

Request for Approval of a Non-Substantive Change to the
National Health and Nutrition Examination Survey

OMB No. 0920-0950
(Expiration: 04/30/2023)

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1. Circumstances making the collection of information necessary

This request is for a non-substantive change to the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0950, Exp. Date 04/30/2023), conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). NHANES is conducted annually. The NHANES consists of three primary methods of data collection: the personal interviews, the physical examinations (conducted in the Mobile Examination Center (MEC)) including laboratory assessments, and follow-up interviews that take place after the examinations. A major advantage of continuous NHANES data collection is the ability to address emerging public health issues and provide objective data on health conditions and issues by adding/changing/modifying survey content.

On April 12, 2021, OMB approved the 2021 – 2022 data collection cycle. The supporting statements requested approval to 1) collect data in years 2021-2022 with modifications to adapt the survey due to the coronavirus disease (COVID-19) pandemic and related concerns; 2) collect follow-up data and conduct activities related to data collection/processing (for survey year 2022) into 2023; 3) conduct developmental projects to support data collection for 2023 and beyond; and 4) conduct non-response projects, as needed.

Due to the ever-evolving changes of the COVID-19 pandemic, NHANES is proposing the following modifications to the approved 2021 – 2022 NHANES survey:

1. Modify the COVID-19 questionnaire (COQ) to collect:
 - a. The total number of doses the participant received, including boosters
 - b. The manufacturer name for all doses received
 - c. The month and year of when each dose was administered
 - d. The COVID-19 questions are asked a second time in the MEC to capture any changes that may have taken place since they were first asked in the Household Interview. These questions will also be updated, as noted above, and reworded to more clearly articulate that we are looking for changes since they are first asked.
2. Perform anti-SARS-CoV-2 IgG quantitative antibody testing

More specifically, this document proposes the addition and revision of COVID-19 questionnaire items that will capture detailed information on COVID-19 vaccine manufacturers and total doses received, including booster doses, as well as vaccination month and year. NHANES will be able to assess waning immunity using the serology data by time since vaccination. A clean version of the modified 2021 – 2022 COQ content in the Sample Participant (SP) questionnaire is provided in **Attachment 1a**. A track changes version of the COQ is shown in **Attachment 1b**. A clean version of the modified COQ administered during the MEC interview is provided in **Attachment 2a**. A track changes version of this questionnaire is shown in **Attachment 2b**.

Second, the proposed modifications include a “place holder” request that will allow NHANES to conduct anti-SARS-CoV-2 IgG quantitative antibody testing once a certified lab has been identified. Currently, NHANES performs only qualitative serology testing (i.e., anti-SARS-CoV-2 Spike (S1) and Nucleocapsid (N)).

With the modification of the COVID-19 questionnaire to collect the total number of doses the participant received, the manufacturer name of all doses, and the month/year of when each dose was administered, NHANES anticipates that the change in burden will be minimal enough to be absorbed in the estimated annualized burden itemized in **Table 2**. The approved average burden estimates of one hour and two and a half hours for the Household Interview and MEC Examination, respectively, are enough to account for the addition of only one COVID-19 question and related looping logic that account for all administered vaccine doses.

2. Purpose and use of the information collection

The major objectives of NHANES are to:

1. Estimate the number and percentage of persons in the U.S. population and designated subgroups with selected diseases and risk factors,
2. Monitor trends in the prevalence, awareness, treatment and control of selected diseases,
3. Monitor trends in risk behaviors and environmental exposures,
4. Analyze risk factors for selected diseases,
5. Study the relationship between diet, nutrition, and health,
6. Explore emerging public health issues and new technologies, and
7. Establish and maintain a national probability sample of baseline information on health and nutritional status.

Under Section 2c(ii), of Executive Order on Ensuring an Equitable Pandemic Response and Recovery, it says,

(c) Data Collection. To address the data shortfalls identified in section 1 of this order, and consistent with applicable law, the Task Force shall:

- (ii) develop, in collaboration with the heads of relevant agencies, a set of longer-term recommendations to address these data shortfalls and other foundational data challenges, including those relating to data intersectionality, that must be tackled in order to better prepare and respond to future pandemics

NHANES Interviews

We collect questionnaire data as stand-alone components or to complement one or more examination or laboratory assessments. As a result of the COVID-19 pandemic, asking questions in the home is less desirable. For safety reasons, NHANES 2021-2022, screening, household and family interviews previously conducted via in-person interview in the home are administered either in-person, through multi-mode methods, or over the phone to reduce person-to-person contact. For example, in addition to the existing use of interviewer-administered computer-assisted personal interviewing (CAPI) and audio computer-assisted self-interviewing (ACASI) methods, trained interviewers may now ask questions of NHANES participants over the phone or using online tools or call center technology. NHANES may also make use of self-administered approaches of data collection, such as online surveys or paper surveys that participants mail back. Both initial and follow-up activities may be administered in these ways.

A summary of the approved changes in interview modes between NHANES 2019-2020 and 2021-2022 are provided in **Table 1** below.

Table 1. NHANES 2021-2022: Mode of Data Collection Components

Order	Component	2019-2020	2021-2022
1	Household Screener & Relationship Questionnaire	In-person	Multi-mode
2	Sample Participant & Family Questionnaires	In-person	Telephone & In-person
3	MEC Exam: Interview portion	In-person, some ACASI	Primarily ACASI
4	1 st Dietary Recall	In-person (at MEC)	Telephone (post MEC)
5	2nd Dietary Recall	Telephone (post MEC)	Telephone (post MEC)
6	Food Consumer Behavior Survey	Telephone (post MEC)	Telephone (post MEC)

The NHANES interview consists of the following major components:

1. Household Screener Questionnaire (determines eligibility) and the Non-Response Bias Module
2. Household Family Relationship Questionnaire
3. Household Sample Participant Questionnaire
4. Household Family Questionnaire
5. MEC Questionnaire (CAPI and ACASI)
6. Telephone Dietary Interview Day 1 (24-Hour Dietary Recall, Post-Dietary Recall Questions and Dietary Supplements)
7. Telephone Dietary Recall Day 2 and Dietary Supplements
8. Special Follow-Up Questionnaires (FCBS) (Telephone)

NHANES is proposing modifications to the covid questionnaire (i.e., COQ), which is a specific component included in the following questionnaires listed above:

- Sample Participant Questionnaire
- MEC Questionnaire

Inclusion of the COQ in the MEC interview is essential to capture any changes that may have taken place since administration of the COQ during the SP Interview. Upon identification of a certified laboratory, NHANES is requesting approval of the implementation of anti-SARS-CoV-2 IgG quantitative antibody testing. The identification and acquisition of a laboratory to perform this testing is in progress. Proposed modifications are described in detail below.

COQ modifications

Current COVID-19 questions collect information related to COVID infection and testing. These

questions are adapted from NCHS's National Health Interview Survey (NHIS), and Research and Development Survey (RANDS), or the National Institutes of Health's (NIH) MESA questionnaires. Two questions are included to determine whether a participant ever had COVID-19 and the severity of their symptoms. This information is important as early clinical reports indicated COVID-19 infection may cause lingering symptoms and possible long-term health impacts that span many organ systems. Self-reported symptom severity, in combination with our laboratory and examination findings, and knowing if someone had COVID-19, combined with the knowledge of symptoms (or lack thereof), are important for future health studies and our understanding of COVID-19's impact on health across multiple SP demographics (e.g., age, race/ethnicity) and those with medical conditions (e.g., obesity, diabetes, weakened immune systems, etc.).

Questions on COVID-19 testing and vaccinations are included in the SP and MEC interview to collect information on the testing history for active or past infections, the outcomes, and the most recent date of these tests and vaccinations received. NHANES is proposing the revision of COQ content to collect data on all doses received, manufacturer names of administered COVID-19 vaccines, and the month/year of all doses administered to sample participants (**see Attachments 1b and 2b**). These data, in combination with NHANES serology results, will enable researchers to determine if participants had natural immunity from previous infection or immunity from vaccination. Additionally, researchers may assess for possible waning immunity in addition to the serologic impact of heterologous doses.

Questions determining whether a sample participant had an overnight hospital stay for COVID-19, lives with a household member who has ever tested positive for COVID-19, has a weakened immune system due to a health condition or medications, and has received the flu vaccination in the last 12 months will remain in the COQ. The information on overnight hospital stay is needed to understand disease severity with risk factors for COVID-19 in addition to its long-term health impacts and complements the self-reported severity question described above. The items related to immune response are needed to understand if participants were more susceptible to more severe COVID-19 disease; and/or did not have detectable antibodies on serology due to their weakened immune systems not being able to generate antibodies. The purpose of the final two items is to understand transmission of the virus within the household and compare these responses and serology results to those other sampled household members, and to potentially rule out influenza as a possible cause of any COVID-19 like symptoms that may cause illness.

Anti-SARS-CoV-2 IgG quantitative antibody testing

NHANES proposes the addition of anti-SARS-CoV-2 IgG quantitative antibody testing to the 2021 – 2022 cycle. As NHANES works to secure a certified laboratory for quantitative antibody testing, we are requesting a “place holder” for approval of this testing until a lab is identified and acquired for use by NHANES. Quantitative testing has utility in assessing the immune status of infected and/or vaccinated sample participants by providing a quantification of IgG antibodies against SARS-CoV-2.

9. Explanation of any payment or gift to respondents

The modifications described in this non-substantive clearance request will not result in the receipt of any additional incentives. Participants will receive the approved incentives given to current NHANES participants.

12. Estimates of annualized burden hours and costs

The Household Interview and MEC Interview and Examination are budgeted for an average of one hour and two and a half hours, respectively. The maximum number of respondents for each is 5,600. The maximum burden for the Household Interview is 5,600 hours, and the maximum burden for the MEC Interview and Examination is 14,000 hours (**see Table 2**). These burden hours were budgeted and approved in the original OMB submission. The modification of the COQ in both the Household Interview and MEC Interview will be minimal enough to be absorbed in the estimated annualized burden itemized in **Table 2**. The current burden hours and cost should suffice for the addition of only one COVID-19 question and related looping logic that account for all doses administered to the sample participant.

Table 2. Annualized Burden Hours for Household and MEC Interviews

Type of Respondent	Form	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Individuals in households	Household Interview	5,600	1	1	5,600
Individuals in households	MEC Interview and Examination	5,600	1	2.5	14,000
Total					19,600

15. Explanation for program changes and adjustments

The proposed modifications to the COQ content and serology testing described in this submission do not change the estimated average burden hours from the previously approved clearance (**see Table 3**).

<u>Type of Respondent</u>	<u>Form Name</u>	<u>Number of Respondents</u>	<u>Number of Responses per Respondent</u>	<u>Average Burden per Response (in hours)</u>	<u>Total Burden (in hours)</u>
<u>Individuals in households</u>	<u>Screener</u>	<u>8,300</u>	<u>1</u>	<u>10/60</u>	<u>1,383</u>
<u>Individuals in households</u>	<u>Household Interview</u>	<u>5,600</u>	<u>1</u>	<u>1</u>	<u>5,600</u>
<u>Individuals in households</u>	<u>MEC Interview & Examination</u>	<u>5,600</u>	<u>1</u>	<u>2.5</u>	<u>14,000</u>
<u>Individuals in households</u>	<u>Day 1 and Day 2 Telephone Dietary Recall & Dietary Supplements</u>	<u>5,600</u>	<u>1</u>	<u>1.3</u>	<u>7,280</u>
<u>Individuals in households</u>	<u>Flexible Consumer Behavior Survey Phone Follow-Up</u>	<u>5,600</u>	<u>1</u>	<u>20/60</u>	<u>1,867</u>
<u>Individuals in households</u>	<u>Developmental Projects & Special Studies</u>	<u>3,500</u>	<u>1</u>	<u>3</u>	<u>10,500</u>
<u>Individuals in households</u>	<u>24-hour wearable device projects</u>	<u>1,000</u>	<u>1</u>	<u>25</u>	<u>25,000</u>
<u>Total</u>					<u>65,630</u>

Table 3. 2021 – 2022 Approved Annualized Burden Hours

List of attachments

Attachment 1a COQ_revision_211120 (clean)

Attachment 1b COQ_revision_211120 (marked copy)

Attachment 2a COQMEC_revision_211120 (clean)

Attachment 2b COQMEC_revision_211120 (marked copy)