

Supporting Statement B for Request for Clearance
National Health and Nutrition Examination Survey

OMB No. 0920-0950

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Supporting Statement B

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

B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Overview of the Continuous NHANES Sample Design

In 2021-22, the program is making changes to respond to the current situation due to the COVID-19 pandemic. The proposed changes being requested include those that reduce frequency of in-person interactions necessary between field interviewers and the public.

The NHANES sample design is based on a continuous on-going annual survey of the non-institutionalized, civilian population of the United States. From 1999, each single year and any combination of consecutive years comprises a nationally representative sample of the U.S. population, except for 2019-2020 cycle, which is a two-year nationally representative sample. The primary objective of NHANES is to estimate a broad range of descriptive health and nutrition statistics for sex, race/Hispanic origin, age and income subdomains of the U.S. population. Data are publicly released every two years to improve the analytic stability of estimates and to decrease disclosure risk. From 1999-2020 several subgroups are oversampled to ensure adequate sample sizes for selected population subgroups. Those groups include African Americans, Hispanics, Asian Americans, older persons, and low-income whites.

As with previous NHANES surveys, the design for the current NHANES is a stratified, multistage area probability sample of the civilian non-institutionalized population of the U.S. In hierarchical order, the stages of the sample selection are first: selection of Primary Sampling Units or PSUs (counties or small groups of contiguous counties); second: segments within PSU (a block or group of blocks containing a cluster of households); third: households within segments; and fourth: one or more survey participants within households. The assumption is that the field operations will include two mobile examination center (MEC) teams in operation and approximately 5,000 persons examined in 15 PSUs per year. The expected sample size is based on past NHANES experience with response rates for each subdomain of interest.

Background on the Sample Design for NHANES 2021-2022

Since 2007, statisticians have selected a four-year sample for NHANES with each year being a nationally representative sample. Previous four-year designs were NHANES 2007-2010¹, NHANES 2011-14², and NHANES 2015-18 (See Attachment 6b). The sample design originally selected for NHANES 2019-2022 was similar to the NHANES 2015-2018 with one exception. To increase operational efficiency, a new design was implemented in 2019-20 to produce a nationally representative sample over the course of a two-year cycle instead of annually. To avoid unexpected uncontrollable data collection termination like COVID-19, each year of NHANES 2021-2022 is again an annual nationally representative sample. See Attachment 6a for the 2021-22 sample design tables. Because of declining response rates, it has become difficult to reach the target number of examinations (5,000/year) with the current design. NHANES 2021-2022 oversamples children (0-19 years old) but not by race, Hispanic origin or income as previous cycles. Dropping race, Hispanic origin and income oversampling

significantly reduces the number of screened households to find an eligible target person. In a COVID-19 environment, this modification allows NHANES to minimize in-person contact with households due to safety considerations.

NHANES 2021-2022 Sample

The NHANES will collect data on a single year nationally representative sample during 2021-2022, and this submission is limited to seeking approval for the NHANES 2021-2022 sample. The program needs to be flexible in an era of budget uncertainty and plans to evaluate options for NHANES 2023-24. Should funding fall short, the NHANES program may choose to stop oversampling in 2023-24 and draw a new sample. In any case, the program will submit a future change request to seek approval for the NHANES 2023-24 sample design.

References

1. https://www.cdc.gov/nchs/data/series/sr_02/sr02_160.pdf
2. https://www.cdc.gov/nchs/data/series/sr_02/sr02_162.pdf
3. https://www.cdc.gov/nchs/data/series/sr_02/sr02-184-508.pdf

2. Procedures for the Collection of Information

Data Collection Procedures

A contractor is responsible for data collection procedures. The responsibilities of the contractor include:

- select Primary Sampling Units (PSUs) and other units of the sample design
- list all dwelling units within each segment
- make advance arrangements for each location
- provide input on NCHS's publicity/outreach methods and materials
- hire and train field staff
- set up and maintain field activities
- set up and maintain the MECs
- translate all questionnaires into Spanish and use translators for other languages, when needed
- create manuals and training programs for all field procedures (including training in NCHS confidentiality guidelines and regulations)
- list the households to be sampled
- select a sample of the civilian non-institutional U.S. population
- conduct household eligibility screening
- administer extended telephone interviews with sampled participants
- perform all interview and examination procedures in the examination centers
- design and carry out quality control procedures and transmit survey data to NCHS.

At any given time during the calendar year, examinations are conducted at two survey locations simultaneously. This means the field staff and household interviewing staff support two complete examination teams at the same time for the eleven months of the year NHANES is in operation. NHANES is not in operation for about two weeks at New Years and for about two weeks in the summer.

Months prior to data collection, the contractor initiates the listing of each segment within every

PSU (driving each street in the segment to list all dwelling units and using supplemental software to assist the listing process), which identifies households to be potentially included in NHANES. Selected households will be screened for eligibility using a multi-mode, “push-to-web” approach. The contact and screening strategy is described below.

- Households will receive an initial letter inviting them to go online and complete the household eligibility screening questionnaire. The letter will also provide a toll-free telephone number to complete the survey by phone with a field representative. Each household is assigned a secure user-id that is provided in the mailing.
- Approximately one week after the first letter is mailed, households will be sent a reminder postcard again asking for their participation. Those who already responded, and addresses found to be undeliverable will be excluded from this and all subsequent mailings.
- A third mailing will be sent via FedEx to nonrespondents approximately one week following the postcard delivery. This mailing will include a hard copy questionnaire to ensure households without, or with limited, internet access are able to participate in the survey. The accompanying letter will again request participation and offer multiple options for response.
- The final mailing will be sent approximately 2 weeks before Field Interviewers will begin visiting nonresponding households in-person. This letter notifies the occupant(s) that they may be visited by an interviewer, the purpose of the visit, and the options for self-response.
- When the interviewer arrives at the home, he or she shows official identification and briefly explains the purpose of the survey. If the person answering the screener questions has not seen the final mailing, a copy is given to him/her. The interviewer then administers the Household Screener Questionnaire Module to determine eligibility.

Individual household members found to be eligible to participate will be contacted by a field interviewer to complete a “gaining cooperation” visit. The goal of this interaction is for the interviewer to answer questions about participation, explain the household questionnaires to participants who are at least 16 years old, and inform them of their rights and of the confidentiality protections afforded to them.

For the 2021-2022 data collection cycle, the sampled participant (SP) interview will be conducted by telephone. Field interviewers will schedule telephone interviews with participants and provide a packet of materials at this time. The content of the packet will be discussed in detail at the beginning of the scheduled interview. The packet contains a letter of appreciation thanking the participant and describing the accompanying booklet. The booklet contains:

- copies of all NHANES Informed Consent documents
- a brochure describing NHANES commitment to maintaining participants privacy and confidentiality
- a listing of all of the examinations and measures participants will be asked to complete at the mobile examination center
- a series of printed cards with response categories from specific questions on the survey (“hand cards”). These serve as an aid for the participant when completing the interview

The packet also includes an unfunded VISA debit card and FAQ documents describing the process for accessing incentives as the stages of NHANES are completed.

All participants will be asked to provide informed consent before the interview begins. At the start of the telephone-based SP interview, the respondent is verbally asked to agree to

participate in the household interview portion of the survey. For participants who are 7-17 years of age, a parent or guardian consents and the child assents. Consents, Assents and related document are in Attachments 11a-11g). Informed consent will be captured verbally and recorded. A written copy of the Informed Consent language is provided prior to participants in the booklet described above.

For persons under 16 who are eligible, the household questionnaire interview is conducted with a proxy, usually the parent or guardian of the survey participant. If there is no one living in the household who is over 16, the teenage participant can be interviewed him/herself. If emancipated minors are prohibited by state law to participate, they will be sampled, but not asked to participate and therefore are non-responders.

The 2021-22 household screener and interview questions appear in Attachments 3b and 3c, respectively. Household interview hand cards are in Attachment 3d. The Sample Participant and Family Questionnaires are recorded for quality control purposes. Verbal consent is obtained and recorded at the beginning of the questionnaire.

When the questionnaire is completed, the interviewer reviews information about the MEC examination and asks the participant to set an appointment. If the participant agrees, the interviewer then telephones the field staff to make the examination appointments. The interviewer informs the participants that they will receive an incentive for participating in the examination, as well as help with out of pocket expenses such as transportation and childcare, if necessary. If the participant has questions or cannot come at the randomly assigned time, the interviewer will resolve these or other outstanding issues. As part of explaining incentives the interviewer will inform the participant that they will receive the incentive if they come to the examination. Additionally, the interviewer may mention that participation in components occurring after the examination (dietary interviews by phone) may also result in an incentive.

When arriving at the MEC all participants, interpreters, observers, and staff will be screened for COVID-19 symptoms outside of the building. The screening will include answering a series of questions related to symptoms and exposures, having a temperature check and having a COVID-19 antigen test. If anyone has symptoms or tests positive, they will not be allowed in the MEC (Attachment 14k). Once inside the MEC, the Coordinator (receptionist) greets them and verifies their identity. Next, MEC staff will review the informed consent brochure and consent forms for the MEC examinations (Attachments 11d and 11g) with the participant and respond to any questions and concerns. Participants will be asked to read, and sign consent forms for the examinations and storage of specimens once all their questions have been answered. MEC staff ask the participant to change into a disposable set of exam clothes and slippers. At this point, we also give the participant a container to provide a urine specimen while they are changing into their exam clothes.

In addition to the Coordinator, the survey team at each MEC consists of a clinician, certified medical technologists, health technicians (at least two of whom are radiological technicians), a certified phlebotomist, and a facility equipment specialist.

The 2020-21 MEC questionnaire and examination data collection forms are in Attachment 3e. The corresponding hand cards are in Attachment 3f. Some of the medical findings of the examination are given to the examinees before they leave the MEC. The remaining examination results are mailed to participants at a later date (usually between 3-4 months after their MEC exam took place). The sexually transmitted disease (STD) laboratory test results are not mailed with the other exam results, but rather reported to participants only via telephone to further

protect their confidentiality. The participants call NCHS for the results and provide the personalized password they created during their MEC examination. Examples of the Reports of Findings given to examinees and a description of the Reports of Findings process are included in Attachment 14h.

We propose to collect two dietary interviews via telephone in the 2021-22 NHANES. Currently, NHANES conducts 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 the NHANES survey restarts in 2021. Interviews will be conducted in English or Spanish. When the participant goes to the MEC, staff will schedule an appointment for the participant to be called 3-7 days later to complete the Day 1 Dietary Interview. We will give a Food Model Booklet and dietary kit to each family to estimate portions consumed (Attachments 3g and 3h). 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. At the end of the Day 2 Dietary Interview, the interviewer will ask if the participants aged 16 years and over will complete the Flexible Consumer Behavior Survey (FCBS) phone follow-up module (Attachments 3i and 3j), which asks about food shopping habits. An adult will be asked to complete the FCBS for participants aged 1-15 years old.

Sample Design

As with previous NHANES surveys, the design for NHANES 2021-22 is a stratified, multistage area probability sample of the civilian non-institutionalized population of the United States. The stages of the sample selection are first: selection of Primary Sampling Units (PSUs) (a county or a group of contiguous counties); second: segments within PSUs (a block or group of blocks containing a cluster of dwelling units); third: dwelling units within segments; and fourth: participants within occupied dwelling units.

NHANES will have two examination teams that operate continuously and travel from one PSU to another approximately every 6 weeks in a given year. Because of the time required for setting up, dismantling, relocating, and calibrating equipment, it has been determined, from previous NHANES that the MECs must be at each location for at least 4 weeks to be operationally feasible and cost effective. An upper bound of 8 weeks at each location was established to have an adequate number of PSUs for producing acceptable between-PSU sampling variances. The operational and statistical constraints result in an expected sample of 5,000 examined persons and 15 PSUs per year for NHANES.

Selection of Primary Sampling Units (PSUs)

To determine a probability of selection for each PSU, a measure of size (MOS) based on the most recently available projection from Census data is established for each PSU. For the 2021-2022 sample, the MOS reflects the total civilian noninstitutionalized population in the PSU.

Selection of Sample Persons within Households

The sample of persons within the household is selected through the multimode screening process described above. The household will complete the screener via the web, a paper copy, or by calling the provided toll-free telephone number. If they do not respond using any of these methods, the contractor will send an interviewer to the household to gather the information.

Participants are then selected based on the age selection probabilities.

In 2021-22, within all selected households, anyone aged 0-19 years and 60 years and older will be eligible. In addition, one or two people aged 20-59, residing in the selected households, will be eligible as well. A computer program on the interviewer's laptop will identify who should be selected in the household using a predetermined algorithm.

The expected sample domain distributions resulting are found in Table 2 of attachment 5a. Each gender, and age-specific row is a subdomain of interest for NHANES. Unlike previous survey cycles, NHANES 2021-2022 subdomains are defined only by age and gender, regardless of race, Hispanic origin, or income level. This reflects the elimination of oversampling of these population subgroups in order to help reduce screener burden and minimizes in-person contacts in a pandemic environment.

Estimation

To produce unbiased cross-sectional estimates for the civilian, noninstitutionalized population of the United States, the sample data will be inflated to the level of the population from which the sample is drawn. As in previous NHANES, the sampling weight for each sample person will be the product of three factors: the reciprocal of the probability of selection; an adjustment for nonresponse; and a calibration adjustment factor to make the resulting survey estimates in each age, sex, race, and Hispanic origin category approximately equal to independent control totals from the Public Use Microdata Sample (PUMS) of the American Community Survey (ACS) conducted by the U.S. Bureau of the Census.

Variances for NHANES can be estimated using a number of procedures and software programs. To allow for the computation of variance estimates, sample design variables are included on the public use data files. These variables are analogous to the typical stratum and PSU variables that were used in NHANES III, but the current design variables have been "masked" to limit the possibility of geographic disclosure. Masked design variables have been used by NHANES since the 1999-2000 data release. Examples of widely available software programs capable of producing variance estimates from complex surveys include: SUDAAN (Research Triangle Institute), WesVar (Westat), SAS Survey Procedures (SAS Institute), STATA (StataCorp) and R Survey Package (Lumley).

Analytic guidelines are provided on the NHANES website:

- http://www.cdc.gov/nchs/data/series/sr_02/sr02_161.pdf
- <https://wwwn.cdc.gov/nchs/data/nhanes/analyticguidelines/11-16-analytic-guidelines.pdf>
- <https://wwwn.cdc.gov/nchs/data/nhanes/analyticguidelines/17-18-sampling-variability-nonresponse-508.pdf>

These documents provide a broad overview of the statistical and methodological issues the user needs to be aware of when analyzing data from a complex, continuous survey like NHANES. These are updated and expanded periodically.

Quality Control

Two primary sources of error enter into a survey such as NHANES: sampling error and non-sampling error. Both types of errors can affect the estimates produced from the survey and may lead to a substantial loss in precision in statistical tests. Therefore, an extensive quality control system is a critical element in the operation of NHANES. The objective of the NHANES quality control program is to minimize measurement errors, to control them, or to measure these errors.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Interviewers have access to a variety of materials to assist them in sample person induction and nonresponse conversion. There is a follow-up letter that is, when possible, customized to fit the circumstance of each individual sample person who refuses the interview, examination or both. Attachment 12 contains the generic version of this letter. In addition to the follow-up letter that is sent to every potential sample person who refuses, interviewers have additional tools ranging from refusal conversion training, techniques for especially challenging conversions, to brochures and materials to help gain respondent cooperation. During the interviewing process there are multiple attempts made by the interviewer to gain cooperation for the screener interview or household person interview.

Other methods to maximize response include:

- Arrange for free transportation to MEC for sample persons or for incentives to help cover out of pocket expenses
- Allow a companion (parent, caregiver, etc.) to accompany participant through the exam
- Allow guest MEC exams for select non-participants such as community leaders, parents/guardians of SP child participants or local public health officials
- Provide a report of examination of findings
- Bilingual staff (Spanish)
- Interpreters for languages other than Spanish
- Advance publicity and contact with/endorsements from community leaders and groups
- Sampling multiple individuals in a household
- Flexible examination schedule including evenings and weekends
- Telephone reminders before scheduled appointments
- Customized follow-up efforts
- Recorded clips for TV stations
- Multimedia presentation on interviewers' tablet computers
- Evaluative studies of response where appropriate
- A website page dedicated specifically for survey participants
- "Make a Plan" tracker tool which serves as a reminder for participants to complete each stage of the survey (see Attachment 13d)

Participation in the MEC examinations is also emphasized . If sample persons are apprehensive or reluctant to participate in the examination, there are a number of techniques that can be employed by the interviewer once a reason for noncooperation has been determined. Some techniques are the same as those used to convince sample persons to participate in the household interview while others are unique to the examination component.

Appointment reminders are an additional tool used for compliance. For sample persons who have scheduled an examination appointment, a reminder is sent in advance. Additionally, within forty-eight hours of their examination appointment, all sample persons receive a reminder telephone call. For sample persons who do not have phones, whose phones are not working, or who have not been contacted by phone for some other reason, a home visit is made. If the contact attempts are unsuccessful, an appointment slip is left at the household for each sample person. If a sample person cancels an examination appointment, recontact is made immediately.

Lastly, we are continuing the following steps to improve response rates:

- Collecting and analyzing paradata to better understand the characteristics of the

recruitment process

- Since May of 2016, the contractor and staff from NCHS are continually working to address declining response rates.
- Increased efforts (e.g., new advertising and outreach sources, etc.) to recruit and train more qualified/experienced full time and backup household interviewers.
- Enhancement of the “obtaining cooperation” portion of the initial interviewer training and Interviewer Manual to include more “real life” practice modules.
- 2018 to present, we are retraining field interviewers to sharpen their doorstep presentation skills and equipping them with talking points to combat real-day concerns about participation.
- Supervisory field staff are encouraged to provide more one-on-one interviewer training on refusal conversion strategies.
- The Listers, staff who visit PSUs at least four months prior to the opening of stands, are asked to provide more information about every segment they visit so that we can address potential problems as early as possible, especially locked buildings, gated communities, and college campuses.
- The Advance Team addresses community support beginning with their earliest contacts with community leaders.
- NCHS works with the contractor in an effort to obtain more media coverage at every sampled PSU.
- The contractor provides NCHS with additional names of prominent people and organizations which could assist with endorsements.
- The contractor obtains more local endorsements for every stand beginning as early as four months prior to the start of a stand.
- The NHANES operations branch works more closely with contractor to assist in obtaining community and national endorsements in support of the survey.

Should the above efforts lead to changes in outreach\background\administrative materials etc. or to the development of new materials for use in NHANES, then the program would submit a non-substantive clearance request.

4. Tests of Procedures or Methods to be Undertaken

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

completion of required exam components, subject cooperation and refusal conversion, staff productivity, and adequacy of facility and supplies. NCHS staff, the contractor's development staff and consultants participate in the evaluation effort.

In certain cases, additional testing using non-NHANES respondents may be necessary. This could occur, for example, when the NHANES is developing a method to be used in the survey that can be tested or calibrated outside the NHANES survey setting. For example, prior to pilot testing a NHANES 24-hour urine collection within the survey, a calibration study was done with volunteers who received an incentive.

There may also be a need to conduct testing within NHANES for projects that may supplement/compliment NHANES or that may be implemented in alternative settings such as within other health studies, in home environments or in non-NHANES subgroups. For example, in 2012, NHANES conducted a Health Measures at Home Methodology Study (HMHS) among a small subset of NHANES participants. This involved collecting height, weight, blood pressure and dried blood spots both in NHANES participants' homes and in the NHANES MEC. This project was conducted because NCHS sought to investigate the feasibility of incorporating physical measures and biologic specimen collection into the National Health Interview Survey (NHIS) (OMB No. 0920-0214, Exp. Date 12/31/2020) by implementing the HMHS within NHANES.

Summary of 2021-22 NHANES Developmental Projects

NHANES expects to plan future developmental projects for testing or implementation within the NHANES 2021-22 environment. These will focus on planning for NHANES 2023 and beyond. These may include activities such as non-response related initiatives, testing of new components, tests of new equipment, crossover studies between current and proposed methods, test of different study modes, settings or technology, outreach materials, incentive strategies, sample storage and processing or sample designs.

The projects may include a focus on NHANES content such as:

- Height and weight measurement
- Measuring blood pressure
- Assessment of nutrition intake
- Biospecimen (blood and urine) collection at MEC (overall) and processing of specific analytes (listed below)
- Dental caries and tooth count
- Liver elastography
- Dietary supplements – at household and MEC
- Audiometry
- Assessment of visual acuity only
- Physical Activity Monitoring
- DEXA
- Physical functioning (grip strength, sit/stand, timed walk)
- Screening related to COVID-19
- 24-hour wearable device testing

Other considerations these projects may address in include:

- Modifications to existing exam protocol
- Equipment (is installation of equipment necessary (e.g., audio booth)?)
- Examiner (is a specialist necessary (e.g., dentist, physician))
- Time to complete exam (report percentiles by age groups and not just mean).
- Space utilized on MEC
- Streamlining household questions
- Assessing any MEC exclusion questions
- Looking at ways to be more efficient regarding the time from end of data collection to QC data release
- Streamlining the QC process
- Determining when gold standard exams are and are not needed
- Evaluating the data editing process (including internal editing, or consultants/collaborators' input?)
- Assess the feasibility of self-collection of biometric data
- Harnessing new innovations that may become available
- Pilot testing needed before 2023, possibly in settings other than the NHANES environment

For these projects and any currently unforeseen developmental projects related to future NHANES content, a non-substantive change package or GenIC request (under the approved package OMB Control No. 0920-1208, Exp. 08/31/2023) would be submitted to OMB before undertaking the project.

For these projects and any currently unforeseen developmental projects **not** related to future NHANES content (e.g., a project done for a different survey, such as a community HANES), a non-substantive change package, GenIC, (under the approved package OMB Control No. 0920-1208, Exp. 08/31/2023) or a full revision, as appropriate, would be submitted to OMB before undertaking the study.

Special Studies and Additional Health and Nutrition Studies

This request also seeks permission for the Division of Health and Nutrition Examination Surveys (DHANES) to plan or test components for special studies or additional components outside the current NHANES sample. Such projects could directly relate to the future or current content of NHANES. An example might be testing wearable devices among volunteers first, to assess the potential of using such devices in NHANES. Or, such projects could relate to studies complimentary to NHANES. An example might be a follow-up of past NHANES participants or studies like the 2012 NHANES National Youth Fitness Survey (NNYFS). Or such projects could relate to the content of other health and nutrition studies, such as a community HANES.

NHANES is including burden hours to accommodate developmental projects and special studies (Attachment 12) involving up to 3,500 persons (Section A12, Table 1, line 5). NHANES understands that submitting a nonsubstantive request to OMB for clearance would be required before starting such projects.

Nonresponse and Gaining Cooperation Investigations

Nonresponse and gaining cooperation investigations under DHHS task order contracts or other contract mechanisms may be necessary should nonresponse rates make that advisable. Details of any such investigations that involve public participation will be described under a non-substantive change package using burden from developmental projects.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

1) The following person will be consulted in the statistical aspects of the design of the developmental projects related to DHANES and other:

Ryne Paulose, PhD
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2) The following person is responsible for data collection activities:

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3) The following person is responsible for analysis of the NHANES data:

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