Supporting Statement A for Request for Clearance

# National Health and Nutrition Examination Survey
# Birth Certificate Linkage Study – Pregnant Women

## OMB No. 0920-NEW

## Contact Information

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This is a request for a new approval for the National Center for Health Statistics (NCHS) to conduct a National Health and Nutrition Examination Survey (NHANES) birth certificate linkage study. The new project planned is the NHANES – Birth Certificate Linkage for pregnant women who have participated in past NHANES (OMB No. 0920-0237). This study is being done in collaboration with the Center for Disease Control and Prevention's National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health (NCCDPHP/DRH). A two-year approval is requested.

The National Center for Health Statistics (NCHS) seeks to obtain copies of birth certificates for children whose births resulted from pregnancies of women who were pregnant at the time they participated in NHANES 1999-2010. The result will be the ability to link information abstracted from the birth certificates to their mother's biomedical and demographic measures collected in NHANES.

The NHANES Birth Certificate Linkage Study for pregnant women represents a cost and time effective opportunity to gather data that can be used to examine the relationship between maternal health and exposures during pregnancy and the later health of her child. This project will combine maternal characteristics measured during the NHANES exam, information from the child's birth certificate, and subsequent information about the child.

We are seeking approval to:

1. Recontact women who were pregnant during their participation in NHANES 1999-2010 to obtain consent from them to obtain birth records (referred to as the birth certificate linkage consent form)
2. Ask the mother a set of new questions about the health of their child, such as weight, respiratory health, physical functioning, etc.
3. Obtain birth certification from stat vital statistic offices

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary.

The National Health and Nutrition Examination Survey (NHANES) contributes to the mission of CDC by collecting objective data that are used to promote health and to prevent and control disease and disability. NHANES involves collecting questionnaire, physical examination, and laboratory (including blood and urine) data. The study provides detailed information about respondents' health at one point in time. For this new project, the respondents of interest are women who were pregnant when they participated in NHANES during the interval, 1999-2010.

A full understanding of factors related to child health is possible only if information related to fetal development and birth is considered. In general, gathering prospective data encompassing maternal health, intra-uterine exposures, birth outcome, and subsequent child health status is time-consuming and expensive, requiring a longitudinal study. However, linking previously collected data from pregnant women to the birth certificates of children resulting from that pregnancy, coupled with the contemporary collection of data on the child's health status, would

be a relatively quick and efficient method for mimicking data collected via a prospective longitudinal study. This linkage is possible, using recently collected NHANES data.

No other U.S. national survey has the physical examination and nutritional data that NHANES collects on pregnant women. Questionnaire data includes information on maternal diet, smoking, medication use, mental health, and demographic factors. Physical examination data includes accurate anthropometric measures (as opposed to self-reported measures in many studies) and blood pressure. Laboratory data include blood, urine, and hair concentrations of basic biochemical and inflammatory markers, and heavy metals. In addition, some of these pregnant women were part of a one-third sub-sample who had measurements of other environmental chemicals such as PCBs and pesticides.

Children resulting from the pregnancies of NHANES women range from birth – 13 years of age. Basic child health information will be collected via a phone interview with the mother. Data collection will be limited to conditions with reasonable potential, based on prior research, for association with intra-uterine exposures; and with high enough prevalence to allow for appropriate analysis. Such conditions include asthma, attention deficit hyperactivity disorder (ADHD), autism spectrum disorder, and obesity.

For the current proposed project, an overall linkage rate of 70% is anticipated, accounting for the ability to contact the women, gain linkage consent, and find and link the birth certificates. Thus, given approximately 1500 pregnant women in the NHANES over-sample and non-oversample combined, and accounting for pregnancy losses, the final linked sample size is estimated to be approximately 1050.

## Background

For this project there will be a total estimated sample of 1500 pregnant women. These women come from two sources. The first source is the NHANES oversample of pregnant women that took place from 1999 through 2006. This over-sample resulted in approximately 170 pregnant women per year being in NHANES. The second source is women who were pregnant during NHANES 2007-2010, though they were not oversampled. There are approximately 150 women from years 2007-2010. These data represent a unique opportunity to bring together U.S. data on maternal health, exposures during pregnancy, pregnancy outcome, and subsequent child health, without the time and expense of conducting a longitudinal study and without having to rely on retrospectively collected data and associated recall biases.

To improve the precision of the estimates for pregnant women, a supplemental sample of pregnant women was selected in NHANES from 1999-2006. This supplemental sample resulted in a total of 1,350 pregnant women in the NHANES sample from 1999-2006 from 31 states. Although this supplemental sample was discontinued after 2006, there are about 150 additional pregnant women in the NHANES sample for the years 2007-2010.

There is prior experience linking NHANES data with birth certificates. In the early 2000's, data

on children age 2 months through 6 years in NHANES III were linked to their birth certificates. In that effort, 95% of the requested birth certificates were obtained from the States and linked to the NHANES data. Findings from this earlier linkage include:

Hediger ML, Overpeck MD, Maurer KR, Kuczmarski RJ, McGlynn A, Davis WW. Growth of infants and young children born small- or large-for-gestational-age: findings from the third National Health and Nutrition Examination Survey. Arch Pediatr Adolesc Med 1998 Dec;152(12):1225-31.

Hediger ML, Overpeck MD, McGlynn A, Kuczmarski RJ, Maurer KR, Davis WW. Growth and fatness at three to six years of age of children born small- or large-for-gestational-age. Pediatrics 1999;104:e33.

Hediger ML, Overpeck MD, Ruan WJ, Troendle JF. Early infant feeding and growth status of US-born infants and children aged 4-71 mo: analyses from the third National Health and Nutrition Examination Survey, 1988-1994. Am J Clin Nutr. 2000 Jul;72(1):159-67.

Authorization

Section 306 of the Public Health Service Act (42 U.S.C. 242k) directs the National Center for Health Statistics to collect statistics on subjects such as: the extent and nature of illness and disability of the population; environmental, social and other health hazards; and determinants of health (Attachment 1).

Privacy Impact Assessment

The information needed for the Privacy Impact Assessment is provided below.

Overview of the Data Collection System

An Advance Letter (see Attachment 3) will be sent to each woman who was pregnant when they participated in NHANES 1999-2010. A written birth certificate linkage consent form (see Attachment 4) and return mailing envelope will be sent along with the advance letter.

The Birth Certificate Linkage Study Telephone Interviews (see Attachment 5a) will then be conducted including:

- Identification of correct individual
- Pregnancy outcome questions
- Permission to link to birth certificate
- Child development questions

The Birth Certificate Linkage Activities

After the signed birth certificate linkage consent form is received birth certificates will be requested from each appropriate U.S. State or Territory, according to their existing procedures (Attachments 5b, 5c, 5d).

Items of Information to be Collected

Child's Demographic Information

- Name
- Date of birth
- Place of birth
- Gender
- Name of Hospital where child was born
- Child's birth certificate information
- Last 4 digits of Child's Social Security Number (SSN)

Parents' Demographic Information

- Mother's name, including Maiden Name
- Mother's SSN
- Mailing Address
- Phone Numbers
- Medical Information and Notes
- Any other data needed to verify identify of the mother
- Pregnancy outcome information
- Current child health status information, such as weight, respiratory health, physical functioning, etc.
- Father's name on birth certificate

Information in Identifiable Form (IIF)

Information in identifiable form (IIF) is collected for linkage with other federal sources of data, to allow future re-contact of participants. All of these items have been routinely approved and collected in past NHANES. These items need to be verified for this project to ensure we have contacted the correct person. The identifiable information includes:

- Name
- Date of Birth
- Social Security Number (SSN)
- Mother's Maiden Name
- Mailing Address
- Phone Numbers
- Medical Information and Notes
- Place of child's birth

- Child's birth certificate information
- Father's name on birth certificate

Some of these are described in detailed in A.11 Justifications for Sensitive Questions.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age
There is no web-based data collection in NHANES. There is no website content directed at children under 13 years of age.

2. Purpose and Use of the Information Collection

The purposes and uses of this study are detailed below. Interviews will include former NHANES participants. Participation is voluntary.

The data collected in this study will be linked with the NHANES data for women who were pregnant when they participated in the 1999-2010 NHANES survey. Examples of the types of data uses that may be possible with the resulting linked data include researching topics such as Maternal health behaviors and childhood health conditions; Comparison of reported maternal smoking/tobacco use (active and passive) reported on birth certificates, smoking as self-reported in NHANES, and measured maternal cotinine levels; Late preterm birth and risk of childhood respiratory conditions and developmental delays; Effect of active smoking and passive exposure on gestational age and fetal growth ; risk of complications during pregnancy and risk of adverse pregnancy outcomes; Association of childhood obesity with pregnancy body mass index (BMI) and with gestational diabetes (GDM); Diet quality and physical activity during pregnancy and risk of GDM; Birth size and risk of childhood obesity

Many knowledge gaps exist in these research areas, and this linkage project will provide a currently unavailable data source to research these gaps.

Privacy Impact Assessment Information

A new Privacy Impact Assessment will be submitted, if it is determined that this project does not fall under the overall NHANES Privacy Impact Assessment that was submitted on July 10, 2009.

The NHANES continues to collect personal identifying information, on a confidential basis, needed to re-contact respondents and to match respondents to administrative records such as the National Death Index. The ability to track respondents and match to other records greatly expands the usefulness of the data at very low cost.

Only those NCHS employees, specially designated agents, and our full research partners, who must use the personal information for a specific purpose, can use such data.

The collection of information in identifiable form requires strong measures to ensure that private information is not disclosed in a breach of confidentiality. All NCHS employees as well as all contract staff receive appropriate training and sign a "Nondisclosure Statement." Staffs of collaborating agencies are also required to sign this statement and outside agencies are required to enter into a more formal agreement with NCHS. The transmission and storage of confidential data are protected through procedures such as encryption and carefully restricted access.

3. Use of Information Technology and Burden Reduction

The interview will be administered using computer assisted telephone interview (CATI) software and procedure. NHANES uses survey information technology architecture (SITA) that supports fully automated and integrated information technology, relying on innovation and modern tools, and state of the art technology and information science.

4. Efforts to Identify Duplication and Use of Similar Information

NHANES is a unique source of health information on the U.S. population. Each year health interview and examination data are obtained. There are no other studies that collect the detailed health, dietary, laboratory and examination data that NHANES does. Linkage of NHANES data and birth certificate information has not been conducted on data collected in the continuous NHANES (1999-2010). A previous linkage study was done using data from NHANES III (1988-1994).

5. Impact on Small Businesses or Other Small Entities
Only individuals will be asked to participate. No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently
Respondents will participate in the data collection only one time.

There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines for 5CFR1320.5
This data collection fully complies with regulation 5CFR1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

a. Federal Register Notice

In compliance with 5 CFR 1320.8(d), a notice soliciting comments on the collection for NHANES was published in the Federal Register on February 22, 2011, volume 76, number 35, pp. 9784-9785. See Attachment 2a for a copy of the notice. Two public comments were received. These comments and the corresponding agency responses are in Attachment 2b.

b. Outside Consultation

The content for this project NHANES was developed with input from NCCDPHP, Division of Reproductive Health and the NCHS Office of Analysis and Epidemiology (OAE). The NCHS Board of Scientific Counselors (BSC) will be briefed about this project.

The major efforts taken to support collaboration processes include conference calls with multiple staff member in NCCDPHP as well as internal meetings, emails and other communication among DHANES and Office of Analysis and Epidemiology (OAE) staff.

9. Explanation of any Payment or Gifts to Respondents
To maximize response rates for obtaining written content for birth certificate linkage, $35 will be provided as a token of appreciation. These NHANES participants received remuneration for their past NHANES participation, including any post MEC examination activities they took part in immediately following their original NHANES participation. Providing remuneration for this new project is in keeping the usual protocol for NHANES for follow-up activities. It is also important in terms of maximizing response rate for this project.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974 (5 U.S.C. 552a) "requires the safeguarding of individuals", and Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) requires the safeguarding of both individuals and establishments against invasion of privacy. Contractors who collect information identifying individuals and/or establishments must stipulate the appropriate safeguards to be taken regarding such information. The Privacy Act also provides for the confidential treatment of records of individuals, which are maintained by a Federal agency according to either individual's name or some other identifier. This law also requires that such records in NCHS are to be protected from "uses other than those purposes for which they were collected."

The confidentiality of individuals participating in NHANES is protected by section 308(d) of the Public Health Service Act (42 USC 242m), which states:

"No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306,...may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form..."

In addition, legislation covering confidentiality is provided according to section 513 of the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA) (PL-107-347), which states:

"Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by section 512, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this title, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than $250,000, or both."

The technical issues related to data storage and transmittal will be coordinated with information technology staff at NCHS and the data collection contractor. 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.

In summary, the files will be returned to NCHS through approved secure data transfer methods. NCHS will review the extract files for accuracy and completeness and remove any personally identifiable data. If the files are determined to be correct and complete, NCHS will then notify the contracting agency that they should destroy all NCHS data obtained under the project agreement and written confirmation of file destruction is sent by the contracting institution's data custodian.

Record linkage project contractual agreements require the use of secure data transfer methods including: data encryption requirements for all files, transmission of data through secure data network (SDN) or traceable delivery of encrypted media. Passwords to open encrypted files are sent separately from the encrypted media. All record linkage contractual agreements require the participating agencies to maintain a level of data security that is greater than or equal to NCHS standards established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III, Security of Federal Automated Information Systems, which sets forth guidelines for security plan documentation for automated information systems.

Consequently, all information collected in NHANES will be kept confidential, with an exception for suspected child abuse.

All questions and procedures have been reviewed by the NCHS Ethics Review Board (formerly called the NCHS Institutional Review Board) and the data collection contractor's institutional review board for issues of sensitivity and safety (see Attachment 6).

Privacy Impact Assessment Information

A. The NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer have reviewed this package and have determined that the Privacy Act is applicable. This study is covered under

Privacy Act System of Records Notice 09-20-0164 ("Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population").

B. It is the responsibility of all employees of NCHS, including NCHS contract staff, to protect and preserve all NHANES data (this includes all oral or recorded information in any form or medium) from unauthorized persons and uses. The confidentiality of individuals participating in NHANES is protected by section 308(d) of the Public Health Service Act (42 USC 242m). All NCHS employees as well as all contract staff have received appropriate training and made a commitment to assure confidentiality and have signed a "Nondisclosure Affidavit". Staffs of collaborating agencies are also required to sign this statement and agencies are required to enter into a formal Designated Agent Agreement with NCHS before access to non-public data is permitted. It is understood that protection of the confidentiality of records is a vital and essential element of the operation of NCHS, and that Federal law demands that NCHS provide full protection at all times of the confidential data in its custody. Only authorized personnel are allowed access to confidential records and only when their work requires it. When confidential materials are moved between locations, records are maintained to insure that there is no loss in transit and when confidential information is not in use, it is stored in secure conditions.

NCHS policy requires physical protection of records in the field, and has delineated these requirements for the data collection contractor. The contractor also has its own policy and procedures regarding assurance of confidentiality and a pledge that all employees involved in NHANES must sign. The contractor provides all safeguards mandated by Privacy ACT and Confidentiality legislation to protect the confidentiality of the data. The contractor's data security procedures comply fully with security requirements delineated by the Information Resources Management Office of CDC.

C. An Advance Letter will be mailed to each potential participant identified, announcing the upcoming telephone interviewer and explaining the confidential treatment of their responses. A birth certificate linkage consent form, which will contain the confidentiality assurance, will be mailed with the Advance Letter. This document requests consent to obtain a birth certificate from the State vital statistics office. The consent to participate in the phone survey is oral and contained in Attachment 5a.

It is NCHS policy to make NHANES data available via public use data files to the scientific community whenever possible. Confidential data will never be released to the public however. For example, all personal information that could be potentially identifiable (including participant name, address, survey location number, sample person number), are removed from the public release files. The NCHS Disclosure Review Board reviews all files that will be released, to assure that directly or indirectly identifiable data are not included.

D. Respondents are notified of the voluntary nature of the survey through the Advance letter (Attachment 3). 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.

11. Justifications for Sensitive Questions

Objective data of a sensitive nature are described in this section. Content of a sensitive nature in the examination is discussed in the NHANES informed consent document, which will be provided as an attachment to the final submission of this document.

a. Social Security Number
The last four digits of Social Security Number (SSN) for both the mother and child are requested via telephone interview. The mother's last four digits will be used to verify that we have re-contacted the correct person and to link the mother's NHANES information to the child's birth certificate record. The child's last four digits will be collected to link the mother's NHANES interview and exam data to additional vital statistics, health, nutrition, and other related records of the child such as Medicaid and food assistance programs.

Permission to link for the mother is obtained from NHANES respondents as follows:
"The Department of Health and Human Services will conduct statistical research by combining {your/his/her} survey data with vital, health, nutrition and other related records. {Your/SP's} social security number is used only for these purposes and the Department will not release it to anyone, including any government agency, for any other reason. Providing this information is voluntary and is collected under the authority of Section 306 of the Public Health Service Act. There will be no effect on {your/his/her} benefits if you do not provide it."

ONLY READ IF ASKED. [Public Health Service Act is title 42, United States Code, section 242k.]

Permission to collect the last four digits of child's SSN is obtained in the questionnaire via phone interview (Attachment 5a). This information will allow us to conduct additional health research by linking the mother's NHANES interview and exam data to the child's vital statistics, health, nutrition, and other related records such as Medicaid and food assistance programs.

Because some of the research topics include potentially sensitive questions, in the informed consent procedure, all respondents are advised of the voluntary nature of their participation.

All questions and procedures have been reviewed by the NCHS Ethics Review Board (formerly called the NCHS Institutional Review Board) and the data collection contractor's institutional review board for issues of sensitivity and safety (see Attachment 6).

12. Estimates of Annualized Burden Hours and Costs

a. Time Estimates

This submission requests OMB approval to contact approximately 1,500 women (an annual average of 750 women) via telephone to determine if they are the past NHANES survey participant (SP) of interest and to collect additional information on them and their babies. A total time estimate of 20 minutes per person is requested. This includes time for participants to read the advance letter, participate in the phone survey and read and sign the birth certificate linkage consent form. Attachment 5a contains the

telephone script and questionnaire and Attachment 4 contains the birth certificate linkage consent form. The total annual burden is 250 hours.

For state/territory birth certificate staff, a time of 5 minutes per birth certificate record retrieved is requested (Attachment 5d) for a total of 62 hours.

The total annual burden requested for this project is 312 hours.

TABLE 1 – ANNUALIZED BURDEN HOURS AND COSTS

| Type of Respondent | Form | Number of Respondents | Number of Responses per respondent | Average Burden per Response (in hours) | Total Burden Hours |
|---|---|---|---|---|---|
| 1. Women who were pregnant during NHANES 1999-2010 | Health Questionnaire / Birth Certificate Linkage Consent Form | 750 | 1 | 20/60 | 250 |
| 3. State/local vital statistics staff (one per U.S. State or Territory) | Locate and transmit birth certificates | 57 | 13 | 5/60 | 62 |
| Total | | | | | 312 |

b. Cost to Respondents

At an average wage rate of $21.00 per hour and an average length of interview of about 20 minutes for the 750 former NHANES respondents, the average cost per respondent is about $7.00. This is an average across all levels of participation which can range from women who say no to participating (in the first few minutes of the telephone interview) through women who agree to participate in all aspects of the project. At an average wage rate of $26.00 per hour and an average length of document retrieval time of about 5 minutes per record for the 57 state/local vital statistics staff, the average cost per vital statistics representative is about $30.56. (Wage rate information is from the Bureau of Labor Statistics: http://www.bls.gov/ncs/ocs/sp/nctb1344.pdf. This estimated cost does not represent an out of pocket expense, but represents a monetary value attributed to the time spent doing the interview or vital statistics records retrieval. Also state/local vital statistics departments will be paid the going rate for purchasing birth certificates.

| Total NHANES Respondent Burden Hours | Respondent Wage Rate per Hour | Total estimated costs |
|---|---|---|
| 250 | $21.00 | $5,250 |

| Total State/Local Vital Statistics Staff Burden Hours | Respondent Wage Rate per Hour | Total estimated costs |
|---|---|---|
| 67 | $26.00 | $1,742 |

13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

None.

14. Annualized Cost to the Federal Government

This project is estimated as a two year survey. The total cost is estimated as $523,282, which makes the annualized cost an estimated $ 261,641. A proportion of these costs are paid by funds transferred to the CDC budget from the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Division of Reproductive Health. It is estimated that of the majority of survey costs will be covered through this support.

15. Explanation for Program Changes or Adjustments

This is a new study.

16. Plans for Tabulation and Publication and Project Time Schedule

The data collected in NHANES Birth Certificate Linkage projects will be released in several formats: limited access data sets, NCHS Vital and Health Statistics and Data Briefs, the CDC Morbidity and Mortality Weekly Report, and peer reviewed journal articles. Data will be presented and disseminated at professional meetings. The NCHS National Conference on Health Statistics provides an excellent means of notifying data users about upcoming data releases, showcasing the latest data releases, and providing tutorials on how to use NHANES data.

Analyses and presentations will be made by NCHS staff and other CDC staff in collaboration with consultants and staff from other Federal agencies and collaborating organizations.

Published reports and presentations will address numerous topics in the areas of health and nutritional status of children related to birth status and the health of the mother during pregnancy.

Table 16-1 PROPOSED TIME SCHEDULE: DATA RELEASE, AND REPORTING ACTIVITIES

The timetable for key activities for the 2012 survey is as follows:

| Time after Clearance | |
|---|---|
| -- | Receive OMB clearance |
| Immediate | Begin data collection via telephone |
| 3 months | Submit Birth Certificate (BC) Requests to states |

| | |
|---|---|
| 6 months | Review data receipt and re-request BC if necessary |
| 8 months | Assemble preliminary file with BC data |
| 10 months | Perform QC on data files |
| 12 months | Prepare documentation for data file |
| 14 months | Provide data file to collaborator for pre-release QC |
| 17 months | Post data file for restricted use on NHANES website |
| 18 months-2 years | First publications from NCHS and NCCDPHP |

17. Reason(s) Display of OMB Expiration Date is Inappropriate

None

18. Exceptions to Certification for Paperwork Reduction Act Submissions.

There are no exceptions to the certification.