

Attachment 3a

National Health and Nutrition Examination Survey (NHANES) Electronic Digital Signature to Document Consent (Phase II) Description

Eligibility: All NHANES participants who currently sign hard copy consents/assents.

Informed Consent: No additional consents other than the regular NHANES consents are needed.

Exclusion Criteria: None.

Project Procedures: NHANES participants who sign Mobile Examination Center (MEC) consent/assent forms will be provided the ability to sign electronically rather than sign paper copies. There are no changes to the consent protocol currently in place, except for the following:

- The signature will be captured electronically.
- The current description for age “under 16” on the Authorization for Transportation form will be changed to “birth to 15 years old”. (See Attachment 3e for the original form and Attachment 3l for the revised form.)
- The current description for age “under 18” on the Authorization for Transportation form will be changed to “birth to 17”. (See Attachment 3e for the original form and Attachment 3l for the revised form.)

Interviewer instructions for the consent process will be displayed on the screen of the interviewer’s laptop/pentop. The information on the first screen will be a mirror image of the blank copy of the consent form(s) that will be provided to each respondent. Subsequent screens will display the appropriate check boxes (if needed) and the appropriate signature blocks for each form. If the respondent requests a copy of a printed form(s) with all of the information captured electronically, this will be provided. The e-consents for Phase II will include the following MEC consent forms:

- Consent/Assent and Parental Permission for Examination at the MEC
- Child Assent (SPs 7-11) for the Examination at the MEC
- Consent/Assent and Parental Permission for Specimen Storage and Continuing Studies
- Authorization for Transportation Arrangements for Persons under 18 Years of Age

The change from hard copy signature to electronic signature does not increase the burden to respondents for the consent process.