Supporting Statement A for Request for Clearance
Developmental Projects to Improve the National Health and Nutrition Examination Survey And Related NCHS Programs Generic

New Information Collection Request

November 29, 2017

Contact Information:

David Woodwell, MPH
Chief, Planning Branch
National Health and Nutrition Examination Survey
National Center for Health Statistics/CDC
3311 Toledo Road
Hyattsville, MD 20782

Telephone: 301-458-4327
FAX: 301-458-4028

E-mail: DWoodwell@cdc.gov

Table of Contents

List of Attachments

Developmental Studies to Improve the National Health and

Nutrition Examination Survey and Related NCHS Programs Generic

New Information Collection Request

- The goal of this submission is to obtain Generic OMB clearance to facilitate conducting projects related to developing NHANES or other health related surveys or studies.
- The intended use of the resulting data is to help refine/improve upon existing survey design and procedures as well as explore/evaluate proposed survey content, methods or approaches.
- The methods to be used will vary by specific projects covered by this Generic request. In some cases, probability sampling may be employed. In other cases, convenience samples may be employed.
- The subpopulation to be studied will be a sample of or volunteers from the civilian, non-institutionalized U.S. population, all ages.
- The data will be analyzed using appropriate statistical approaches and methods based on the nature of the development project.

Section A: Justification

1. Circumstances Making the Collection of Information Necessary

This submission requests approval for a generic, three-year clearance to conduct developmental projects to improve the National Health and Nutrition Examination Survey (NHANES) (OMB No. 090-0950, Exp. Date 12/31/2019) and related NCHS programs. The NHANES is conducted by the Division of Health and Nutrition Examination Surveys (DHNES) within the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). DHNES will submit to the Office of Management and Budget (OMB) a subsequent Information Collection Request (GenIC) for each data collection effort proposed under this clearance request.

This clearance covers survey research and activities that will help evaluate and improve upon issues such as survey design and operations, as well as examine the feasibility and address challenges that may arise with developing future content for the NHANES or similar surveys. This generic request covers developmental projects with aims such as:

(1) Explore ways to refine and improve upon existing survey design and procedures aimed at increasing participation and response rates, developing and refining survey items and exam procedures and

(2) Explore, test and evaluate proposed survey designs, content, methods and alternative approaches to activities such as outreach, screening, participant recruitment/retention, data collection, or other health survey activities for NHANES or NCHS-wide projects.

The goal of these projects is to evaluate and enhance DHNES or NCHS existing and proposed data collection activities to increase research capacity and improve survey data quality. The information collected through this Generic Information Collection Request will not be used to make generalizable statements about the population of interest or to inform public policy; however, methodological findings from these projects may be reported.

Authorization:
Four public laws authorize or necessitate the collection of information about the health of the American people. Excerpts of these laws are in Attachment A.

a) 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.
b) Section 4403 (Joint Nutrition Monitoring And Related Research Activities) of the Food, Conservation, and Energy Act of 2008 (P.L. 110-234) specifies that the Secretary and the Secretary of Health and Human Services shall continue to provide jointly for national nutrition monitoring and related research activities carried out as of the date of enactment of this Act.
c) The Food Quality Protection Act of 1996 (P.L. 104-170) requires the implementation of surveys to collect data on food consumption patterns of infants and children and data on dietary exposure to pesticides among infants and children.
d) Title 21 – Food and Drugs, Chapter 9 of the Federal Food, Drug, and Cosmetic Act (21 USC 393) authorizes the collection of information to support the Food and Drug Administration's objective to obtain current, timely, and policy-relevant consumer information to carry out its statutory functions.

The Division of Health and Nutrition Examination Surveys (DHNES) is one of four data collection divisions within the National Center for Health Statistics (NCHS). The mission of NHANES and related programs is to produce descriptive statistics, which measure the health and nutrition status of the general population. Through the use of physical examinations, laboratory tests, and interviews NHANES studies the relationship between diet, nutrition and health in a representative sample of the United States. NHANES monitors the prevalence of chronic conditions and risk factors. NHANES data are used to produce national reference data on height, weight, and nutrient levels in the blood. Results from more recent NHANES can be compared to findings reported from previous surveys to monitor changes in the health of the U.S. population over time. NHANES has been a continuous survey since 1999.

The continuous operation of NHANES presents unique challenges in testing new components. As protocols and systems are designed and developed, they are fielded. Each examination component is operationalized and evaluated for feasibility of exam room arrangement and procedures, performance of equipment, efficiency, completion times and interaction with the system. Procedures are conducted with trained examiners and actual subjects of the required ages to ensure accurate testing of the components and systems. Standard operating procedures are evaluated for efficiency and coordination of subject flow through the Mobile Examination Center (MEC), completion of required exam components, subject cooperation and

refusal conversion, staff productivity, and adequacy of facility and supplies. NCHS staff, the contractor's development staff and consultants participate in the evaluation effort.

In certain cases, additional testing using non-NHANES respondents may be necessary. This could occur, for example, when the NHANES is developing a method to be used in the survey that can be tested outside the NHANES survey setting. For example, prior to adding the Liver Ultrasound Elastography exam to NHANES in 2017-18, a pilot study to test the liver ultrasound equipment was conducted among volunteers.

There may also be a need to conduct testing within NHANES for projects that may supplement/compliment NHANES or that may be implemented in alternative settings such as within other health studies, in home environments or in non-NHANES subgroups. For example in 2012, NHANES conducted a Health Measures at Home Methodology Study (HMHS) among a small subset of NHANES participants. This involved collecting height, weight, blood pressure and dried blood spots both in NHANES participants' homes and in the NHANES MEC. This project was conducted because NCHS sought to investigate the feasibility of incorporating physical measures and biologic specimen collection into the National Health Interview Survey (NHIS) (OMB No. 0920-0214, Exp. Date 12/31/2019) by implementing the HMHS within NHANES.

The OMB document "Questions and Answers When Designing Surveys for Information Collections," describes generic surveys: "A generic clearance is considered only when the agency is able to demonstrate that there is a need for multiple, similar collections, but that the specifics of each collection cannot be determined until shortly before the data are to be collected… Individual collections should not raise any substantive or policy issues or go beyond the methods specified in the generic ICR." See the following website for further information: https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/inforeg/pmc_survey_guidance_2006.pdf

This generic clearance request is in accordance with this description. The developmental projects covered in this clearance are intended to be broad with research aims designed to: (1) explore ways to refine and improve upon existing survey designs and exam procedures; (2) explore and evaluate proposed survey designs and alternative approaches to data collection; and (3) test or compare existing or new equipment. Therefore, specifics cannot be determined for any particular projects until shortly before the data are to be collected or the activities take place.

The NCHS mission is "to provide statistical information as the Nation's principal health statistics agency that will guide actions and policies to improve the health of the American people"[1] NCHS is authorized to collect data under Section 306 of the Public Health Service Act (42 U.S.C. 242k). See Attachment A.

2. Purpose and Use of the Information Collection

Projects submitted under this generic clearance would benefit DHNES in its efforts to improve the quality and efficiency of all of its survey operations and design relevant to the National Health and Nutrition Examination Surveys and related NCHS programs.

[1] Centers for Disease Control and Prevention (CDC) website, written by CDC's Office of Enterprise Communication. Available at http://www.cdc.gov/about/mission.htm. Accessed May 2014.

NHANES consists of three primary methods of data collection: personal interview, examination (including follow-up activities), and laboratory assessments. The purpose and use of projects under the NHANES generic may include developmental projects necessary for activities such as:

- Testing new procedures, equipment, and approaches that are going to be folded into NHANES
- Designing and testing examination components
- Designing and testing survey questions
- Creating procedures for new studies, including biomonitoring and clinical measures
- Creating new cohorts, including a pregnancy and/or a birth – 24 month cohort
- Testing of the cognitive and interpretive aspects of survey methodology
- Feasibility testing of proposed new components or modifications to existing components
- Testing of human-computer interfaces/usability
- Assessing the acceptability of proposed NHANES components among likely participants
- Testing alternative approaches to existing NHANES procedures, including activities related to improving nonresponse
- Testing the use of or variations/adjustments in incentives
- Testing content of web based (including self-administered) surveys
- Testing the feasibility of obtaining bodily fluid specimens (e.g. blood, urine, semen, saliva, breastmilk) and tissue sample (swabs)
- Testing digital imaging technology and related procedures (e.g., retinal scan, liver ultrasound, Dual-energy X-ray absorptiometry (DEXA), prescription and over-the-counter dietary supplements bottles, infant formula nutrition labels)
- Testing the feasibility of and procedure/processes for accessing participant's medical records from healthcare settings (e.g., hospitals, physician offices, etc.)
- Testing the feasibility and protocols for examination measurements in the home or other settings
- Testing survey materials and procedures to improve response rates, including changes to advance materials and protocols, changes to the incentive structure, introduction of new and timely outreach and awareness procedures including the use of social media
- Conducting crossover studies to bridge new methodology being phased in with old methodology being phased out
- Creating and testing digital survey materials

The types of participants covered by the NHANES generic may include:

- Current or past NHANES participants
- Family or household members of NHANES participants
- Individuals eligible to be participants in NHANES, but who did not actually screen into the survey
- Convenience samples
- Volunteers from the general public
- Subject matter experts or consultants such as survey methodologist, academic researchers, clinicians or other health care providers
- Individuals abroad who would be part of a collaborative development project(s) between NCHS and related public health agencies and/or public health researchers abroad.

The type of participant involved in a given developmental project would be determined by the nature of the project. Certain projects may involve participants traveling to a survey site or examination center, etc. The details of each project will be included in the specific GenIC

submission. However, below are a few examples of how participants might be matched to projects.

- Focus groups among NHANES field staff or other contract staff to collect information that may inform or may be used for evaluating issues surrounding survey operations and logistics, non-response
- Cognitive testing of questionnaires among volunteers to assess question meaning, administration, comprehension or harmony of meaning across different language translations
- Equipment testing among a convenience sample
- Conduct a developmental project or testing ahead of a proposed special study among individuals who were eligible to participant in NHANES, but that did not screen into the survey originally or among a convenience sample. (No actual special studies would be deployed under this request.)
- Feasibility testing among current NHANES participants
- Focus groups among subject matter experts or consultants related to designing new content or revising existing content, best practices or emerging technologies or methodologies
- Feasibility testing of self-collected specimens in the home (such as follow-up human papillomavirus (HPV) collection or semen collection) among NHANES participants or volunteers
- Testing self-screening methods (such as web based or paper questionnaires etc.) among potential NHANES participants
- Testing of longitudinal survey exam content or procedures among past NHANES participants
- Collection of health measures/biologic specimens (such as blood pressure or blood sample from finger stick etc.) in the home or other non-mobile site by survey field staff among NHANES participants or volunteers

In an effort to improve the existing survey design and/or procedures, including different incentives approaches, projects may include:

- efforts to improve recruitment and enrollment;
- testing of new survey content;
- testing data collection procedures and strategies including the use of mobile or web based technologies;
- cognitive testing of survey questions;
- translations of survey materials or instructions;
- survey related focus groups;
- comparing data collection on a given topic using different protocols, differing equipment or across different time periods;
- assessment of the feasibility of data collection; and
- development of protocols that will locate, identify, and collect accurate survey data in the least labor-intensive and burdensome manner for participants.

Developmental projects may also be carried out to help plan surveys that are not directly related to NHANES, such as community studies or studies conducted among specific target groups or subdomains which may not be nationally representative.

3. Use of improved information technology and burden reduction

The specific data collection procedure will be addressed in each GenIC, including use of improved information technology and burden reduction. There are no legal obstacles to reduce the burden.

4. Efforts to identify duplication and use of similar information

NHANES is a unique source of health information on the U.S. population. There are no other studies that collect the detailed health, dietary, laboratory and examination data that NHANES does. These developmental activities will be internal projects related to the NHANES or other NCHS wide projects. Therefore, there is no similar data to be identified.

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

These research activities are expected to be one-time data collections.

–

7. Special circumstances related to the guidelines of 5 CFR 1320.5

This data collection fully complies with regulation 5 CFR 1320.5.

8. Comments in response to the Federal Register notice and efforts to consult outside the agency

In compliance with 5 CFR 1320.8(d), a notice soliciting comments on this generic package was published in the Federal Register on April 20, 2017, volume 82, number 75, pp. 18650 - 18652. One comment was received. See Attachment B1 for a copy of the notice. See Attachment B2 for a copy of the comment and the corresponding agency response.

Consultations will be described in each individual GenIC.

9. Explanation of Any Payment or Gift to Respondents

To maximize response rates for the examination, NHANES participants have been given incentives for their examination participation since the 1970s. Project specific incentives for participation in developmental studies will be addressed in each survey-specific GenIC.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

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").

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(d)) 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 be protected from "uses other than those purposes for which they were collected."

The confidentiality of individuals participating in the GenICs under this Developmental Studies to Improve the National Health and Nutrition Examination Survey and Related Programs Generic are protected by section 308(d) of the Public Health Service Act (42 USC 242m(d)), 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."

NCHS also makes the following Confidentiality Pledge:

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 (42USC 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, Title 5 of Public Law 107-347). 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, NCHS complies with the Federal Cybersecurity Enhancement Act of 2015. This law requires the federal government to protect federal computer networks by using computer security programs to identify cybersecurity risks like hacking, internet attacks, and other security weaknesses. If information sent through government networks triggers a cyber-threat indicator, the information may be intercepted and reviewed for cyber threats by computer network experts working for, or on behalf, of the government.

All study data will be collected under the pledge of confidentiality. Consequently, all information collected in Developmental Studies to Improve the National Health and Nutrition Examination Survey and Related Programs will be kept confidential, with an exception for suspected child abuse and requirements of the Cybersecurity Act of 2015.When indicated, studies will collect, on a confidential basis, data needed to re-contact respondents for additional information and for participation in potential follow-back surveys, and possibly to match respondents to administrative records. The ability to track respondents and match to other records greatly expands the usefulness of these data at very low cost.

Only those NCHS employees, contract staff, and full research partners who must use the personal information for a specific purpose can access and use such data resulted from the studies. Everyone else who uses the data can do so only after all identifiable information is removed.

For more than 50 years, NCHS has protected confidential information collected in its surveys. The collection of identifiable information requires strong measures to ensure that private information is not disclosed accidentally or deliberately in a breach of confidentiality. All NCHS employees, as well as all contract staff, receive appropriate confidentiality training and sign a "Nondisclosure Statement." Staff members of collaborating agencies are also required to sign this statement, and outside agencies are required to enter into a more formal agreement with NCHS. All contractor and NCHS project staff follow strict procedures to collect, monitor, and analyze these data. This procedure prevents information from being removed from the area for purposes other than official NCHS survey data collection. The transmission and storage of confidential data are protected through procedures such as encryption and carefully restricted access. Only those NCHS employees and our full research partners who must use the personal information for a specific purpose may have access to and use such data.

Prior to release of any data collected under this clearance, the NCHS Disclosure Review Board (DRB) reviews the information to ensure that disclosure risk is at a minimum. Tabulated data are reviewed to ensure that no disclosure risk exists.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The National Health and Nutrition Examination Survey is subject to annual review by NCHS' Research Ethics Review Board (ERB) and is approved to continue data collection through 11/10/2017 (see Attachment C). All GenICs submitted under the Developmental Studies to Improve the National Health and Nutrition Examination Survey and Related Programs Generic will be subject to their own respective ERB review.

Any sensitive questions would be discussed in each project specific GenIC.

12. Estimates of annualized burden hours and costs

a. Time Estimates

This submission requests OMB approval for three years of data collection. The estimated total burden for one year of NHANES Generic projects is 9,215 hours. The overall burden estimates are presented in Table 1 below. The burden for each individual project will be shown in each GenIC.

Table 1. Estimates of Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
Individuals or households	Developmental Projects & Focus Group documents	1,500	1	1.5	2,250
Volunteers	Developmental Projects & Focus Group documents	300	1	1.5	450
Individuals or households, Volunteers, NHANES Participants	24 hour developmental projects	200	1	25	5,000
NHANES participants	Developmental Projects	1,000	1	1.5	1,500
Subject Matter Experts	Focus Group / Developmental Project Documents	15	1	1	15
Total					9,215

B. Annualized Cost to Respondents

The hourly wage rate of $23.86 per person (except Line 5: subject matter experts) is based on income from wages and salary table from the Bureau of Labor Statistics: http://www.bls.gov/oes/current/oes_nat.htm#00-0000. This wage rate for the category “all occupations” was used since respondents do not fall into a single economic or occupational category. For respondents in line 5: subject matter experts, the overall wage rate for “medical scientist” ($45.68) in the above BLS table was used. (NOTE: There are no costs for participants. They may receive an incentive as a token of appreciation and to help with out-of-pocket expenses such as baby sitting/child care and transportation, when appropriate.).

TABLE 2 – Annualized cost to respondents.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Individuals or households	Developmental Projects & Focus Group documents	2,250	$23.86	$53,685
volunteers	Developmental Projects & Focus Group documents	450	$23.86	$10,737
Individuals or households, Volunteers, NHANES Participants	24 hour developmental projects	5,000	$23.86	$119,300
NHANES participants	Developmental Projects Documents	1,500	$23.86	$35,790
Subject Matter Experts	Focus Group / Developmental Project Documents	15	$45.68	$685
Total				$220,197

13. Estimates of other total annual cost burden to respondents or record keepers

None.

14. Annualized cost to the Federal government

While actual annualized costs will vary dependent on the scope of future survey submissions, it is anticipated that the costs related to staff salaries for planning and implementing the future surveys might average $100,000.

15. Explanation for program changes or adjustments

This is a new generic submission.

16. Plans for tabulation and publication and project time schedule

No national estimates are being produced, so there is no schedule for data release. Results of developmental/methodologic research may be released in methodologic papers or other presentations.

17. Reason(s) display of OMB expiration date is inappropriate

None

18. Exceptions of certification for Paperwork Reduction Act submissions

There are no exceptions to the certification.