

Supporting Statement A for Request for Clearance

National Health and Nutrition Examination Survey

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Contact Information:

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

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

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Supporting Statement A

National Center for Health Statistics (NCHS) National Health and Nutrition Examination Survey (NHANES)

- The goal of the study is to assess the health and nutritional status of adults and children in the United States.
- The intended use of the resulting data is to monitor public health and promote health by preventing and controlling disease and disability.
- The method to be used is a cross-sectional survey employing a stratified, multistage area probability sample.
- The subpopulation to be studied is a nationally representative sample of the civilian, non-institutionalized U.S. population, all ages.
- The data will be analyzed using appropriate statistical approaches and models, such as logistic regression.

This is a request for revision to the National Health and Nutrition Examination Survey (NHANES) current OMB clearance (OMB NO. 0920-0950, Exp. Date 11/30/2021). The program is requesting a three-year clearance.

The National Center for Health Statistics (NCHS), part of the Centers for Disease Control and Prevention (CDC) conducts NHANES. NHANES is a major ongoing source of information collecting data on the health and nutritional status of the civilian, non-institutionalized population of the United States.

The Program is submitting this revision request to:

- Collect data in years 2021-2022;
- Collect follow-up data and conduct activities related to data collection/processing (for survey year 2022) through 2023;
- Conduct developmental projects to support data collection for 2023 and beyond; and
- Conduct non-response projects as needed.

Brief Summary of Planned Changes for the 2021-2022 NHANES

This request includes obtaining clearance to conduct the following: household eligibility screenings; sample person, household, and family interviews; physical examinations and interviews at the Mobile Examination Center (MEC); laboratory assessments at the MEC; telephone follow-up interviews and other follow-up activities in 2021-2022.

Changes due to the COVID-19 Disease Pandemic

The Program is making changes specific to 2021-22 data collection to adapt the survey due to

the COVID-19 disease pandemic and related concerns. The Program consulted with collaborators, stakeholders, and the NCHS Board of Scientific Counselors (BSC) to communicate and seek input on changes being considered. Plans to adapt the survey, with focus on the safety of participants and staff and considering public health data needs related to COVID-19. These changes impact a broad range of survey areas, such as sample design, operational procedures (e.g., interview and examination modes and MEC hours), NHANES content (questionnaires, exam components, and laboratory measures), and outreach materials. Due to these changes, NHANES 2021-22 may not be comparable with previous or future NHANES cycles. (The goal of the program is to return to the pre-pandemic NHANES procedures in 2023 and beyond, provided it is safe to do so.)

Details of the sample design by cycle.,

- 1999 – 2018:
 - o Each single year *is* nationally representative
 - o Any combination of consecutive years is nationally representative
- 2019 – 2020:
 - o Each single year is NOT nationally representative
 - This change was made to increase operational efficiency, including:
 - Allowed the MECs to stay in one location longer, which allowed for more screening and interviewing time; and
 - Reduced the travel distance of the MECs by allowing them to stay in one region of the country in a given year vs. crisscrossing the country.
 - o Nationally representative when the two years of data are combined
 - Because the survey was paused in March 2020, new content in 2019–2020 is only be available through restricted access
 - Content in 2019–2020 that was also collected in previous cycles of NHANES may be publicly available in a merged 2017–March 2020 pre-pandemic data file.
- 2021 – 2022:
 - o Each single year *is* nationally representative
 - o Any combination of consecutive years *is* nationally representative
 - This sample design strategy is expected to stay in place for the next cycle of NHANES in 2023 and beyond.

NHANES will collect data on a single-year nationally representative sample of 5,000 people during 2021–2022, oversampling children (0-19 years old) and older persons (60 years and over). In contrast to past cycles, however, NHANES 2021–2022 will not oversample by race, Hispanic origin, or income. Dropping the race, Hispanic origin, and income oversampling significantly reduces the number of screened households, thereby minimizing in-person contact with households due to safety considerations for staff, and the potential that staff could act as a vector for spreading COVID-19. The NHANES program will continue to consider the reduction in ability to generalize about smaller sociodemographic groups and consider options for studies that provide valuable data for populations hit particularly hard by the pandemic.

Sample design changes are discussed in greater detail in Supporting Statement B and Attachment 5a. Sample design information for NHANES 2019-2020 is in Attachment 5b.

The Program acknowledges that during the pandemic potential participants may be more hesitant to agree to an in-person interview in their home, or a physical examination in the MEC. NHANES operational adaptations to address these and other COVID-19 related concerns in 2021-2022 include:

- Shortening interview times to reduce burden and help maximize response rates;
 - The average household interview time was reduced from 1.5 hours to approximately 1.0 hour.
- Adding a COVID-19 screening questionnaire and temperature check, conducted outside the MEC, prior to entry;
- Shortening MEC examination times to reduce burden and help maximize response rates;
 - Average MEC exam time of 4 hours has been reduced to 2.5 hours.
 - 2 hours are for the actual exam, though individual exam time for participants varies.
 - Younger sampled participants (SPs) may have fewer exam components, and therefore may spend less time in the MEC.
 - Older SPs may have more exam components, and therefore may spend more time in the MEC.
 - 30 minutes was added to allow for extra cleaning of MEC rooms.
- Changing interview and MEC examination modes to reduce person to person contact for safety reasons (see page 9);
- Redesigning MEC layouts and enhancing MEC cleaning procedures to address COVID-19 related safety concerns; and
- Reducing the number of people allowed in the MEC at the same time.
 - Keeping the MECs open up to 12 hours a day to collect information from the same amount of people even though fewer can be in the MEC at the same time.

A priority in making COVID-19 related changes to NHANES content is to add COVID-19 antibody laboratory assessments and COVID-19 questions relevant to interpreting these assessments. The COVID-19 antibody assessment in NHANES will allow for assessing undiagnosed COVID-19 in a nationally representative sample. It will also allow for distinguishing between COVID-19 antibodies due to vaccination vs. COVID-19 antibodies due to infection. COVID-19 related questions will ask about exposure related information. This information can be used along with data already collected in NHANES, such as diabetes status, obesity, occupation, hypertension, food security, mental health, and access to health care.

Proposed changes to the 2021-2022 NHANES content include:

Adding/modifying due to COVID-19:

- Adding COVID-19 screening that will include questions to determine exposure, and temperature checks prior to entry to the MEC;
- Adding new laboratory content including the addition of a COVID-19 serology (antibody) test, and modifying select existing laboratory content (see pages 11-13);
- Adding new questions related to COVID-19 to support laboratory testing;

- Adding or modifying introductions to and the wording of existing questions (see a summary of questionnaire changes in Attachment 3a) to enhance flow and reduce burden, given mode changes;
- Modifying the mode of the interview conducted in the examination center from in-person interviewer-administered to an audio-computer assisted self-interview (ACASI);
- Modifying the of Dietary Intake Day 1 by moving it from the MEC to a telephone interview;
- Modifying the mode of the dietary supplement use and prescription medication use in the past 30 days questionnaire by moving it from an in-person interview to a telephone interview;
- Modifying when participants receive existing NHANES incentives to align them with examination and interview mode changes instead of just after the exam (as previously done);
- Adding a \$25 incentive for the sample person interview to accompany the mode change. This is a re-allocation of when incentives are given. It does not raise the total incentive amount a participant receives (see page 9 for a summary and Attachment 4 for a detailed report supporting this request);
- Dropping all vision sub-components of the balance test (Modified Romberg Test is continuing);
- Dropping Spine and Femur scans in the dual energy X-ray absorptiometry (DXA) exam (full body scans are continuing); and
- Dropping heart rate measurement for children 0-7 years (resting pulse rate and blood pressure measurement are continuing for participants 8 years and older).

Adding/modifying due to funding:

- The medical provider on the MEC may now be a clinician, such as a Registered Nurse, Nurse Practitioner, Physician Assistant, or a physician. In some cases, when the MEC is operating under extended hours, a remote clinician will be used. In those situations, participants will receive referral and consultations, that they usually receive in-person from the clinician in the MEC, through an audio or teleconference from a trained survey clinician.

Cycling out due to COVID-19:

- Oral health examination
- Home water sample collection to test for fluoride
- Salt home collection for iodine assessment
- HPV oral rinse
- HPV swabs (male and female)
- Audiometry exam, including the words-in noise exam
- Infant formula ingredients collection
- DXA spine and femur
- Cognitive functioning assessment

Cycling out due to funding:

- Chromium/cobalt
- TB assessment
- Urine Flow Rate

Before going to any location, the Program will work with its contractor to determine whether each selected primary sampling unit (PSU) is safe for the survey to operate. The contractor has developed a customized dashboard specific to the survey. This dashboard is based on information from Brown University ([Risk Levels - Global Epidemics](#)).

Please find a summary of changes to the examination and questionnaire instruments in Attachment 3a.

NHANES may need to make iterative changes to survey plans because of the COVID-19 pandemic. If necessary, the program may propose new or revised clearance requests using the most appropriate mechanism available, such as a non-substantive change, a generic information collection (GenICs), a full revision, a modification to an existing submission, or a request to conduct developmental or special studies. These projects could include NHANES participants (present or past), members of the health care community (such as records retrieval staff, health care providers, etc.) as well as volunteers (non-NHANES participants) who may receive incentives or tokens of appreciation.

It is anticipated that NHANES 2021-2022 data will become available 9 months after the end of data collection. As such, it may not be immediately available for data driven responses to the pandemic. It will, however, provide nationally representative data that includes objectives health measures, and therefore remain a unique data source to the research community. Every effort is being made to reduce the length of time from the end of data collect to first public release.

A. Justification

1. Circumstances Making the Collection of Information Necessary

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 1.

- 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.

2. Purpose and Use of the Information Collection

Since March of 2020, NHANES has been out of the field due to the pandemic. The ramifications of this include:

- The survey year is no longer January to January. It will begin with the first month possible, following approval of this clearance request.
- This impact of COVID-19 related changes on the NHANES sample design is discussed in Supporting Statement B beginning on page 3.
- The impact of COVID-19 related changes on the NHANES burden estimates is discussed beginning on page 25 of Supporting Statement A.

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 2021-2022 is oversampling children (0-19 years old) and older persons (60 years and over), an age group disproportionately affected by COVID-19. While NHANES is not oversampling by race, Hispanic origin, or income, survey sample size should still allow for assessments among non-Hispanic black, Hispanic, and Asian groups as a whole. See Supporting Statement B, page 3 for the details.

The NHANES consists of three primary methods of data collection: the personal interviews, the examination (including follow-up activities), and the laboratory assessments. Results from 2021-2022 NHANES will be used to assess current health measures in the U.S. population during the COVID-19 pandemic. Due to changes in the survey, made to address this pandemic, it may not be comparable to previous or future NHANES.

NHANES Interviews

We collect questionnaire data as stand-alone components or to complement one or more examination or laboratory assessments. Current circumstances make asking questions in the home less desirable. For safety reasons, NHANES 2021-2022, screening, household and family interviews previously conducted via in-person interview in the home may be 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 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 changes in interview modes between NHANES 2019-2020 and 2021-2022 are provided in the table below. Interviews will also be modified or shortened to reduce respondent burden and to reduce the amount of interaction among participants and NHANES staff.

NHANES 2021-2022: Mode of Data Collection Components (changes due to COVID-19 related safety concerns)

Order	Component	2019-2020	2021-2022
1	Household Screener & Relationship Questionnaire	In-person	Multi-mode
2	Survey Participant (SP) & Family Questionnaires	In-person	Telephone
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) (SCQ) and the Non-Response Bias Module
2. Household Family Relationship Questionnaire (SFQ)
3. Household Sample Participant Questionnaire (HPQ)
4. Household Family Questionnaire (HFQ)
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)

The NHANES staff conducted a thorough review of the questionnaire content and made changes to focus on retaining questions that are directly related to the interpretation of exam or lab data collected in the survey and relevant to assess the pandemic's effect on health topics. As a result, the household HPQ and HFQ retained 337 questions from the original 769 questions in the previous cycle. There are 14 new questions added in various sections in HPQ and HFQ. In addition, a new section was added in HPQ to ask 17 COVID-19 infection and testing related questions. There are 94 questions retained from the 184 questions in the MEC interview questionnaire in the previous cycle. The reduction in number of questions was to shorten the overall length of the survey, for safety reasons and to promote the best response rate possible during the pandemic.

Attachment 3a provides a description of all questionnaire changes (including modifications) and the rationales for them. The complete set of 2021-2022 questionnaires (1-7 as described above), hand cards and the Flexible Consumer Behavior Survey are in Attachments 3b-3j (the 2019-2020 questionnaires and hand cards are in Attachment 3k.). Each questionnaire attachment begins with a table of contents that lists questionnaire sections by their component name and corresponding 3-letter component abbreviation.

Below is a brief description of a new questionnaire section and a brief description of modifications to the Dietary Interview.

COVID-19 (COQ) (new)

NHANES proposes adding a new section to 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 NIH's MESA questionnaires. They are chosen to be included in the survey to assess the timing of infection, exposure, and vaccination status. In addition, they will provide information on the severity of the response to the infection as well as other indicators of immunosuppression. These items are essential in the interpretation of laboratory results on COVID-19 serology.

Two questions have been included to determine whether a participant ever had COVID-19 and the severity of their symptoms. This information is important as early clinical reports indicate COVID-19 infection may cause lingering symptoms and possible long-term health impacts that span many organ systems. Self-reported symptom severity, in combination of our laboratory and examinations findings, knowing if someone had COVID-19, combined with the knowledge of what symptoms (or lack thereof), may be important for future health studies and our understanding of COVID-19's impact on health across the multiple participant demographics (age, race/ethnicity) and those with or other medical conditions (obesity, diabetes, weakened immune systems, etc.).

Questions on COVID-19 testing and vaccinations are also included to collect information on the testing history for active or past infections, the outcomes, and most recent date of these tests

and vaccination received. These data, in combination with NHANES serology test results, will enable researchers to determine if participants had natural immunity from previous infection, immunity from vaccination, and the length of immunity from infection or vaccination based on the dates reported.

Additional questions are proposed, including whether a participant had an overnight hospital stay for COVID-19, has diagnosed weakened immune system, is taking medication for weakened immune system, if any household member ever tested positive for COVID-19, and if the participant received the flu vaccination in last 12 months. 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 are 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.

Day 1 and Day 2 Dietary Interviews (modified for safety reasons)

NHANES proposes collecting two dietary interviews via telephone in the 2021-2022 NHANES. Previously, NHANES conducted an in-person dietary interview at the mobile examination center (Day 1) and a second dietary interview by phone (Day 2). Given the current circumstances due to the COVID-19 pandemic, we propose to change the mode of the in-person interview (Day 1) to also be via phone to limit face-to-face interaction with respondents. That is, we propose both Day 1 and Day 2 Dietary Interviews be conducted via telephone when NHANES restarts in 2021. Interviews will be conducted in English or Spanish. When the participant goes to the MEC for their examination, staff will schedule an appointment for the participant to be called 3-7 days later to complete the Day 1 Dietary Interview over the phone. A participant (or family if more than one from a household) will be given a Food Model Booklet and dietary kit to estimate portions consumed. At the end of the Day 1 Dietary Interview, the interviewer will ask if he/she can schedule an appointment for a second dietary interview. An incentive of \$25 will be provided for each interview. There is no change in the protocol for proxy interviews.

Please find an overall summary of 2021-22 changes to NHANES questionnaire content, including changes needed to adapt the survey in response to COVID-19, in Attachment 3a. See attachments 3b-3d for the screener and household interview, inclusive of the related hand cards. See Attachments 3e-3j for a summary of NHANES MEC questionnaires, exams and phone follow-up interviews (dietary recall and the Flexible Consumer Behavior Survey (FCBS)), along with corresponding hand cards. See Attachment 3k for the 2019-2020 data collection forms (including exam forms and hand cards).

NHANES Examination

NHANES continues to monitor trends in the prevalence and treatment of many conditions with content included on the examination, laboratory, and questionnaires.

The following exam content continues without change from previous NHANES:

- Anthropometry - Body Measures

- Liver Elastography (all eligible participants 18+; see Attachment 3e for exclusion criteria)

The following examination content is being modified:

Clinician Examination (modified)

For budgetary reasons and to increase operational efficiency, NHANES is modifying the examination that formerly only physicians conducted, to allow a broader range of health care providers (nurse practitioners, physicians assistants, etc.) to conduct the examination. This provides greater flexibility in hiring and resource management. For safety reasons due to COVID-19, the examination will also be modified to eliminate vaginal and penile swabs in 2021-2022. In some cases, when the MEC is operating under extended hours, the clinician's role may be filled by a remote clinician on staff. In these situations, participants will receive referral and consultations, that they usually receive in-person from the clinician in the MEC, through an audio or teleconference from a trained clinician from the study remotely.

Standing Balance Component

For safety reasons, the program is dropping the vision contrast sensitivity, visual acuity, and lensometer sub-components from the balance component. NHANES will continue with only the Modified Romberg test so as to shorten the time participants are in the MEC. The target age group for the standing balance component is also changing from participants 40+ to participants 20-69 years old. This data is central to developing and implementing national estimates of balance dysfunction and the factors related to this disorder. The program will ask interview questions, related to balance dysfunction and a history of falls, to compliment the examination data.

DXA (modified to include lung volume)

The target age group for the DXA body composition assessment component is participants ages 8-59. The DXA whole body scans will provide information on lean mass, fat mass, percent body fat, and regional body volume including lung volume. The DXA whole body scan will provide nationally representative data:

- To assess obesity, defined as an excess of body fat;
- To study the association between body composition and other health conditions and risk factors, such as cardiovascular disease, diabetes, hypertension, physical activity, and dietary patterns; and
- To study the association between lung volume and other health conditions, such as COVID-19 related diseases.

A fan beam bone densitometer will be used for acquiring the whole-body scans. Total estimated time for completing DXA component is about 15 minutes. Whole body scan acquisition takes 3 minutes. Scans will be administered by experienced NHANES radiology technicians. Scans of the femur and spine will not be conducted in 2021-22.

Blood Pressure Measurement (modified)

For safety reasons, measurement of resting pulse rate will be discontinued for children 0-7 years of age. This change is made to reduce the overall MEC exam time for this age group. Resting pulse rate will still be measured for survey participants 8 years and older as part of their blood pressure measurements. Blood pressure has always been

measured among participants 8 years and older. No changes anticipated for this protocol or the target age group in the 2021-2022 cycle.

Attachment 3a provides a description of all MEC examination changes. See Attachment 3e for NHANES 2021-22 MEC examination data collection forms. See Attachment 3k for data collection forms (including exam forms and hand cards) used in NHANES 2019-2020.

The following examination content is being dropped:

Audiometry component

The audiometry exam component, including Words-in-Noise, will be dropped for the 2021-2022 survey cycle. The rationales for dropping the audiometry component are:

- To reduce the overall time for the NHANES data collection. The audiometry exam is one of the longest exam components. Removing the audiometry exam will save about 16 minutes for youths aged 6-19 years, and 22 minutes for older adults 70 years and over.
- To minimize the risk of COVID-19 transmission. The audiometry room is one of the smallest rooms in the MEC. The door needs to be closed during the audiometry exam. The sound booth ventilation system recycles the air. These factors may increase the risk of COVID-19 transmission. However, the audiometry booths in the MECs will be maintained to support pilot studies comparing the current audiometric protocol to the new NHANES 2023+ hearing test protocol that will be developed and recommended.

Oral health component

The Oral Health examination will not be conducted for safety reasons as this examination would require survey participant to remove their mask.

NHANES Laboratory Assessments

Although NHANES is adding new lab content, the volume of blood being collected from SPs is the same as what was collected in 2019-20. This is possible because several labs were dropped in 2021-22; new tests can be conducted with the same volume of blood that would have been collected from those tests which have been dropped. The new test for COVID serology represents only 0.6 ml of blood being collected.

Laboratory Assessment changes for 2021-2022:

Returning laboratory tests in 2021

- Vitamin D; trans Fatty Acids

New Laboratory Tests in 2021

- Serum Terpenes: α -Pinene, β -Pinene, β -Myrcene, Δ -3-Carene, Limonene, β -Caryophyllene, α -Humulene
- Magnesium
- HPV, serum
- Alpha-1-acid-glycoprotein (AGP)
- Acrylonitrile
- Blood butyrylcholinesterase activity, blood butyrylcholinesterase concentration, and red blood cell acetylcholinesterase activity

- Enterovirus D68
- COVID-19 serology (antibody)
- VOC metabolites in urine

Modified Laboratory Tests in 2021

- Hepatitis D (new testing method, findings will be reportable)
- Sex steroid hormone panel (now starting at 3+)
- Urine VOC Metabolites (adding an additional 5)
- Herbicides and metabolites (adding an additional 6)
- Flame retardant metabolites (adding an additional 2)

Dropped Laboratory Tests in 2021

- Home water sample collection to test for fluoride (for safety reasons)
- Salt home collection for iodine assessment (for safety reasons)
- HPV Oral Rinse (for safety reasons)
- HPV Swabs (male and female) (for safety reasons)
- Urine Flow Rate (for budgetary reasons)
- Chromium and cobalt (for budgetary reasons)
- Tuberculosis testing (for budgetary reasons)
- Environmental Toxicants in urine: three neonicotinoid insecticide biomarkers, two organophosphorus insecticides, two pyrethroid pesticides (for budgetary reasons)

Continuing Laboratory Tests in 2021-2022

- Pregnancy Tests (urine) (female participants ages 8-59)
- Hematology (Complete Blood Count) (all participants 1+)
- Metals: Lead, cadmium, mercury, mercury speciation, selenium, and manganese in whole blood (all participants 1+)
- Folates and Folate Forms in whole blood and serum (all participants 1+)
- Cytomegalovirus (CMV) in serum (all participants 1-5)
- Ferritin in serum (all participants 1-5 and 12+)
- Transferrin Receptor in serum (all participants 1-5 years old; and female participants 12-49)
- Fasting glucose in plasma and Insulin in serum (all morning participants 12+) and Glycohemoglobin in whole blood (all participants 12+)
- Hemoglobinopathies in whole blood: four hemoglobin variants (all participants 12+)
- Total and HDL Cholesterol in serum (all participants ages 6+)
- LDL Cholesterol and Triglycerides in serum (all participants ages 12+)
- Standard Biochemistry Profile, iron and iron binding in serum (all participants ages 12+)
- Nutritional biomarker in whole blood: 32 RBC fatty acids, and six RBC folate forms (all participants 6+)
- Thyroid Panel in serum: eight thyroid biomarkers (all participants 3-5 and 1/3 6+)
- Sex Steroid Hormones: FSH, LH (all participants 6+) and AMH (female participants 6+)
- Urinary Albumin and Creatinine and Albumin/Creatinine Ratio in urine (all participants 3+)
- C-Reactive Protein (high-sensitivity) in serum (all participants 1+)

- Hepatitis viruses (all participants 6+); anti-HBs in serum (all participants ages 2-5 only) in serum
- Chlamydia trachomatis (all participants ages 14-39), Trichomonas vaginalis and Mycoplasma genitalium in urine (all participants ages 14-59)
- Herpes Simplex 1 and 2 in serum (all participants ages 14-49)
- Human Immunodeficiency Virus in serum (HIV) (all participants ages 18-59)
- Liver Disease Genetics Markers (all participants ages 12+) (see Attachment 19)

Environmental Chemical Exposures:

- Per- and polyfluoroalkyl substances (PFASs) in serum (1/3 subsample ages 12+)
- Dioxins, persistent organic pollutants (POPs), brominated flame retardants (BFRs), polybrominated diphenyl ethers, polychlorinated dibenzo-p-dioxins and dibenzofurans, polychlorinated biphenyls (PCBs), organochlorine pesticides, dioxins, and furans in serum (1/3 subsample ages 12+)
- Metals in urine (all participants ages 3-5 and 1/3 subsample ages 6+)
- Perchlorate, Nitrate, Thiocyanate in urine (all participants ages 3-5, 1/3 subsample ages 6+)
- Pyrethroid Pesticides, Herbicides, and Organophosphate Insecticides Metabolites in urine (all participants ages 3-5 and 1/3 subsample ages 6+)
- Insect repellent: DEET metabolite; flame retardants; neonicotinoid insecticide biomarkers; organophosphorus insecticides: dialkyl phosphate metabolites; and volatile organic compound (VOC) metabolite in urine (all participants 3-5 and 1/3 subsample ages 6+)
- Environmental toxicants in whole blood: volatile organic compounds (VOC) (1/2 participants ages 12+)
- Environmental toxicant in serum: cotinine (ages 3+)
- Environmental toxicants in urine: tobacco biomarkers (tobacco-specific nitrosamines and heterocyclic aromatic amines) and personal care and consumer product chemicals and metabolites (all participants 3-5 and 1/3 subsample ages 6+)
- Polycyclic Aromatic Hydrocarbons (PAH) (Urine) (all participants 3-5, 1/3 participants 6+)

See Attachment 6a for the 2021-2022 and earlier Laboratory Assessment tables. See Attachment 6b for the 2019-2020 and earlier Laboratory Assessment tables. See Attachment 7 for the 3-5 years old urine fact sheet provided to parents.

3. Use of Improved Information Technology and Burden Reduction

The majority of NHANES data are collected from respondents electronically. NHANES uses survey information technology architecture (SITA) that supports fully automated and integrated information technology. SITA provides increased capabilities that allow processing of complex data with significantly less editing than in previous NHANES surveys.

SITA provides NHANES with access to all data that are collected, much of which is available in real-time. The nature of the survey requires that data be accessible at multiple sites including contractor facilities, MECs, laboratories, and NCHS headquarters, etc. SITA supports: 1) survey planning and design, 2) data collection, 3) data receipt, control, and quality assurance, 4) reporting of survey results to survey participants, 5) data review, editing, and analysis, 6) generation and documentation of public use data products, 7) tracking of survey respondents, and 8) generation of status reports on all aspects of the survey.

There are no legal obstacles to reducing 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. Each year health interview and examination data are obtained. No other studies collect the detailed health, dietary, laboratory and examination data that NHANES does. Duplication of effort is avoided through contacts and discussions with numerous Federal Government agencies during the content development and planning stage of NHANES. The agencies consulted for NHANES 2021-2022 are listed in Attachment 8 of this clearance request.

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

The continuous nature of the NHANES is necessary for several reasons. First, many of the data items collected in the NHANES are used for tracking of health events and circumstances, including tracking of the National Objectives for Health Promotion and Disease Prevention. Second, the continuous design makes it possible to aggregate data over longer periods of time to include enough cases to study rare events and small populations. Third, nutrition monitoring legislation explicitly calls for continuous coverage to monitor nutrition changes as they occur (see Attachment 1). Fourth, a continuous survey is more cost effective because it makes possible a stable field staff, which increases the quality of the data and avoids start-up and shut-down costs. Reducing the frequency of data collection would undermine all of these desirable features of the NHANES.

In March of 2020, NHANES, for the first time since continuous data collection began in 1999, was paused due to COVID-19. As a result, the 2019-2020 cycle will not be completed, and a 2-year national representative dataset will not be able to be released. Data that had been collected previously will be able to be combined with earlier years, but new components that started in 2019 will not be publicly released.

Respondents are asked to respond to the NHANES only one time.

7. Special Circumstances Relating to the Guidelines for 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

a. Federal Register Notice

A 60-day Federal Register Notice was published on July 20, 2020, volume 85, number 139, pp. 43848-49. CDC received 2 non-substantive comments in total. See Attachments 2a and 2b, respectively, for a copy of the notice and comment.

b. Outside Consultation

NHANES is a collaborative undertaking. The program seeks broad input from the research community, academia, federal agencies, and other interested parties to maximize the utility of the survey data. NHANES consults with its collaborators and interested agencies through meetings, conference calls, or via email. The program uses a formal proposal solicitation process prior to future content planning and development.

The program published proposal guidelines, in October 2018, for new 2021-2022 content on the NHANES website. DHANES received over 30 letters of intent in response to this solicitation process. In addition, the program sent correspondence to dozens of persons who indicated their interest in being kept informed of NHANES activities.

NCHS staff gave presentations throughout the year at major medical and public health professional meetings as well as internal meetings organized by other Federal agencies. The meetings provided an excellent forum for updating stakeholders on survey activities and data products.

9. Explanation of Any Payment or Gift to Respondents

To maximize response rates for the examination, NHANES participants have received incentives as tokens of appreciation for their examination participation since the 1970s. The 2021-2022 examination and post examination NHANES incentives are shown in the tables below. The total incentive amounts are the same as those used in 2019-2020.

The program is requesting a new conditional incentive of \$25 at the sample person interview level, based on findings of an incentive study conducted in 2019. This pilot tested conditional respondent incentives for the screening and SP interview components of NHANES. The purpose of this pilot was to evaluate the effect different incentive levels have on response, effort, and data quality. At the screening level, the program tested the impact of \$0, \$2 and \$5 incentives. At the SP interview level, the program tested the impact of \$0, \$20 and \$40 incentives. The project covered ten NHANES locations across seven states.

Our request to add a new \$25 conditional incentive at the SP interview level is based on the observed increases in response, reduction in level of effort, and increased cooperation from specific SP groups, such as youth and Asians. A brief summary of these findings is found on page 12 of Supporting Statement B. A detailed report of this project is in Attachment 4. The program cannot implement a \$40 incentive, as tested, without increasing our overall incentive amount.

Examination incentive

Subgroup	2021-2022 Incentive
16 and older	\$85
12-15	\$60
Under 12	\$40

Post-primary examination incentive

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Post-primary Exam	2021-2022 Incentive
Dietary Phone Follow Up #1	\$25
Dietary Phone Follow Up #2	\$25
FCBS Phone Follow-Up	\$15

If participants must hire a sitter to care for children, elderly, or handicapped persons so that the participant can leave their home to be examined in the MEC, they are allowed to receive \$5.25 an hour for up to 6 hours to help with out-of-pocket costs. Participants also receive help with out-of-pocket costs related to transportation for driving to the MEC, or for when a taxi is needed.

Incentives to help participants with out-of-pocket transportation costs

TRANSPORTATION Related Incentives 2021–2022		
Incentives to help with Sample Participant (SP) Transportation - Mileages to MEC	Cities	Rural Areas
<16 miles	\$30	\$25
16–30 miles	\$45	\$40
31–59 miles	\$55	\$50
>60 miles	\$70	\$65

Other efforts are made to maintain and increase response rates on a day-to-day basis (See Section B. 3. Methods to Maximize Response Rates and Deal with Nonresponse).

During 2021-2022, NHANES may request permission to test additional incentives in an effort to address decreasing response rates. The response rate for participants examined in 2019 was 46%. Attachment 9 contains a graph of NHANES examination response rates from 1999-2019 as well as a brief history of NHANES incentives.

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

This submission has been reviewed by Information Collection Review Office (ICRO), who determined that the Privacy Act does apply. The NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer have also reviewed this package and have determined that the Privacy Act is applicable because the GenICs may include the collection of information in identifiable form. The applicable System of Records Notice is 09-20-0167 Health Resources Utilization Statistics. Specific Privacy Act applicability will be addressed in each GenIC.

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.

Overview of the Data Collection Process

For 2021-2022, a contractor will carry out the NHANES data collection. The contractor's responsibilities include the following activities.

- makes advance arrangements for each location
- sets up and maintains field activities and examination centers
- translates all questionnaires as required
- hires and trains field staff; including conducting mock interviews and examinations among incentivized volunteers to ensure adequate hands-on experience
- creates procedure manuals and training programs
- conducts a dress rehearsal among volunteers prior to fielding full NHANES 2021-22
- conducts all interviews in the households
- designs and carries out quality control procedures, including MEC equipment calibration and dry run exams
- performs all interview and examination procedures in the examination centers
- arranges for gold standard examinations conducted by subject matter experts as part of the quality control process, and
- transmits interview, examination and laboratory data to NCHS

Further details on the data collection procedures are included in Supporting Statement section "B. 2. Procedures for the Collection of Information" and in the referenced attachments.

The following is a summary of the attachments related to the data collection procedures:

Multi-mode Screening Material:

- Advance Contact 1: Letter (Attachment 10a)
- Spanish Advance Contact 1: Letter (Attachment 10b)
- Advance Contact 2: Postcard – (Attachment 10c)
- Spanish Advance Contact 2: Postcard (Attachment 10d)
- Advance Contact 3: Reminder Letter – Express Delivery – (Attachment 10e)
- Spanish Advance Contact 3: Reminder Letter – Express Delivery – (Attachment 10f)
- Advance Contact 4: Final Reminder Letter – (Attachment 10g)
- Spanish Advance Contact 4: Final Reminder Letter – (Attachment 10h)

Consent Material:

- Home Interview Consent Form – (Attachment 11a)
- Health Measurements List – (Attachment 11b)
- Health Measurements List – Dry Run (Attachment 11c)
- MEC Assent Brochure (7-11 years) (Attachment 11d)
- MEC Adult/Parental Consent/Assent Brochure (Attachment 11e)
- MEC Adult/Parental/Child Consent/Assent Form (Attachment 11f)
- Future Research Consent Form for Specimen Storage and Continuing Studies without DNA Testing (Attachment 11g)

Nonresponse:

- Nonresponse Letter (Attachment 12)

Interview Material:

- Introductory Letter for SP Questionnaire (Attachment 13a)
- Confidentiality Flyer (Attachment 13b)
- Sample Selection Brochure (Attachment 13c)
- Make a Plan Card (Attachment 13d)
- Welcome to NHANES Brochure (Attachment 13e)
- Overview Brochure (Attachment 13f)

MEC Material:

- Appointment slips, script, and letters – (4 documents) (Attachments 14a-14d)
- Lab Blood Flyer (Attachment 14e)
- Environmental Exposures Flyer (Attachment 14f)
- Report of Findings Sample (Attachment 14g)
- Community Service Letter (Attachment 14h)
- Principal Letter (Attachment 14i)
- COVID 19 Safety Flyer (Attachment 14j)

Items of Information to be Collected

NHANES consists of the examination, conducted in the Mobile Examination Center (MEC), laboratory analytes, the household interview and follow-up activities, which take place after the MEC exam. See below for additional information about the information collected in the examination, laboratory assessments, and interviews.

NHANES Examination

- Anthropometry - body measures
- Standing balance
- Dual energy x-ray absorptiometry (DXA)
- Blood pressure measurement
- Liver elastography (all eligible participants 12+; see Attachment 3e for exclusion criteria)

NHANES Laboratory Assessments

- Renal and hepatic function
- Environmental chemical exposures
- Infectious disease and immunization status assessments
- Nutritional status
- Biologic specimen banking
- Anemia status
- Biochemical and lipid profile

- Inflammatory disease
- Hormone panel
- Diabetes panel
- Biochemical panel
- Inflammatory disease profile

NHANES Interviews

- Demographic Information
- General health information
- Food security and nutrition program participation
- Dietary recall
- Dietary supplement use
- Prescription drug use
- Mental health
- Alcohol use
- Cigarette and tobacco use
- Reproductive health and history
- COVID-19 information

Information in Identifiable Form (IIF)

Information in identifiable form (IIF) is collected for linkage with other federal sources of data, to allow future recontact of participants and to notify participants of health test results. The identifiable information includes:

- Name
- Date of birth
- Social security number (SSN)
- Medicare beneficiary number
- Name of mother
- Name of father
- Parent's relationship to child
- Child's date of birth
- Child's sex
- Mailing address
- Phone numbers
- E-mail address
- Medical information and notes
- Employment status
- Contact information for two people close to the respondent

Please see "A.11 Justifications for Sensitive Questions" for more details.

The NHANES continues to collect personally identifying information (PII), on a confidential basis, needed to re-contact respondents and to match respondents to administrative records such as the National Death Index (OMB. No. 0920-0215, Exp. Date 03/31/2023). 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 collaborators, who must use the personal information for a specific purpose, can use such data.

NHANES mails a series of invitations to each household in the sample segments asking them to

complete the Household Screener questionnaire. These mailings (Attachments 10a-10h) include an Initial Invitation Letter, a Reminder Postcard, a Reminder Letter with accompanying hardcopy questionnaire, and Final Letter announcing the upcoming arrival of an NHANES interviewer. The informed consent documents (Attachments 11a-11g) for the interview, the examination and the stored specimens each repeat the confidentiality assurance

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. 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 ensure that there is no loss in transit and when confidential information is not in use, it is stored in secure conditions. The transmission and storage of confidential data are protected through procedures such as encryption and carefully restricted access.

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 the 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.

It is NCHS policy to make NHANES data available via public use data files to the scientific community. However, NHANES does not release confidential data to the public. 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, to assure that directly or indirectly identifiable data are not included in public releases.

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

The National Health and Nutrition Examination Survey is subject to annual review by the NCHS Ethics Review Board and is approved to continue data collection through 3/26/2021 (see Attachment 15).

Descriptions of self-reported and objective data of a sensitive nature are as follows.

a. Social Security Number

Social Security Number (SSN) of all participants is requested in the household interview as a key item. The information is used to link administrative and vital records, such as the National Death Index (NDI), to the survey information. Additionally, in 2021-2022 NHANES will continue to use the SSN to link with the Supplemental Nutrition Assistance Program (SNAP) (previously called the Food Stamp Program) and Women, Infants and Children (WIC) Program

administrative records from the USDA.

Permission to link is obtained from respondents as follows:

In the Household:

“The National Center for Health Statistics will conduct statistical studies 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. 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. What is {your/SP's} Social Security Number?”

If the respondent is reluctant or need more information, the following text is read:

“[I understand your concern.] By matching NHANES data with other health-related records, researchers can study health conditions like heart attacks and diabetes in depth. They can also better understand health care use and health care costs for all Americans. These findings will help doctors assist patients in making smart choices. This type of studies will not be possible, if we don't have the social security number for the linkage. I can share other examples with you if you like. May I please have {your/SP's} Social Security Number?”

In the MEC:

“The National Center for Health Statistics will conduct statistical studies 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 Center 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. What is {your/SP's} Social Security Number?”

If the respondent is reluctant or need more information, the following text is read:

“I understand your concern. Would you provide us with the last four digits of {your/SP's} Social Security Number? This information will allow researchers to match NHANES survey data with health-related records to study important things like changes in health status, eating patterns and health care costs. [May I have the last four digits of {your/SP's} Social Security Number]”

b. CMS Health Insurance Claim Number

Participants covered by Medicare will be asked to provide the CMS Health Insurance Claim Number. This will be used to link to Medicare records for further health studies and also to link with other records for possible recontact of NHANES participants.

The question is asked as follows:

“Please look at your Medicare card and tell me the Medicare Number on the card. This number is needed to allow Medicare records of the Center for Medicare and Medicaid Services to be easily and accurately located and identified for statistical purposes. Providing the Medicare Number is voluntary and collected under the authority of Section 306 of the Public Health Service Act. Whether the number is given or not, there will be no effect on {your/his/her} benefits. This number will be held confidential. [The Public Health Service Act is Title 42, United States Code, Section 242K.]”

c. Residency Status

Information about country of birth and length of residency in the U.S. is requested and may be sensitive for recent immigrants. This information is important in analyzing health and nutrition data because acculturation may be related to use of the health care system, diet, and health practices. Additionally, recent immigrants may not have access to health, nutrition, and income assistance programs that affect access to health care and health and nutrition status. Interviewers will be trained to reassure participants that the information is confidential and will be used for statistical reporting only.

d. Other Content

Some of the NHANES topics include potentially sensitive questions or examinations. In the informed consent procedure, all sample persons are advised of the voluntary nature of their participation in the survey or in any of its content. Again, during the physical examination, each sample person is reminded that he or she can refuse to answer questions or to undergo any parts of the examination they find objectionable.

The NCHS Ethics Review Board (formerly called the NCHS Institutional Review Board) reviews all questions and procedures (see Attachment 15). The potential sensitivity of questions and procedures is an evaluation criterion in determining content of the survey. The multipurpose nature of NHANES makes it necessary to exclude topics so sensitive that they may interfere with participation.

Questions and procedures thought to be sensitive are listed below. Most of these are questions commonly asked in health care settings. NHANES asks sensitive questions in private settings within the Mobile Examination Center (MEC).

- i. Sexual behavior and sexually transmitted diseases: Several sexually transmitted diseases are part of NHANES—herpes simplex I and II, HIV, hepatitis B and C, trichomonas vaginalis, chlamydia, and human papilloma virus (HPV). Information is obtained through questionnaires, exams, and lab tests. It is essential to clarify risk factors and identify at-risk population subgroups associated with infection in order to plan and evaluate prevention programs. This requires self-reported information on sexual behavior combined with objective data on infection.

Questions on sexual activity are asked of males and females 14 to 69 years. These questions will be administered using audio computer-assisted self-interview (ACASI) methods in a private room. The results of tests for sexually transmitted diseases will not be mailed to examinees for reasons of confidentiality. Examinees will be given a toll-free number they can call, with the use of a self-selected password, to obtain their lab results.

- ii. Drugs, alcohol, and tobacco: Drug, alcohol, and tobacco use are risk factors for many of the health conditions studied in NHANES. Participants 12 years and older will be asked about alcohol consumption and tobacco use. Illicit drug use questions are asked of participants 12 to 59 years. All these questions will be administered using ACASI methods in a private room in the mobile examination center.

- iii. Reproductive health and menstruation: Questions on reproductive health history asked of

females 12 years and older may be considered sensitive by some respondents. The interviews will be conducted in a private room in the mobile examination center using ACASI methods.

Age of first menstruation will be obtained for females 8 years and older. This question will be asked of parents of girls 8 to 11 years of age. This information is necessary for interpretation of biochemical and hematological assessments. As a safety screen for the dual X-ray absorptiometry (DXA), a pregnancy test will be performed on menstruating females ages 8-11 and all females 12 through 59 years.

- iv. Mental health: Adolescents and adults 12 years and older will be asked a short depression screening module called the Patient Health Questionnaire or the "PHQ-9." The questions are taken from the depression module of the PRIME-MD, a self-administered questionnaire that was first used in clinical setting. The interviews will be conducted in a private room in the mobile examination center using ACASI methods.
- v. Male and female urologic health: Conditions such as urinary incontinence and gynecologic infections affect millions of Americans. The information collected in NHANES is critical to understanding the magnitude of these problems and their impact on health and quality of life. The interviews will be conducted in a private room in the mobile examination center using ACASI methods.
- vi. Future content: As discussed in the Responding to Emerging Public Health Issues, New Technology and Future Survey Options portion of section A.2., during NHANES, new content may be pilot-tested or added, as new diagnostic procedures become available or as new conditions emerge. This content will be handled in similar fashion to that discussed above in the introduction to this section (A. 11d Other Content). Information will be explicitly discussed in the informed consent document if the content is considered sensitive, and appropriate privacy and confidentiality safeguards included.

12. Estimates of Annualized Burden Hours and Costs

a. Time Estimates

This submission requests OMB approval for three years of data collection. The table below shows the estimated annual burden for each survey component within this submission. The total estimated burden for one year of NHANES is 30,130 hours, including screening, dress rehearsal, household interview, examination and follow-up interviews (lines 1-5 of the table below). The remaining 35,500 hours of burden are for developmental projects, pilots, work in advance of special studies, etc. The total requested burden for all projects combined is 65,630 hours.

The annual estimated burden for the various components of NHANES, including the dress rehearsal are below:

The NHANES screener (attachment 3b) is budgeted for 10 minutes -- the maximum number of respondents would be 8,300 and the maximum burden 1,383 hours. The estimate for screening was doubled from that of NHANES 2019-20 to account for the additions of a self-screening mode to the survey, due to the pandemic. The NHANES household interview (Attachment 3c) is budgeted for 1 hour -- the maximum number of respondents would be 5,600 and the maximum burden 5,600 hours. This estimate is a net of 30 minutes less than

NHANES 2019-20. This reflects a reduction in the total numbers of questions being asked in the interview. But includes additional time for activities SPs may do on their own, such as reading instructions and returning forms by mail, if using a multi-mode option for completing interviews themselves. The NHANES MEC Interview and Examination (Attachment 3e) is budgeted for 2.5 hours -- the maximum number of participants would be 5,600 and the maximum burden 14,000 hours. The reduction from 4-hour exams in NHANES 2019-20 to 2.5 hours exams is due to dropping time consuming components not clearly related to COVID-19 risk factors. It is also due to moving the day one dietary recall to a telephone interview. The 2021-22 estimated average exam time is 2 hours. An additional 30 minutes has been added to account for extra cleaning time in the MEC between participants moving among exam rooms etc. The day 1 and day 2 telephone Dietary Recall and Dietary Supplements (Attachment 3g) is budgeted for 1.3 hours -- the maximum number of respondents would be 5,600 and the maximum burden 7,280 hours. The Flexible Consumer Behavior Survey Phone Follow-Up (Attachments 3i and 3j) is budgeted for 20 minutes -- the maximum number of respondents would be 5,600 and the maximum burden 1,867 hours. Adult respondents who participate in all of the above aspects of NHANES can expect a total estimated burden of up to 5.3 hours. This is a reduction from the 2019-20 estimate of 6.4 hours. While the 2021-22 interviews and MEC examinations are shorted, the 5.3 overall burden estimate for adults also included the addition of time for safety measures such as extra MEC cleaning and COVID symptom screening etc.

Up to 3,500 additional persons (including non-NHANES respondents) might participate in Developmental projects (such as pilot tests or methodological studies) or testing ahead of Special Studies, if budgeted. The average burden for these respondents is 3 hours (Attachment 16). The estimated total burden for one year for special studies is 10,500 hours.

Up to 1,000 additional persons (including non-NHANES respondents) might participate in a 24-hour wearable device project. The average burden for these respondents is 25 hours (Attachment 17). The estimated total burden for one year for would be 25,000 hours.

TABLE 1 – ANNUALIZED BURDEN HOURS

<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>

b. Cost to Respondents

The hourly wage rate of \$25.72 per person is based on income from wages and salary from the Bureau of Labor Statistics: http://www.bls.gov/oes/current/oes_nat.htm#00-0000 (last accessed 12/9/2020). This wage rate for all persons was used since respondents do not fall into a single economic or occupational category. (NOTE: There are no out-of-pocket costs to survey participants. Participants are given an incentive as a token of appreciation for their time and to help with out of pocket expenses such as childcare and transportation.)

TABLE 2 – Cost to Respondents

<u>Type of Respondent</u>	<u>Form Name</u>	<u>Total Burden (in hours)</u>	<u>Hourly Wage Rate</u>	<u>Total Respondent Costs</u>
<u>Individuals in households</u>	<u> Screener</u>	<u>1,383</u>	\$25.72	\$35,571
<u>Individuals in households</u>	<u>Household Interview</u>	<u>5,600</u>	\$25.72	\$144,032
<u>Individuals in households</u>	<u>MEC Interview & Examination</u>	<u>14,000</u>	\$25.72	\$360,080
<u>Individuals in households</u>	<u>Day 1 and Day 2 Telephone Dietary Recall & Dietary Supplements</u>	<u>7,280</u>	\$25.72	\$187,242
<u>Individuals in households</u>	<u>Flexible Consumer Behavior Survey Phone Follow-Up</u>	<u>1,867</u>	\$25.72	\$48,019
<u>Individuals in households</u>	<u>Developmental Projects & Special Studies</u>	<u>10,500</u>	\$25.72	\$270,060
<u>Individuals in households</u>	<u>24-hour wearable device projects</u>	<u>25,000</u>	\$25.72	\$643,000
<u>Total</u>				<u>\$1,688,004</u>

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

There are no additional costs.

14. Annualized Cost to the Federal Government

This project is a multi-year, continuous survey, with survey planning, data processing and analysis, and data collection occurring simultaneously. These figures are broad estimates based

on past NHANES data collection budget estimates. Staff costs were primarily based on Division of Health and Nutrition Examination Surveys personnel costs, which were obtained from the NCHS Office of Financial Resources. A proportion of these costs are paid by funds transferred to the CDC budget from collaborating agencies. It is estimated that about 45 percent of survey costs will be covered through this support from agencies outside of NCHS.

Table 1. Estimated survey cost per year

Category	Annualized Cost
Equipment, exam centers, data collection and processing, contracts, labs/readings	\$40,000,000
NCHS staff costs for survey planning, data analysis and overhead	\$6,000,000
NCHS printing, travel, supplies, etc. for NHANES staff	\$200,000
Total	\$46,200,000

15. Explanation for Program Changes or Adjustments

The requested burden for this submission, 65,630 hours, is 2,787 hours less than the 68,417 hours of burden approved for NHANES 2019-20. This reduction is due to survey changes including: no oversampling, shorter interviews, and shorter mobile examination center visits. However, some of these reductions were offset by the addition of burden due to the two dress rehearsals.

16. Plans for Tabulation and Publication and Project Time Schedule

The following are key activities and projected completion goals for the 2021-2022 NHANES:

Activity	Projected Completion
• Planning survey content	Ten months before OMB approval
• 2021-2022 data collection	Three years after OMB approval
• First public release of data	Two years and ten months after OMB approval
• First publication of summary statistics	Two years and ten months after OMB approval

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

We have several forms that are triplicate, NCR-type pages pasted into glossy, multi-page brochures, which require considerable advance time for printing. To save substantial printing costs, since 1999 OMB has granted an exception from printing the expiration date on these forms for data collection. We request that exemption be continued through the term of this clearance.

18. Exceptions to Certification for Paperwork Reduction Act Submissions.

There are no exceptions to the certification.