

Supporting Statement B

Request for Clearance

National Health and Nutrition Examination Survey

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Supporting Statement B

B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Overview of the Continuous NHANES Sample Design

In 1999, NHANES became a continuous ongoing survey to provide more timely data on the health and nutritional status of the U.S. population and to allow more flexibility in response to the need for data to address emerging public health concerns. From 1999 to 2018, NHANES used multiyear sample designs with varied lengths for 2-year data collection and release cycles. Because of the COVID-19 pandemic, the NHANES 2019–2020 data collection could not be completed. In August 2021, NHANES went back into the field with a new 2-year design. For 2025–2026, NHANES will include a 2-year sample design with nationally representative data released after the end of data collection for the 2-year cycle.

Except for data collection periods August 2021–August 2023, NHANES has oversampled racial/ethnic and age subgroups to ensure adequate sample sizes for analyses and desired levels of the precision for estimates calculated for these groups. For the August 2021–August 2023 collection period, only minors (0–19) and older people (60+) were oversampled and there was no oversampling for any racial/ethnic group. The NHANES 2025–2026 design will return to the approach of oversampling racial/ethnic and age subgroups. This approach will be done through a composite size measure that reflects population counts for race and ethnicity (persons reported as Hispanic, non-Hispanic Black, or Other category) by age group in years (0–4, 5–11, 12–17, 18–64, and 65 and older), and oversampling dwelling units (DUs) that are likely to have children and at least one resident who is non-Hispanic Black using sampling frame information. This multistage oversampling approach is expected to allow random selection of at least one resident from every recruited DU, a departure from prior NHANES designs where certain DUs were excused from participation after completing the screening interview. Quarterly, DU sample sizes (and sampling rates within DU) will be modified as needed toward the goal of meeting the targeted number of examined persons by race/ethnicity and age group.

Background on the Sample Design for NHANES 2025–2026

The primary objective of NHANES is to estimate a broad range of descriptive health and nutritional statistics for sex, race/Hispanic origin, and age subdomains of the U.S. population. While each single year is nationally representative, data are publicly released every 2 years to improve the analytic stability of estimates and to decrease disclosure risk.

The design for NHANES 2025–2026 remains a stratified, multistage probability sample of the civilian non-institutionalized population of the United States. In hierarchical order, the stages of the sample selection are first: selection of Primary Sampling Units (PSUs) (public use microdata areas [PUMAs]); second: Secondary Sampling Units (SSUs) within PSU (Census block groups [CBGs] or a collection of CBGs containing a cluster of DUs); third: DUs within SSUs; and fourth: one or more survey participants within DUs. The field operations include five Mobile Examination Center (MEC) teams in operation and approximately 5,000 Survey Participants (SPs) examined in 20 PSUs per year compared to 15 PSUs per year in the August 2021–August 2023 NHANES cycle. The expected sample size is based on past NHANES experience with response rates for each subdomain of interest.

NHANES 2025–2026 is oversampling children (0–17 years of age), older persons (65 years of age and older), and non-Hispanic Black persons. As discussed above, this oversampling occurs at several stages. The PSUs and SSUs are selected proportional to size using a composite size measure that oversamples the non-Hispanic Black population, children, and older persons.

Then, DUs within the SSUs are stratified according to their predicted probability of having people who are non-Hispanic Black or younger than 18 years of age.

The 2025–2026 NHANES data are expected to provide national estimates overall, by sex, by race-Hispanic origin, and by age group with more precision than the previous cycles' sample design given the increased number of PSUs compared to prior cycles. NHANES data should also have enough sample size for two-way subgroups (race-sex, race-age, and age-sex) for most subgroups. However, estimates for some population subgroups, such as non-Hispanic Asian by sex, non-Hispanic Asian by age, or non-Hispanic Black persons in the age group of 40-59 years might depend on the prevalence of a given outcome. Sample sizes for three-way subgroups (sex-race-age) may be too small. This is expected considering that in past NHANES it was still necessary to combine more than one cycle of data to get stable estimates for conditions with small prevalence by sex-race-age. The NHANES 2025–2026 design should, however, have smaller variance estimates across race and Hispanic origin and age for outcome variables with similar sample sizes. This is the result of two key factors: (1) more PSUs are selected each year, which reduces clustering; and (2) the PSUs have more homogenous sizes because PUMAs are more similar in population sizes than counties, which will yield less weight variation. Prior to the 2025-2026 cycle, the continuous NHANES usually had 15 PSUs per year (30 per two-year cycle).¹ For the 2025-2026 sample design, scenarios with 15, 20, 25, and 30 PSUs per year were evaluated. These scenarios all assumed 5,000 completed MEC exams per year. An additional scenario assumed 4,500 completed exams and 20 PSUs. Scenarios were compared on design effect and effect sample size using 16 statistical estimates commonly made from NHANES data. The former measures the impact of clustering on variance of estimates and the latter assesses the impact of clustering on the amount of unique statistical information that would be available for the nominal sample size (i.e., 5,000 or 4,500). As shown in Appendix B, median design effect goes down as average effective sample size goes up. The scenario with 20 PSUs and 5,000 exams reflected the best balance between gains in statistical efficiency and for our cost situation. Relative to a 15 PSU design, the 20 PSU design will have approximately an additional 256 respondents worth of independent statistical information (i.e., average effect sample size 256 higher with 20 PSUs than 15 PSUs) (see Appendix B for details).

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
4. https://www.cdc.gov/nchs/data/series/sr_02/sr02-190.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 to select a sample of the civilian non-institutional U.S. population
- List all DUs within segments a) with an estimated coverage rate exceeding approximately 80 percent, b) where drop point addresses are more than approximately 20% of addresses (see details below under “Selection of Dwelling Units”), and c)

¹ The 1999 data collection year had 12 PSUs and the 2020 data collection had 3 PSUs due to data collection being stopped early due to the COVID-19 pandemic.

persons in non-college dorm group quarters account for more than 5% of the target population

- Revise or develop publicity/outreach materials, translate materials into Spanish, and translate a subset of materials into other languages
- Hire and train field, telephone, and MEC staff
- Provide toll-free telephone support to participants and the public
- 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, telephone, and MEC procedures (including training in National Center for Health Statistics (NCHS) confidentiality guidelines and regulations)
- Conduct household screening for eligibility
- Administer in-home interviews with SPs and collect household environmental samples
- Administer dietary telephone interviews with SPs
- Perform all interview and examination procedures at the MEC
- Administer post-MEC data and specimen collection activities
- Conduct observations and reviews of interviews and MEC exams to assess staff performance and quality of data collection
- Design and carry out quality control procedures and transmit survey data to NCHS

NHANES will have five examination teams that operate continuously and travel from one PSU to another approximately every 10 weeks. 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 10 weeks at each PSU 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 20 PSUs per year for NHANES. NHANES is not in operation for about 2 weeks at the beginning of the year and for about 2 weeks in the summer.

Prior to data collection, the contractor completes the sample selection using Address-Based Sampling (ABS) methods. When needed, the contractor initiates an electronic listing of DUs for sampling to supplement ABS methods. Using ABS methods and listed segments, the contractor identifies households to be potentially included in NHANES. Selected households are screened for eligibility at the doorstep or inside the home with an adult resident. The contact and screening strategy is described below.

- Households will be mailed an advance letter 1 week prior to beginning contact attempts. The letter will briefly describe the survey, provide contact information for NHANES, and explain that a Field Interviewer (FI) will be visiting the DU.
- Approximately 1 week after the advance letter is mailed, an interviewer will attempt to make in-person contact with the household.
- When the interviewer arrives at the home, he or she shows official identification and briefly explains the purpose of the survey. The interviewer will refer to the advance letter

and, if the resident does not recall receiving the letter, will provide a copy for the resident to keep.

- With the resident's cooperation, the interviewer will administer the Screener Questionnaire (**Attachment 6a**) and determine whether anyone in the DU is selected. As part of the questionnaire, the FI will ask for a phone number for use in verifying the quality of their work.

Once the screener has been completed, an algorithm will determine whether anyone living in the DU is eligible to participate in NHANES – a majority of households are expected to have an eligible DU member under the 2025-2026 sample design. If there are no eligible DU members (e.g., all DU members are minors or active duty military), the interviewer will thank the respondent and conclude the DU contact. If one or more eligible DU members are selected, the interviewer will immediately seek to obtain their cooperation for the interview. If the participant agrees to participate but needs to set up an appointment, the FI will schedule the appointment. Once a person agrees to be interviewed and examined, the FI will follow a rigorous set of rules for administering the home interviews, appointing SPs to the MEC examination and scheduling telephone dietary interviews.

FI and MEC staff will be supplied with copies of NHANES materials to provide answers to commonly asked participant questions and for use in eliciting participation in the various NHANES data collection activities.

All participants are asked to provide informed consent before the interview begins. At the start of the consent process for the Survey Participant Questionnaire, a copy of the home interview study statement will be given to the SP (**Attachment 11b**). The interviewer will play a short video using their computer device and obtain the participant's verbal consent for the Survey Participant Questionnaire. If a non-SP completes the Household Questionnaire, the FI will obtain verbal consent from that adult DU member by reading a script to them. The Survey Participant and Household Questionnaire interviews are recorded for quality control purposes. Verbal consent to record is obtained and recorded at the beginning of the questionnaire.

Toward the end of the Survey Participant Questionnaire, the FI will request consent for data linkage and, if the SP agrees, will ask for their Social Security number. Social Security numbers are collected for the sole purpose of conducting potential linkage studies, such as death certificate and Medicare records linkage. NHANES asks every SP who consented to the data linkage to provide their Social Security number, but no Social Security numbers of DU members who have not been selected to participate in NHANES are collected. If minors are selected, adult proxy respondents are asked to provide the Social Security number of the child SP. A proxy is an adult legal guardian for child participants or for adult participants who cannot respond for themselves because of some physical or mental impairment.

Prior to the collection of the SP's Social Security number, the SP will watch a short video that explains the importance and benefits of linking their survey responses with existing health-related records. After the video, the FI will answer any questions the SP might have and obtain consent for data linkage. Permission to link to the Social Security number is granted when the SP indicates a "yes" response to the linkage question. Regardless of a participant's response to the data linkage consent, the rest of the questionnaire will be administered. Participants who consent to data linkage but decline to provide their Social Security number will be asked this item again during their MEC visit.

When the Survey Participant Questionnaire is completed, the FI will attempt to recruit the participant for the MEC examination and dietary telephone interviews.

MEC Examination

First, the FI reviews information about the MEC examination and asks the participant to set up an appointment. The interviewer informs the participants that they will receive an incentive for participating in the examination and help with out-of-pocket expenses, such as transportation and childcare, if necessary. All participants who schedule a MEC appointment will receive an appointment reminder letter (**Attachment 11e**) approximately 4 days before their appointment. The letter will be sent to participants to remind them of the MEC appointment date and time and provide important instructions for the exam including when to begin fasting, if appropriate. Before the MEC examination, participants (or their proxy) will receive another reminder either in a text message, an email, or a phone call, if permission was obtained when scheduling their MEC appointment. For participants 12–17 years of age, additional parental/guardian permission is obtained to send the minor reminder texts, emails, or a phone call about the exam. NHANES call center support staff will place all appointment reminder calls.

MEC examinations are conducted by teams of highly trained health care professionals (referred to as MEC staff). The team at each MEC consists of a registered nurse (RN), certified laboratory technologists (lab techs), certified medical laboratory technicians (MLTs), biomedical equipment specialist (BMES), registered dental hygienist (RDH), and radiology technologist (rad tech). At arrival to the MEC, MEC staff will do an initial visual assessment of the SP to ensure their general wellbeing and apparent capacity to complete the MEC exam. After introducing themselves as an NHANES staff member, the staff will confirm the SP's identity, date of birth and age provided at the time of scheduling the MEC exam. The introduction will also include the opportunity for the SP to provide their preferred pronouns. Then, based on the SP's age, informed consent will be obtained.

1. First the MEC staff will provide the SP or proxy with a Mobile Exam Center Consent Booklet and Detailed List of NHANES Blood and Urine Laboratory Tests (**Attachment 11b**). The booklet provides information on what MEC examination participation entails, a list of the health measurements to be obtained, confidentiality, participant's rights, and a blank copy of the Examination at the Mobile Exam Center and Future Studies Consent form. The Detailed List of NHANES Blood and Urine Laboratory Tests provides the full list of reportable labs that SPs receive for their blood and urine samples.
2. The MEC staff will then set up a brief consent video for the SP to view that introduces the MEC examination and reviews information that is important for the SP's ability to provide informed consent. Presentation within a recorded video will ensure consistency in consent administration with engaging visuals. Subtitles can also be displayed with the video for SPs who have a hearing impairment. (Note that subtitles can be turned off for SPs who do not need or want them.)
3. After the consent video ends, participants will have the opportunity to ask MEC staff any questions, and staff will take time to answer them.
4. Once all questions are answered, MEC staff will review the Exam and Future Studies consent form electronically with the participant.
 - a. Participants will be asked to confirm that they have viewed the video and have received the Mobile Exam Center Consent Booklet, and that they freely choose to participate in the exam.
 - b. They will next be asked to provide consent to NHANES to store their blood, urine, and other samples collected as part of the project for use in future health studies by checking either the Yes or No box.
 - c. Finally, the participant will sign the electronic form. MEC staff will also sign the electronic form to confirm that they provided the SP with the consent materials, followed consent protocols, answered any questions, and confirmed the completion of the electronic consent form by the SP.

If the participant indicates that they do not consent to participate in the MEC exam, MEC staff will not proceed with the exam. Consenting to future studies is not required; participants who decline will continue with the MEC exam, and no specimens will be stored for future studies.

The consent process will vary based on the age of the SP. Consent for minors 0–17 years of age is always obtained from an adult parent/guardian proxy and assent for minors 7–17 years of age is always obtained from the minor SP. No minor is examined without documented assent or consent, as appropriate. If the parent/legal guardian refuses any aspect (such as future studies) the assenting minor cannot agree to it. However, if the parent/guardian consents to any aspect (such as future studies) and the assenting minor does not, the minor's decision is the final decision. Furthermore, if the assenting minor does not assent to the MEC exam, the staff will not proceed with the exam even if the parent/guardian has given their consent.

Health measurements and test results will be provided to SPs through a series of Reports of Findings (ROF). A small number of reported results are initially reported to the SPs via a Preliminary ROF at the conclusion of the MEC exam. The Preliminary ROF is limited to those reported results that can be produced within the time of the MEC examination. For the 2025–2026 NHANES, this includes Blood Pressure, Body Measurements, Visual Acuity, Audiometry, Oral Health Assessment, and Complete Blood Count. A Final ROF is made available approximately 12 to 16 weeks later once all components of reportable results have been analyzed (**Attachment 11f**). At times, delays in processing labs or other unusual circumstances may cause the Final ROF to be extended beyond 16 weeks. In such cases, SPs will be made aware of the delay with a notification sent per their preference (electronic or mailed notification). If during the progress of data analysis for the Final ROF an abnormal finding is discovered, the SP will be alerted using an Early ROF notification. All results that appear in either a Preliminary or Early ROF will be reiterated in the SP's Final ROF. This is to ensure that the SP has a comprehensive description of all NHANES reported results for all the exams they were eligible and willing to complete.

Dietary Telephone Interviews

After the FI recruits the participant to the MEC examination while at the home, the FI will also ask the participant to participate in two dietary telephone interviews. At the end of the home interview, FIs will attempt to schedule Day 1 of the dietary interviews. The interviewer informs the participants that they will receive an incentive for participating in the dietary interviews. When participants schedule their Day 1 telephone interview appointment, they will be given an appointment reminder card for the date and time of the interview (**Attachment 11g**). If the participant has not scheduled their first or second dietary interview by the time they finish their MEC examination, the MEC staff will ask them to schedule a dietary telephone interview before exiting the MEC. One or 2 days prior to their dietary interview appointment, the participant or their proxy will receive a reminder call, text message, or email, if permission was obtained when scheduling their dietary interview appointment. For participants 12–17 years of age, additional parental/guardian permission is obtained to send reminder texts, emails, or phone calls to the minor as well. Additionally, participants who complete the Day 1 Dietary Interview will be mailed (by USPS) a Dietary Interview Thank You Letter (**Attachment 11g**). The letter will both acknowledge their contribution to the study and encourage their continued participation in the Day 2 Dietary Interview.

If a participant misses their dietary interview appointment, Telephone Interviewers (TIs) will make call attempts to reschedule the appointment and complete the interview. If they are unable to reach the participant after multiple call attempts, the participant will receive a text message encouraging them to call to reschedule (if they gave permission to receive text messages previously).

Selection of Primary Sampling Units

To determine a probability of selection for each PSU, a measure of size (MOS) is constructed based on the decennial Census data from 2020 and American Community Survey (ACS) (2017–2021) data. For the 2025–2026 sample, the MOS reflects the total civilian non-institutionalized population in the PSU weighted by age group and race/ethnicity. The NHANES 2025–2026 nationally representative 2-year sample will be randomly chosen from 40 PSUs selected out of almost 2,400 PUMAs. A random half-sample of 20 PSUs will be identified from the set of 40 for NHANES 2025; the remaining random half-sample of 20 PSUs will be fielded for NHANES 2026. Each half-sample will be nationally representative.

Selection of Secondary Sampling Units

To determine a probability of selection for each SSU, a MOS is constructed based on the decennial Census data from 2020 and ACS (2017–2021) data. For the 2025–2026 sample, the MOS reflects the total civilian non-institutionalized population in the SSU weighted by age group and race/ethnicity. The sum of the MOS across SSUs within a PSU is equal to the PSU MOS. Within each PSU, 12 SSUs will be selected for a total of 240 SSUs per year. The SSUs are constructed from CBGs where smaller CBGs, those with fewer than 200 occupied DUs and people living in non-institutionalized group quarters, are combined with neighboring CBGs to form an SSU prior to selection.

Selection of Dwelling Units

A sample of approximately 45 DUs per SSU will be selected totaling 10,753 DUs per year. Prior to DU selection, a sampling frame will be created for each randomly chosen SSU and evaluated for coverage bias. NHANES 2025–2026 DUs will be selected from RTI's in-house ABS frame (AAPOR, 2016) either directly or after augmentation with any additional addresses found in the field to improve coverage. Sampling frame augmentation will be accomplished through field enumeration (FE). Field staff conducting FE will be provided with the available ABS addresses in each SSU with low coverage to increase efficiency.

The estimated coverage rate of the SSU-specific ABS frame—defined as the ratio of ABS (locatable, city-style) address count to the 2017–2021 ACS estimated count of occupied DUs—and presence of a relatively large percentage of drop points on the ABS frame, will determine whether the SSU is enumerated prior to data collection. A drop point contains two or more DUs and a single point where mail is delivered because the DUs do not have a unique mailing address. DUs will be selected directly from the ABS frame if a) the estimated coverage rate exceeds approximately 80 percent, b) the percent of drop point addresses is more than 20% of addresses, and c) persons in non-college dorm group quarters account for more than 5% of the target population. FE will be used to supplement all other SSU ABS frames. Cut points to determine whether frame augmentation is needed will be finalized based on the distribution of estimated coverage rates for the selected SSU frames and in light of available project resources.

DUs within the SSU-specific (augmented) ABS frame will be classified into four mutually exclusive strata prior to sampling. The source information for NHANES 2025 stratum classification—presence of Non-Hispanic Black residents and presence of one or more minors (less than 18 years of age)—includes vendor-provided indicators resident on the ABS frame that is supplemented as needed with Census information.

The stratification will be revisited each quarter and again for NHANES 2026 to determine the efficiency of this approach in addition to the utility of predictive models to improve the classification.

If SSUs are randomly selected that contain a college or university, specialized frames will be constructed with information on the number of dorms and rooms within the building. The tailored sampling design for such an SSU will be augmented to accommodate an additional level of sampling—dorm and room within dorm—in such a manner as to limit the variability of the analysis weights.

Non-institutionalized group quarters will be sampled much like a college dorm. Information is requested on the number of quarters at the location and a systematic random sample selected. Characteristics of the residents will be requested to inform the sample design.

Sample size for dorm rooms and quarters within group home will be evaluated in comparison to the overall sampling fraction within the SSU. This affords the inclusion of these unique sample units into the study without adding excessive variability to the weights that can lower the precision of the estimates. However, resident characteristics in light of the exam targets may inform a different strategy.

Selection of SPs Within DUs

Approximately 5,566 DUs are projected for NHANES 2025 to have at least one and no more than three SPs for the study for a total of approximately 10,448 SPs. As with DU selection, sample sizes and within-DU SP selection rates will be revised as needed and in line with project resources each quarter using projected results. We will randomly sample up to 3 people in a household. In households with 1, 2, or 3 people in them, all will be selected. In DUs with 4 or more people, people will be selected probability proportional to size using the age factors above as the measure of size to select 3 people. For example, the following probabilities of selection would be generated for persons in the following DU:

Person	Age	Sampling Factor	Prob
1	3	1.37	0.928
2	5	1.36	0.921
3	36	0.85	0.576
4	37	0.85	0.576

where the probability of selecting the 3-year old is calculated as:

$$p_{\text{toddler}} = 3 \frac{1.37}{1.37 + 1.36 + .85 + .85} = 0.928$$

The person-level sampling frame comes from screener information provided by the DU respondent. Of importance is the exclusion of ineligible persons (e.g., those in active duty military or who do not have the DU as their primary residence) prior to randomly selecting the SPs. Any eligible DU resident without a reported age (group) or race/ethnicity will remain eligible for sampling as discussed below.

Additionally, any eligible SP selected with incomplete or incorrect data on their characteristics will remain in the sample and retain their original probability of selection; corrected information

provided via the SP interview will be used to assess exam targets and in the calibration weighting adjustments.

Approximately 5,566 DUs are projected to yield 10,448 SPs for NHANES 2025. An average of 1.88 persons per DU are selected for participation. This average selection rate is lower than in past cycles with the goal to reduce the effects that correlations for SPs within the same DU could have on the national estimates.

Based on previous NHANES cycles and RTI's experience with similar household surveys, an estimated 56.3 percent of the SPs are expected to complete an interview either directly or by proxy.² A high percentage (85 percent) of interviewed SPs are expected to provide health examination data, toward the goal of 5,000 MEC exams.

Eligible DU members will be classified into one of three age-based strata for NHANES 2025: 0–11 years, 18–64 years/unknown age, and all others (i.e., 12–17 years, and 65 years and older). All eligible persons without a reported age are classified into the 18–64 age group for sampling. The current stratification and sample counts align with the targeted number of exams by age group and by race/ethnicity where DUs with non-Hispanic Black people are sampled at slightly higher rates than those with a Hispanic person in the DU than all other DUs. People 0–11 years of age are sampled at a higher rate than those 12–17 and 65 years of age and older and those are sampled at a higher rate than those 18–64 years of age or with unknown ages.

Estimation

To produce unbiased cross-sectional estimates for the civilian, non-institutionalized population of the United States, the sample data are inflated to the level of the population from which the sample is drawn. As in previous NHANES, the sampling weight for each SP is 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 several demographic categories such as age, sex, race, and Hispanic origin category approximately equal to independent control totals from the Public Use Microdata Sample of the ACS conducted by the U.S. Bureau of the Census. The exact control variables will be determined at the time weights are constructed after reviewing potential for nonresponse bias based on observed factors and reducing unequal weighting effect.

Variances for NHANES can be estimated using several 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 will be “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 (RTI International), WesVar (Westat), SAS Survey Procedures (SAS Institute), Stata (StataCorp), and the 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>

² This conditional response rate was based on changes over time and experience with several large-scale national studies involving NHANES, the National Survey on Drug Use and Health (NSDUH), the National Survey of Family Growth (NSFG), and the National Health Interview Survey (NHIS).

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 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

Over the past few decades, the Program administered experiments, including incentive pilots and MEC follow-up surveys, to determine their effectiveness in increasing response rates and reducing nonresponse bias. Results from these experiments, including the August 2021 – August 2023 MEC nonresponse surveys, have allowed the Program to create new methods to increase response rates and mitigate nonresponse for the proposed 2025 – 2026 survey. Interviewers have access to a variety of materials to assist them in gaining SP cooperation and nonresponse conversion. There is a follow-up letter that is, when possible, customized to fit the circumstance of each individual SP who refuses the interview, examination, or both.

Attachment 11c contains these letters. In addition to the follow-up letter that is sent to a potential SP who refuses, interviewers have additional tools ranging from refusal conversion training and techniques for especially challenging conversions to brochures and materials to help gain respondent cooperation. Multiple attempts made to gain cooperation as each phase of data collection (screener interview, home interview, MEC examination, and dietary interviews).

Other established methods and newly proposed strategies to maximize response for 2025 – 2026 include the following:

- Provide SPs with incentives to help cover out-of-pocket expenses for child or elder care to attend their MEC examination
- Allow a companion (parent, caregiver, etc.) to accompany the participant through the exam
- Provide prepaid transportation allowance for the MEC examination
- Provide a report of examination findings
- Utilize Spanish-speaking bilingual staff for Spanish-speaking SPs and interpreters for languages other than Spanish
- Coordinate advance publicity and contact with endorsements from community leaders and groups
- Create a larger advance planning team with additional resources dedicated to community outreach and engagement
- Revise advance materials aimed at sampled household and community members
- Revise field interviewer training materials based on initial findings from the nonresponse follow-up survey
- Change to PUMAs which decreases geographic distance between participant DUs and the MEC
- Select secondary MEC locations in PSUs where sampled households are geographically dispersed
- Utilize smaller MEC trucks that may potentially travel more within a PSU to reduce the distance SPs travel to the MEC

- Sample multiple individuals in a household
- Provide flexible examination schedule including evenings and weekends
- Utilize telephone call, text message, and email reminders before scheduled appointments
- Customize follow-up efforts based on case-specific needs
- Utilize multimedia material for advance arrangements or outreach purposes (e.g., TV, social media, local officials, community leaders, individuals)
- Evaluate studies of response where appropriate
- Provide a website page dedicated specifically for survey participants

After the SP completes the home interview, they are eligible to participate in both the MEC examination and the dietary telephone interview. Details on strategies to maximize response rates for the MEC examination and dietary interviews are described below.

- MEC Examination

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

Appointment reminders are an additional tool used for compliance. Participants who schedule an examination appointment will receive a MEC appointment slip (**Attachment 11e**) at the time of scheduling and a reminder letter (**Attachment 11e**) approximately 4 days before their appointment. The letter will be sent to participants to remind them of the MEC appointment date and time and provide important instructions for the exam including when to begin fasting, if appropriate. One day before the MEC examination, participants (or their proxy) will receive another reminder by text message, email, or phone call (**Attachments 6o and 11e**), depending on the contact permission obtained when scheduling their MEC appointment. For participants 12–17 years of age, additional parental/guardian permission is obtained to send reminder texts, emails, or phone calls to the minor as well. NHANES call center support staff will place all appointment reminder calls.

If the participant refuses to schedule a MEC appointment, the FI identifies specific refusal concerns and how to address them. If the conversation is unsuccessful, the Field Supervisor (FS) may then request that a MEC Nonresponse Letter (**Attachment 11c**) be mailed to the participant. If an SP cancels an examination appointment and does not reschedule or does not attend their scheduled examination appointment, the participant will receive a text message encouraging them to call to reschedule (if they gave permission to receive text messages previously). If there is no response to these communications, the FS will send an FI to the DU to reschedule the appointment.

- Dietary Interviews

Participation in the dietary interviews is emphasized at multiple time points. After the FI schedules (or attempts to schedule) the MEC examination appointment, the FI will also ask the participant to participate in two dietary telephone interviews and attempt to schedule the Day 1 dietary interview. If the SP is apprehensive or reluctant to participate in the interview the FI will attempt to address the reason for noncooperation. When participants schedule their Day 1 telephone interview appointment, they will be given an appointment reminder card for the date and time of the interview (**Attachment 11g**). If the participant has not scheduled their first or second dietary interview by the time they

finish their MEC examination, the MEC staff will ask them to schedule a dietary telephone interview before exiting the MEC.

One or 2 days prior to their dietary interview appointment, the participant (or their proxy) will receive a reminder call (**Attachment 6o**), text message, or email, if permission was obtained when scheduling their dietary interview appointment. For participants 12–17 years of age, additional parental/guardian permission is obtained to send reminder texts, emails, or phone calls to the minor as well. Additionally, participants who complete the Day 1 Dietary Interview will be mailed a Dietary Interview Thank You Letter (**Attachment 11g**). The letter will both acknowledge their contribution to the study and encourage their continued participation in the Day 2 Dietary Interview.

If a participant misses their dietary interview appointment, TIs will make call attempts to reschedule the appointment and complete the interview. If they are unable to reach the participant after multiple call attempts, the participant will receive a text message encouraging them to call to reschedule (if they gave permission to receive text messages previously).

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

- Collect and analyze paradata to better understand the characteristics of the recruitment process (Analyses will include assessing response rate trends quarterly within each two-year cycle, and across cycles; trends in refusal reasons among DUs and SPs, and trends on other sample unit outcome rates like refusal rates and contact rates.)
- Conduct intensive efforts (e.g., advertising and outreach sources) to recruit and train qualified/experienced full- and part-time traveling FIs and part-time TIs
- Develop an “obtaining cooperation” section of both FI and TI trainings and manuals to include “real life” practice modules
- Train FIs on doorstep presentation skills and equip them with talking points to combat real-day concerns about participation
- Encourage supervisory field staff to provide more one-on-one interviewer training on refusal conversion strategies
- Utilize the listing staff, who visit a subset of SSUs at least 6 months prior to the opening of stands to list the sample, and the Advance Arrangements Team to provide more information about every segment so that we can address potential problems as early as possible, especially locked buildings, gated communities, and college campuses
- Have the Advance Arrangements Team address community support beginning with their earliest contacts with community leaders, and work to obtain more media coverage at every sampled PSU
- Coordinate among NCHS, the NHANES Operations Branch, and the contractor to provide additional names of prominent people and organizations that could assist with community and national endorsements
- Coordinate between NCHS, the NHANES Operations Branch, and the contractor to obtain more local endorsements for every stand beginning as early as 4 months prior to the start of a stand

Lastly, as in past cycles, we require the contractor to conduct a nonresponse bias study to assess whether declining response rates are associated with nonresponse bias. This is required under OMB’s Standard and Guidelines for Statistical Surveys (2006, Guideline 1.3.5, Section 3.2.9) when a survey expects the unit response rates to be under 80%. At the time of this submission, the plan for the 2025-2026 NHANES is in development, but includes the following elements. These incorporate guidelines of the best practice guidelines from the Federal

Committee on Statistical Methods Nonresponse Bias Sub-committee (Madans, Earp, Blumberg, et al., 2023).

1. **Evaluate sample balance on sociodemographic characteristics before nonresponse adjustment and quantify nonresponse bias using area-level data.** To understand whether the NHANES sample (i.e., respondents), adjusted for selection probabilities but not nonresponse, is similar to the US population, we will compare NHANES and ACS estimates (selection-weighted) of demographics such as sex, age (0-11, 12-17, 18-24, 25-34, 35-44, 45-54, 55-64, 65 and older), education (high school or less, some college or associate degree, college or higher degree), race and ethnicity (Hispanic, White non-Hispanic, Black non-Hispanic, and non-Hispanic multi-race combined with Other non-Hispanic), marital status (married, divorced/separated, widowed, never married/not married but living with partner/other), and income. Health insurance status (i.e., whether a person has insurance and which type), also measured by ACS, will be used as well. These estimates are chosen based on expected use in NHANES weights, and their use in NHANES analyses. The list of demographics and health estimates, and their definitions may change as the plan develops. ACS and NHANES estimates will be compared overall and geographically (e.g., at the Census Tract or Block Group level) to understand whether there is a geographic component of nonresponse bias, and whether it should be incorporated into the nonresponse adjustments. Further, they will tell us which demographic characteristics are represented well in the sample and which are likely to have nonresponse or coverage bias.
2. **Investigate the relative contributions of screener, survey participant (SP) interview, and MEC examination nonresponse to nonresponse bias.** Nonresponse and nonresponse bias analyses will be conducted at the screener, SP interview, and MEC examination stages (using appropriate selection weights). Understanding how each stage of data collection contributes to nonresponse bias will help us a) target nonresponse reduction efforts to the stages where they can make the most difference and b) advise data users. These analyses will primarily involve comparing respondents and nonrespondents at each stage based on data collected at the prior stage or before. For example, screener respondents and nonrespondents (i.e., responding and nonresponding Dus) will be compared on characteristics available for all sampled Dus, such as interviewer observations, contact attempt histories, and ACS neighborhood/geographic data. Similarly, SP interview respondents and nonrespondents will be compared on characteristics captured in the screener interview. Finally, we will compare MEC respondents and nonrespondents on data collected in the SP interview and other within-household collections. Of course, at each stage, any prior data can be used. For example, we plan to also compare MEC respondents and nonrespondents on the screener variables measuring DU-level hypertension, diabetes diagnoses, and prescription drug taking.
3. **Compare NHANES estimates to health estimates from other surveys.** A key method to evaluate nonignorable nonresponse bias is to use a benchmark estimate from another survey – ideally one with similar sampling and measurement methodologies, and a substantially higher response rate. Differences in estimates from each survey are interpreted as potential bias, considering differences in the designs of the surveys that can also impact estimates. The National Health Interview Survey (NHIS) and the Medical Expenditure Survey-Household Component (MEPS-HC) will be used as two benchmark surveys for NHANES because they are mostly in-person national surveys with comparable response rates. Fully weighted estimates for several health characteristics will be produced from NHANES data and compared to those from NHANES data and compared to those from NHIS and MEPS-HC. Other surveys may be used as well,

particularly for NHANES' most high-profile estimates, and those for which NHANES is used as the official source. We will document methodological differences between the benchmark surveys and NHANES (e.g., sample designs, modes, question wording, and other methodological features) to make the benchmark comparisons interpretable. The estimates used will include as many of the estimates explored in other nonresponse bias analysis steps as possible so nonresponse bias results can be assessed across method of assessment.

4. **Assess how much final estimates depend on nonresponse weight adjustments.** Weight adjustments for nonresponse aim to correct for nonresponse bias. This analysis will compare selection-weighted survey estimates to final-weighted survey estimates for a select set of variables similar to those used in other analyses. Well-performing weight adjustments are expected to produce a difference in survey estimates, but substantial shifts in estimates would indicate undesirably strong reliance on weighting adjustments.

Should the above efforts lead to changes in outreach/background/administrative materials, etc. or to the development of new materials for use in NHANES, the Program would submit a nonsubstantive 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 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 an 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/complement 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 2018, NHANES conducted the Social Media Pilot Study in six specific NHANES locations. The pilot was conducted to determine the effectiveness of social media on potential participants' awareness of NHANES and ultimately participation in NHANES. Two forms of social media were utilized, Facebook, and Instagram. Results from the study helped inform and determine whether social media should be incorporated into long-term outreach planning for NHANES.

Summary of Potential 2025-2026 NHANES Developmental Projects

NHANES may plan future developmental projects for testing or implementation within the NHANES 2025–2026 environment. These will focus on planning for the next NHANES cycle and beyond. These may include activities such as nonresponse-related initiatives; testing of new components; tests of new equipment; crossover studies between current and proposed methods; and 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
- Dental caries and tooth count
- Liver elastography
- Dietary supplements – at household and MEC
- Audiometry
- Assessment of visual acuity only
- Physical activity monitoring
- DXA
- Physical functioning (grip strength, sit/stand, timed walk)
- 24-hour wearable device testing

Other considerations these projects may address include:

- Modifications to existing exam protocol
- Equipment (if installation of equipment necessary, e.g., audio booth)
- Examiner (if a specialist necessary, e.g., dentist, physician)
- Time to complete exam
- Modifications to target age groups
- 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 2027, possibly in settings other than the NHANES environment
- Development of multimedia materials such as a NHANES participant video or MEC Tour Video

Another set of projects may be needed to inform more substantial changes to the NHANES design and to understand the impact of changes already implemented in the 2025–2026 cycle. These potential studies can be grouped into five areas based on their purpose:

- Studies to understand the comparability and continuity of estimates, both retrospectively and prospectively
 - o Analysis of nonexperimental data
 - o Experimental evaluation, testing methods on additional sample or reinterviewing NHANES participants

- Studies to increase the understanding of the challenges and opportunities of multimode data collection specific to NHANES
 - o Alternative modes to the screener
 - o Alternative modes to the home interview
 - o Alternative modes to the dietary interview
- Options to assess the benefits of moving health exams from MECs to the home
- Approaches to formative work on alternative methods for health exams, beyond those considered above
- Experiments or information collections designed to increase participation in NHANES, such as alternative protocols, incentive levels, content and format of outreach and advance materials, and follow-up surveys.

For these projects and any currently unforeseen developmental projects, NCHS would discuss with OMB whether a nonsubstantive change package or GenICR request (under the approved package OMB Control No. 0920-1208, Exp. 05/31/2026) would suffice 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) options include a GenICR (under the approved package OMB Control No. 0920-1208, Exp. 05/31/2026) or a full revision, as appropriate, would be submitted to OMB before undertaking the study.

Special Studies and Additional Health and Nutrition Studies

This revision request also seeks permission for the Division of Health and Nutrition Examination Surveys (DHNES) to plan or test components for special studies or additional components either within or outside the current NHANES sample. Such projects could directly relate to the future or current content of NHANES.

NHANES is including burden hours to accommodate developmental projects and special studies (**Attachment 13**) involving up to 3,500 persons (**Section A.12, Table 4**). 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 nonsubstantive change package using burden from developmental projects.

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

1. The following persons will be consulted in the statistical aspects of the design of the developmental projects related to DHNES:

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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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Appendix B

Effects of the Number of Primary Sampling Units (PSUs) on Variance of Estimates

PSUs per Year	Median Design Effect (Deff) [±]	Change in Median Deff Compared to 15 PSUs	Average Effective Sample Size	% Change in Average Effective Sample Size Compared to 15 PSUs
15 (Past cycles*)	4.859	Reference Category	1,029	Reference Category
20 (2025-2026)	3.891	-19.92%	1,285	+24.9%
25	3.310	-31.90%	1,511	+46.8%
30	2.924	-39.82%	1,710	+66.2%
20 with 4,500 exams	3.889	-19.96%	1,157	+12.4%

*The continuous NHANES (i.e., since 1999) has had 15 PSUs in all years except 1999 which had 12 and 2020 which had 3.

*Median Deffs and average effective sample sizes were calculated for 16 health measures using 2017–2018 NHANES data: obesity, hypertension, cholesterol, diabetes, at least 12 drinks per year, chlamydia, HIV, hepatitis B, hepatitis C, hearing, body mass index, blood pressure (diastolic), daily dietary intake, triglycerides, blood lead, and serum copper. Deff was calculated as the ratio of the sampling variance under the clustered design to a design with simple random sampling (SRS; e.g., $Deff = \frac{var(p)_{clustered}}{var(p)_{SRS}}$, where p is a proportion or mean of an NHANES variable). Effective sample size was calculated as the nominal sample size (e.g., 5000 or 4500) divided by the Deff.