Attachment D.

# Protocol for Birth Certificate Linkage Study - NHANES 2005-2010 Children (ages 5-10)

# National Health and Nutrition Examination Survey (NHANES) Birth Certificate Linkage Study - NHANES 2005-2010 Children (ages 5-10) OMB no. 0920-0237

Expires: 11/30/2012

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# Birth Certificate Linkage Study - NHANES 2005-2010 Children (ages 5-10) Protocol:

## Study Sample

The sample for this project consists of the records of children who were 5-10 years old when they participated in NHANES 2005-10. The eligible sample of children is approximately 3,800.

## Study Protocol

Westat, Inc. will carry out the data collection under contract. Westat's responsibilities will include contacting the vital statistics offices for the states/local areas/territories where the sample children were born to request state requirements for birth certificates requests and to submit applications to the states for birth certificate records. Information provided to states may include:

- Name
- Gender
- Date of Birth •
- Place of birth •
- Mother's name
- last four digits Social Security Number (SSN)
- Any other data needed to verify correct record retrieval

Retrieval of birth certificate records will be conducted by vital statistic officials from the U.S. states, local area or territories of birth according to their usual procedures. In order to match

birth certificates to NHANES records, it will be necessary to request identifiable rather than deidentified records.

Data collected from the birth certificate records will be entered into a restricted access database and linked to existing NHANES data for each child's records. It will not be publically released. Data will be available through the NCHS Research Data Center (RDC) or special use agreement with the funding collaborators.

The technical issues related to data storage and transmittal will be coordinated with information technology staff at NCHS and Westat. The training for the information technology staff will reinforce the procedures for the processing and storing of confidential data. The contract agreement requires a guarantee from the contractor that data will not be tabulated, analyzed, released or used without prior written approval from the NCHS project officer and the NCHS Confidentiality Officer.

#### Exclusion Criteria

Children who would no longer be minors at the point of records linkage, children born in states/local areas/territories that do not release birth certificate information, and children born outside the United States or U.S. territories will be excluded from this study.

#### Participant Burden for Respondents

For state/local area/territory birth certificate staff, a burden of 2 minutes per record is estimated for the electronic retrieval the relevant information.

### Informed Consent Procedures for Respondents

Consent for link records for children who were aged 5-10 years old when they were in NHANES 2005-2010 was already obtained when these children originally participated in NHANES. Therefore, no additional re-contact or consent process is necessary. Proof of consent for linkage will be provided to U.S states, local areas or territories conducting the records retrieval. Excerpts from 2005-2010 consent forms, showing language used regarding data linkage are provided in Appendix A.

## Justification for Using Vulnerable Populations

Neither child participants nor their parents or legal guardians will be re-contacted, because permission to conduct records linkage of their data was obtained when they originally participated in NHANES. Data for minors are included in this study because they are an important target population group.

#### <u>Risks</u>

There is no more than minimal risk associated with conducting of the NHANES Birth Certificate Linkage Study.

## Reporting

This is a follow-up linkage study. As such there is no information to be reported.

## **Confidentiality Measures**

The protection of individual privacy and confidentiality of personal information is a primary concern to all the programs of NCHS. The survey is conducted with the strongest possible assurances of confidentiality. These include the protections of the Privacy Act of 1974 and an even more rigorous protection of all NCHS data outlined in Section 308(d) of the Public Health Service Act (42 U.S.C. 242m).

# **NHANES Consent Form Excerpts**

## Consent form linkage language - NHANES 2005-2006 Examination Brochure

Combining NHANES results with other facts about you can be useful. An example of this is using Social Security numbers to link survey data with vital statistics and other health records. Also, we may need to contact you in the future. To do this we would ask public or private agencies, such as the Post Office, to provide changes in your address.

#### Consent form linkage language- NHANES 2007-2008 Examination Brochure

Health research using NHANES can be enhanced by combining your survey records with other data sources. An example is linking your survey results with vital statistics and Medicare claims. To do this,

we will ask your permission to collect your Social Security and Medicare numbers. As we told you before, we keep this information safe and secure.

## Consent form linkage language- NHANES 2009-2010 Examination Brochure

Health research using NHANES can be enhanced by combining your survey records with other data sources. An example is linking your survey results with vital statistics and Medicare claims. To do this, we will ask your permission to collect your Social Security and Medicare numbers. As we told you before, we keep this information safe and secure.

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