

Attachment A1

National Health and Nutrition Examination Survey (NHANES) Liver Ultrasound Elastography Pilot Study Description

OMB no. 0920-0950

Expires: 11/30/2016

NHANES Liver Ultrasound Elastography Pilot Study

Eligibility: All NHANES participants 12 years and older are eligible. The maximum number of respondents would be 575.

Informed Consent: Written informed consent will be obtained as part of the regular NHANES consent process for the examination in the Mobile Examination Center (MEC).

Exclusion Criteria: Persons who are unable to lie on their back on the examination table will be excluded from this study. In addition, persons with certain medical considerations, such as skin lesions on their torso or who have an implanted electronic medical device may also be excluded, if advised to do so by a NHANES physician.

Data Collection: The study will take place in the MEC during the regular NHANES examination. We will measure liver fatness and liver stiffness in eligible NHANES participants, 12 years of age and older, to obtain population estimates for hepatic steatosis (fatness) and fibrosis (stiffness) which are influenced by both alcoholic and nonalcoholic liver disease etiologies. To do this, we plan to use vibration-controlled transient ultrasound elastography using a specially designed ultrasound device. Transient elastography is a noninvasive medical assessment that measures the elastic properties of soft tissue. The elastography device proposed for this component is FDA approved and has been introduced in the U.S. and internationally to measure liver fatness and stiffness. It consists of an ultrasound device which taps the participant's skin 10 times, near the lower ribs. Signals reflected back from this tapping provide information about the fatness and stiffness of the liver. The exam on average takes 14 minutes.

To complement this component, a hip measurement will be added back into the anthropometric component. It is estimated that this will take on average 1 minute for (all participants 12 years of age and older). It will be measured using the same method as previously conducted in the 1988-1994 NHANES anthropometry component. So the total amount of time needed per participant for this project is estimated at 15 minutes per person.

Report of Findings:

Findings from the ultrasound measurements will be reported to participants if pilot measurements prove to be valid. Examples of situations for which measurements would not be considered valid include:

- there are no results after multiple attempts
- the ratio of valid measures to the total number of measure is less than 60%

- overall percent with high or low values inconsistent with the medical literature (e.g. no values are elevated or all values are elevated)

In addition, existing NHANES laboratory assessments of liver health, including liver enzymes (ALT, AST, and GGT), bilirubin, and viral hepatitis markers, are already being reported to participants, as part of the main NHANES study. Hip measurements will not be reported back to participants, however other anthropometry measures such as height, weight, waist circumference which are currently in NHANES will continue to be reported back to participants. The liver findings would be reported using a similar format to the standard NHANES report of findings (ROF) form already in use.

Hepatic (liver) Steatosis and Fibrosis Ultrasound Elastography (ages 12 year and older) Form

SP ID _____	Tech ID _____
HEPATIC (liver) STEATOSIS TEST RESULTS	
Test complete Yes No	
Test result for median liver equivalent stiffness measure (E) _____ kilopascals, (kPa)	
Test result for median controlled attenuation parameter (CAP™) _____ decibel per meter, (dB/m)	
REASONS TEST INCOMPLETE OR NOT DONE	
Physical limitation	
SP refusal	
SP ill/emergency	
Out of time	
Equipment failure	
Communication problem	
HEPATIC (liver) FIBROSIS TEST RESULTS	
Test complete Yes No	
Test result for median Young's Modulus (E) _____ kilopascals	
REASONS TEST INCOMPLETE OR NOT DONE	
Physical limitation	
SP refusal	
SP ill/emergency	
Out of time	
Equipment failure	
Communication problem	