Developmental Projects to Improve the
National Health and Nutrition Examination Survey
And Related NCHS Programs Generic
OMB No. 0920-1208 (Expires August 31, 2023)

National Health Interview Survey (NHIS) Follow-up Health Study
Supporting Statement A

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National Health Interview Survey (NHIS) Follow-up Health Study
Supporting Statement A

This is a request to conduct an in-home biomeasure collection feasibility pilot study called National Health Interview Survey (NHIS) Follow-up Health Study under the previously approved Developmental Projects to Improve the National Health and Nutrition Examination Survey and Related NCHS Programs Generic Information Collection (OMB No. 0920-1208, Exp. Date 08/31/2023). This pilot will be conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

The currently approved generic clearance includes a proposal to conduct developmental studies to "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 National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0950, Exp. Date 11/30/2021) or NCHS wide projects." This submission includes a request to initiate one such study for the National Health Interview Survey, also conducted by NCHS. The proposed changes would not exceed the currently approved burden hours.

A. Justification

1. Circumstances Making the Collection of Information Necessary.

The National Center for Health Statistics (NCHS) leads several data collections systems that conduct surveys to monitor the health of the United States population. Two of these programs, the National Health and Nutrition Examination Survey (NHANES) and the National Health Interview Survey (NHIS) collect survey data through in-person household interviews. The goals of both surveys are to track national health status, health care access, and progress toward achieving national health objectives. However, the two surveys have historically produced different kinds of data with different survey designs.

NHANES involves both a household interview and a health exam component. After completing the household interview, NHANES respondents are asked to visit Mobile Examination Centers (MECs) to complete an exam with comprehensive medical, dental, and physiological measurements and provide samples of biospecimens such as blood and urine. The methods used in the exam and the assays performed on the biospecimens comprise a gold-standard for national physical exam and biospecimen data collection and the results comprise the national gold standard data for these measurements. The sample of about 5,000 persons each year, with a biannual data collection schedule, is nationally representative. The sample sizes achievable with NHANES (due to the required infrastructure and other logistics) often preclude using NHANES as a vehicle for regularly producing sub-national estimates from physical measurements and biospecimens data.

NHIS collects survey data on a broad range of health topics annually. NHIS is conducted by the Census Bureau under an interagency agreement with NCHS. Data are collected from one adult (the Sample Adult) and one child, if applicable, per household. The interview is

approximately one hour in duration. The child interviews are conducted with knowledgeable adult proxy respondents. NHIS includes a larger sample than NHANES with about 27,000 Sample Adults each year. NHIS data can be used to calculate annual health estimates by geographic, demographic, and socioeconomic subgroups; however, NHIS does not currently collect physical measurements or biospecimens.

NHANES and NHIS are collaborating to conduct a pilot study called the NHIS Follow-up Health Study. The aim of the study is to investigate whether adult health survey respondents are willing to be visited by a health representative who will collect their physical measurements and biospecimens. The pilot will also inform the feasibility of collecting these measures from a large, geographically dispersed sample like the NHIS. Specifically, the study aims to identify the challenges that could impede participation or impact the quality of physical measurements and biospecimens collected in-home from such a sample. In this pilot study, a subset of Sample Adults who complete the 2021 NHIS will be invited to participate. More details about the knowledge gaps that this pilot study will fill, such as response rates of survey respondents to this kind of follow-up data collection, can be found in Attachment 1a. In light of the COVID pandemic, the program will be implementing a set of safety measures, as described in Attachment 1b.

Since both NHANES and NHIS data collections are continuous, developmental studies must be conducted during their ongoing data collection. The NHIS Follow-up Health Study project represents one such methodological study. The burden hours have already been approved on line 5 (Developmental Projects & Special Studies) of the burden table within the current NHANES generic package (OMB No. 0920-1208, Exp. Date 8/31/2023)

2. Purpose and Use of the Information Collection

The purpose of this pilot is to assess the feasibility of collecting physical measurements and biospecimens from NHIS respondents in their homes. The NHIS Follow-up Health Study proposes to invite 900 adult respondents aged 18 years or old to the 2021 NHIS to participate in the study. The NHIS (OMB No. 0920-0214, Exp Date 12/31/2023) will be administered at usual. At the conclusion of the Sample Adult interview, the interviewer will describe the project and ask permission to give the Sample Adult respondent's contact information to the project staff scheduling the appointments and collecting the data; respondents who refuse will be asked why (see Attachment 1c). A brochure will be left for respondents who agree, when the interview is in person, and will be mailed to such respondents when the interview is over the phone (see Attachment 1d).

If respondents agree to be contacted, then project staff will use a multi-mode approach, which includes phone calls, emails, and texts to schedule the appointment (Attachment 1e). If project staff are unable to reach the respondent by those methods, they will mail a letter and brochure asking respondents to contact the central scheduling number. (Attachment 1f).

Once the project staff make contact via phone with the respondent, they will record and respond appropriately to any participant questions, concerns, and reasons for refusal. They will then screen the respondents who agree to participate for COVID-19 risk using the CDC-recommended COVID screening questions and schedule accordingly (Attachment 1e). The

project staff will also provide instructions about what to do to prepare for the visit (Attachment 1e). Finally, the project staff will ask how (phone/text/email) the respondent would prefer to receive the appointment reminder.

Project staff will send the reminder approximately 24 hours prior to respondents' appointment (see Attachment 1e). If the health representative can reach the respondent by phone, s/he will reiterate the COVID screening questions and reschedule if necessary (Attachment 1e).

On the day of the scheduled visit, the health representative will come to the respondent's home, after following the COVID-19 safety protocols described in Attachment 1b Part 3. If the respondent is available, the health representative will screen him/her for COVID and reschedule if necessary (Attachment 1b and Attachment 1e), provide a paper copy of an informational handout about the measures and lab tests to be conducted (Attachment 1g), administer electronic consent and provide a paper copy of the form(Attachment 1h). Then the health representative will ask the respondent to provide a urine sample. The representative will then measure and record the respondent's height, weight, waist circumference, blood pressure, and resting heart rate and collect a venous blood sample. The urine collection, blood collection, and height, weight, waist, blood pressure, and resting heart rate measurements are described in Attachment 1i. The health representative will also record any concerns or reasons for study component refusal that the participant provides, and will administer a short survey about the participant's study experience, which includes a question about what concerns, if any, the participant had about participating (Attachment 1i).

Before leaving the home, the health representative will provide the participant with a paper report of their height, weight, waist circumference, blood pressure and resting heart rate to keep (Attachment 1j). Participants will be mailed their full report, containing the results from the first report (i.e., height, weight, waist circumference, blood pressure and resting heart rate) as well as the results from the blood and urine tests, several weeks after the home visit (Attachment 1k). The envelope that contains that report will also contain another copy of the Measures and Lab Test explanation handout and the COVID Serology Results handout (Attachment 1g).

The objectives of the NHIS Follow-up Health Study are to evaluate:

- the overall and component-specific response rates for participation in the home exam;
- respondent concerns and reasons that respondents refuse to participate or refuse particular components of the study;
- the feasibility of, and challenges to, scaling up pilot exam procedures to the full geographically-dispersed NHIS sample; and
- the quality of blood and urine samples obtained for laboratory testing.

The pilot will assess the following outcome measures:

- *Response Rates:*
    - The percentage of invited NHIS respondents who agree to be contacted.
    - The percentage of invited NHIS respondents who schedule an appointment.

    - The percentage of invited NHIS respondents who complete each component of the in-home health exam.
    - The percentage of invited NHIS respondents who complete all components
- *Respondent Concerns and Reasons for Refusal:*
    - Identification of the most common participant concerns about participating
    - Percentage of invited NHIS participants who express each of the most common concerns
    - Identification of the most common reasons given for refusal
    - Percentage of invited and refusing NHIS participants who give each of the most common reasons for refusal
- *The feasibility of scaling up pilot exam procedures to the full NHIS sample*
    - The percentage of participants who agreed to be contacted by text and email
    - The mean and median number of contact attempts by text, email, and phone call per completed case
    - The median and mean number of days between interview and health exam
    - The median and mean duration of the in-home exam.
    - The percentage of participants who reschedule the in-home exam.
    - The median and mean time to transport samples (time from collection to lab).
    - The median and mean time to return results to participants after the home visit.
- *The quality of blood and urine samples obtained for laboratory testing*
    - The percentage of samples collected that are viable for testing.

3. Use of Improved Information Technology and Burden Reduction

   The NHIS Follow-up Health Study aims to test the feasibility of reducing respondent burden by conducting health exams in a respondent's home instead of in a mobile exam environment. In-home measurements e.g., blood pressure and anthropometrics will be entered directly into encrypted laptops, to facilitate safe and expedited data transmission. Samples and results will be tracked electronically. Results and tracking systems will utilize software compatible with statistcal packages for data analysis.

   There are no legal obstacles to reducing the burden.
4. Efforts to Identify Duplication and Use of Similar Information

   NHANES and NHIS are both unique sources of health information on the U.S. population. There are no other studies that collect the detailed health, dietary, laboratory and examination data in a standardized environment as does NHANES. There are no other studies that collect the detailed health condition, health care access and utilization data on such a large nationally representative sample as NHIS does. As such, the collaboration between NHANES and NHIS on this project is unique as well and does not represent duplication or use of similar information.
5. Impact on Small Businesses or Other Small Entities

   No small businesses are affected.
6. Consequences of Collecting the Information Less Frequently

The NHIS Follow-up Health Study is a one-time project designed to support the continuous nature of NHIS (OMB No. 0920-0214, Exp Date 12/31/2023) and NHANES (OMB No. 0920-0950, Exp. Date 11/30/2021), allowing new strategies to be tested before they are implemented into the main NHIS survey.

7. Specific Circumstances Relating to the Guidelines of 5 CFR 1320.5

   This request fully complies with the regulation 5 CFR 1320.5.

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 this generic package was published in the Federal Register on December 6, 2019, volume 84, number 235, pp. 66906 – 66908. The notice received one non-substantive comment.

   b. Outside Consultation
   NHIS consulted with NHANES about the development of this project. Outside of NCHS, the program also consulted with other national health surveys that have collected biomeasures in the home, including Add Health conducted by the University of North Carolina, the Household Retirement Survey (HRS) conducted by the University of Michigan, and the National Social Life, Health and Aging Project conducted by the University of Chicago and NORC.

9. Explanation of any payment or gift to respondents.

   The program proposes providing participants in this pilot study with a $75 incentive as a token of appreciation. Respondents will receive this incentive at the conclusion of the home visit.

   Historically, NHIS has not provided an incentive to its respondents. However, to maximize response rates, NHANES participants have been provided with tokens of appreciations to recognize their effort and to encourage their examination participation since the 1970s. Respondents for the proposed field feasibility test are sampled from the 2021 NHIS. The incentive being requested for the NHIS Follow-up Health Study is considered important to response rates, given that respondents will be recruited after completing the NHIS interview with no incentive and will be asked to complete a physical health assessment.

   This incentive is consistent with those used in current NHANES for components with similar level of respondent burden. The incentive is also consistent with that used in the NHANES-Longitudinal Study (LS), for a similar level of respondent burden. (See Attachment 1a). The incentive will be provided in the form of a debit card that will be activated at the end of the home visit.

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 NHIS Follow-up Health Study 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").

Confidentiality will be provided to respondents as assured by Section 308(d) of the Public Health Service Act (42 U.S.C. 242m) as follows:

"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 304, 306, or 307 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 in the case of information obtained in the course of health statistical or epidemiological activities under section 304 or 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 the Confidential Information Protection and Statistical Efficiency Act (Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)) which states:

"(f) Fines and Penalties. -- 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 this section, 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 subchapter, 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."

Standards for Federal government surveys highlight the importance of the interviewers' responsibilities under the Privacy Act of 1974 (5 U.S.C. 552a), the Privacy Act Regulations (34 CFR Part 5b), Section 308(d) of the Public Health Service Act (42 U.S.C. 242m), the Confidential Information Protection and Statistical Efficiency Act (CIPSEA -Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)), HIPAA and other regulations.

NCHS also makes the following Confidentiality Pledge:

Assurance of Confidentiality (shown on all survey forms) – 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 (42U.S.C. 242m) and the Confidential Information Protection and Statistical Efficiency Act (Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)). 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.

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. 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 collaborators 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 collaborators 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

This pilot is subject to review by NCHS' Research Ethics Review Board (ERB). It is being reviewed as an amendment to the NCHS ERB protocol for the NHIS. The NHIS ERB amendment package was approved for data collection through 10/04/2024 (see Attachment

2). This project does not include sensitive questions and all components of the pilot are voluntary.

12. Estimates of Annualized Burden Hours and Cost

a. Time Estimates

The burden hours for this project are already accounted for in line 1 of the burden table for Developmental Projects to Improve the National Health and Nutrition Examination Survey and Related NCHS Programs Generic Information Collection (OMB No. 0920-1208, Exp. Date 08/31/2023). There will be five minutes of burden per Sample Adult at the completion of the NHIS interview when respondents are invited to participate and asked for permission to be contacted for scheduling purposes. An estimated 1,500 NHIS Sample Adults will be asked to participate. We anticipate that 60% of the 1,500 Sample Adults invited – 900 adults – will agree to be contacted for scheduling purposes. The in-home health exam is budgeted for 60 minutes per respondent. We expect 80 percent of the 900 Sample Adult respondents who gave consent to be contacted – 720 adults - will complete the health exam.

The total burden hours for this pilot study is 1170 hours. No additional burden is sought.

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
NHIS Sample Adults	Recruitment Questions	1,500	1	5/60	120
NHIS Sample Adults	COVID-19 screening questions, Scheduling, Reminder, and Preparation Instructions	900	1	10/60	150
NHIS Sample Adults	Home Health Visit	900	1	1	900
Total					1170

b. Annualized Cost to Respondents

The hourly wage rate of $25.72 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 (last accessed December 8, 2020). This wage rate for the category “all occupations” was used since respondents do not fall into a single economic or occupational category. Based on this hourly wage rate, the total estimated costs to respondents is $6,494.80.

TABLE 2 – Annualized cost to respondents

		Total	Hourly	Total

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no additional costs.

14. Annualized Cost to the Federal Government

As shown in the table below, the total cost of the project is estimated to be about $1.6 million. This includes costs to NCHS directly, the U.S. Bureau of the Census through an interagency agreement, and to the project contractor managing the scheduling, physical exams, and reporting.

Total 2021 NHIS Follow-up Health Study Pilot Project Costs	$1.6 million
U.S. Bureau of the Census (Interagency Agreement)	$150,000
Project Contractor	$1.2 million
Study management, Data collection, Reporting	$1.1 million
Travel	$100,000
National Center for Health Statistics	$250,000

15. Explanation for Program Changes and Adjustments.

The project described in this submission does not change the burden hours from the previously approved clearance. The burden hours in this submission are captured in the "Developmental Projects & Focus Group Documents", line 1of the burden table currently approved for the NHANES Generic (parent).

16. Plans for Tabulation and Publications 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.

This pilot study would be conducted as soon as feasible after clearance has been received.

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

Not applicable.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.