

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 2024 and beyond; and 4) conduct non-response projects, as needed.

On January 25, 2022, OMB approved two non-substantive change requests to 1) modify the COVID-19 questionnaire (COQ) to collect data on the vaccine dose(s) administered and manufacturer name; 2) perform anti-SARS-CoV-2 IgG quantitative antibody testing; and 3) restore the MEC exam incentive for adults from \$85 to \$125 at five locations.

On June 17, 2022, OMB approved a non-substantive change request to implement MEC follow-up surveys to better understand barriers to MEC exam participation. Due to the ever-evolving landscape of the COVID-19 pandemic, NHANES is proposing the following additional modifications to the approved 2021 – 2022 NHANES content:

1. Add five additional questions to COQ to collect data on the following:
 - Whether participant has or had experienced post-COVID (also referred to as Long COVID) and related symptoms
 - A hand card with commonly reported post-COVID symptoms will be provided to sample participants (SPs).
 - *Note:* Post-COVID is defined as experiencing symptoms lasting 4 weeks or longer that were not present prior to having COVID-19 or suspecting to have COVID-19.
 - The most bothersome post-COVID symptoms and the impact of symptoms on day-to-day activities
 - The current presence of post-COVID symptoms and the length of occurrence of these symptoms
 - *Note:* Similar to current COVID-related questions collected in the household, the proposed new COQ questions are asked a second time in the MEC to capture any changes that may have taken place since they were first presented during the

Household Interview to obtain updated information that better associates with the serology data collected in the MEC.

2. Add two questions to the Prescription Medication Questionnaire (RXQ) to collect data on the following:
 - Medications prescribed by a doctor or healthcare professional to treat or prevent COVID-19
 - A hand card with a list of medications will be provided to SPs.

Post-COVID is an enduring impact of SARS-CoV-2 on health. The addition of post-COVID COQ and COVID-specific RXQ survey items will allow NHANES to 1) estimate post-COVID prevalence with an annual, nationally representative sample from the 15 locations in the 2022 cycle; 2) identify the more frequent symptoms associated with post-COVID, the length of their occurrence, and the impact of these symptoms on normal day-to-day activities; 3) identify groups that have been more affected by post-COVID; 4) capture common medical practices used to treat or prevent COVID-19 infection that may offer clinical guidance for healthcare providers, patients, and the public; and 5) assist researchers in assessing the impact of heterologous vaccine doses, the occurrence of natural immunity vs. immunity from vaccinations, and waning immunity using NHANES serologic results. NHANES will be providing the first nationally representative sample on post-COVID that is consistent with the latest CDC recommendation (i.e., experiencing symptoms four weeks or later after initial confirmed or suspected COVID-19 infection). Compared to other questionnaire-only based surveys, NHANES will provide more contextual data for post-COVID beyond surveillance estimates, which is critical for public health research efforts.

A clean version of the modified 2021 – 2022 COQ content in the Household Questionnaire is provided in **Att 1a**. A track changes version of the COQ is shown in **Att 1b**. A clean version of the modified COQ administered during the MEC exam is provided in **Att 2a**. A track changes version of this questionnaire is shown in **Att 2b**. Lastly, a clean version of the RXQ questionnaire administered in the Household Questionnaire is provided in **Att 3a**, and a track changes version is shown in **Att 3b**.

As a result of these modifications to COQ and RXQ content, NHANES anticipates that the change in burden (estimated to be approximately 2 minutes to the subset of participants asked) 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 five post-COVID questions and two COVID-related RXQ survey items on medications used to treat or prevent COVID-19.

2. Purpose and use of the information collection

Household Questionnaire Interviews

NHANES collects 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.

MEC Examination

For the 2021-2022 NHANES data collection, the MEC examination visits were shortened from 4 to 2.5 hours to reduce burden and maximize response rates. A MEC visit consists of physical examinations (i.e., anthropometry, standing balance, dual energy x-ray absorptiometry, blood pressure management, liver elastography), laboratory assessments (e.g., renal and hepatic function, biochemical panel, etc.), and more sensitive interview components administered via ACASI (e.g., alcohol use, mental health, etc.). Previously, NHANES also conducted an in-person dietary Day 1 interview at the MEC and a dietary Day 2 interview by phone. NHANES changed the mode of the in-person dietary Day 1 interview to also be via phone to limit face-to-face interaction with participants and mitigate COVID-19 risk. In January of 2022, NHANES received approval to increase the adult MEC exam incentive at 5 locations in efforts to increase MEC exam response rates. Additionally, on June 17, 2022, OMB approved a non-substantive change request to implement MEC follow-up surveys to better understand barriers to MEC exam participation.

A summary of the approved changes in data collection 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)

Order	Component	2019 – 2020	2021 – 2022
5	2nd Dietary Recall	Telephone (post MEC)	Telephone (post MEC)
6	Food Consumer Behavior Survey	Telephone (post MEC)	Telephone (post MEC)

NHANES is proposing modifications to the COVID-19 Questionnaire (i.e., COQ) and the Prescription Medication Questionnaire (i.e., RXQ), which are specific questionnaire components included in the Household Questionnaire. In addition to the COQ presented in the Household Questionnaire, the COQ survey items will be asked a second time during the MEC visit so when the data are linked to COVID-19 serology data, it will reflect any late infections, additional symptom development, or vaccinations that have occurred since the initial Household Interview. Proposed modifications to the COQ and RXQ are described in detail below.

Post-COVID 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-awareness of having COVID and the knowledge of symptom severity (or lack thereof), in combination with our laboratory COVID serology results, and additional laboratory and examination findings 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 collect information on the testing history for active or past infections, the outcomes, and the most recent date of these tests and vaccinations received. Data on all doses received, manufacturer names of administered COVID-19 vaccines, and the month/year of all doses administered to sample participants are collected as well. NHANES is proposing the revision of COVID-19 content to collect data on post-COVID (i.e., Long COVID), related symptoms, and the impact of these symptoms on day-to-day activities and the length of their occurrence (**see Att 1a and Att 1b**). These newly proposed questions are adapted from NCHS's National Health Interview Survey (NHIS), Census Bureau's Household Pulse Survey, CDC's Behavioral Risk Factor Surveillance System (BRFSS), CDC collaborated Red Cross COVID-19 Survey and Porter Novelli Summer Styles Survey, and UK's Office for National Statistics' COVID-19 Infection Survey (CIS). 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. Lastly, post-COVID data will allow NHANES to estimate post-COVID prevalence, identify more frequent symptoms experienced by SPs with post-COVID, the length of occurrence of these symptoms, their impact on day-to-day activities, and identify groups most affected by post-COVID.

Questions determining whether a sample participant had an overnight hospital stay for COVID-19, has a weakened immune system due to a health condition or medications, lives with a household member who has ever tested positive for COVID-19, 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 of other sampled household members, and to potentially rule out influenza as a possible cause of any COVID-19 like symptoms that may cause illness.

Participants are asked to update the information collected in COQ during their MEC visit so the data will reflect infections, symptom development, and vaccinations that have occurred since the initial Household Interview when linked with the serology data (**see Att 2a and Att 2b**).

COVID-19 Prescription Medication RXQ Modifications

NHANES proposes modification of the Prescription Medication Questionnaire (RXQ) in the Household Questionnaire with the addition of questions that inquire about medications prescribed by a doctor or health professional that were taken or received to treat or prevent COVID-19 since March 2020. Sample participants are provided a list of medications to select from for their responses (**see Att 3a and Att 3b**). Currently, the RXQ asks SPs about any medications prescribed in the past 30 days for any health condition, the number of medications taken, and whether aspirin is taken to prevent heart attacks, strokes, or cancer. The addition of COVID-19 medication data will allow NHANES to capture the common medical practices used to treat or prevent COVID-19 infection, and provide useful clinical guidance to the public, patients, and healthcare providers.

9. Explanation of any payment or gift to respondents

The modifications described in this non-substantive change 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, as well as the RXQ in the Household Interview, will add approximately 2 minutes to the burden among the subset of participants who are asked these questions. This additional time 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 five COQ items, two RXQ items, and related gating logic.

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 and RXQ content described in this submission do not change the estimated average burden hours from the previously approved clearance (**see Table 3 below**).

Table 3. 2021 - 2022 Approved Annualized Burden Hours

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

List of attachments

Att. 1a COQ_HH_220808_CLEAN COPY

Att. 1b COQ_HH_220808_MARKED COPY

Att. 2a COQ_MEC_220808_CLEAN COPY

Att. 2b COQ_MEC_220808_MARKED COPY

Att. 3a RXQ_COVID Med_220614_westat_NCHS_CLEAN COPY

Att. 3b RXQ_COVID Med_220614_westat_NCHS_MARKED COPY