800-223-8118. Say that you are calling about Protocol # 2024-01. If you have questions about the study or your results, please call Dr. Duong Nguyen, the NHANES Chief Medical Officer, at: 1-800-452-6115. Please leave a brief message with your name and phone number. Your call will be returned as soon as possible.

By checking the box, I am agreeing to participate in the following:

DXA study

Hematology study

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 volunteer

\_\_\_\_\_  
Date

**Assurance of Confidentiality.** We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors, and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act or CIPSEA (44 U.S.C. 3561-3583). In accordance with CIPSEA, every NCHS employee, contractor, and 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. In addition to the above cited laws, NCHS complies with the Federal Cybersecurity Enhancement Act of 2015 (6 U.S.C. §§ 151 and 151 note) which protects Federal information systems from cybersecurity risks by screening their networks.