Proposal Guidelines
2027-2028 National Health and Nutrition Examination Survey

The following sections need to be included with your submission. Proposals should be no longer than 10 pages in length, excluding supplementary material.

Section 1: Title page, abstract, and table of contents

- Proposal title
- Author(s): Please designate a primary contact person
- Institutional affiliation, mailing address, telephone number, and e-mail address of all authors (NOTE: For CDC proposals include the CDC Ethics Verification Numbers of the CDC investigators)
- Abstract (A brief, clear summary of your proposed content)
- Table of contents (Include the different sections of your proposal and the page numbers on which the sections begin)

Section 2: Project description and justification

This section should include an introduction, brief background and description of the proposed measures (i.e., examinations, laboratory assays, questions), target population, and objectives of the proposed content.

Each proposal also requires rationale related to the public health significance of the proposal topic and resulting measures. Please address one or more of these topic areas in your justification, as appropriate:

1. **Surveillance**: How would the proposed content fill an existing knowledge gap? For example: Is this proposal designed to produce national population health and nutrition parameters? Is the prevalence of this condition known, and how is it expected to change in the future?
2. **Prevention**: What significance would this proposal potentially have in the prevention of diseases or targeting risk factors?

3. **Treatment**: How would the proposed content improve treatment of health conditions? For example: will the resulting data be used to assess the effectiveness of treatment or the extent of untreated disease (e.g., awareness, treatment, and control of hypertension)?
4. **National health promotion/disease prevention objectives**: Would this proposal provide baseline data or be used to assess progress for Healthy People 2030 objectives? If yes, list the objectives and the relevance of the proposed component.
5. **Health policy**: How will this proposal help decision makers design effective public health policy or programs?
6. **Program evaluation**: Will proposal findings yield actionable evidence to assess practices and progress of federal programs, such as the National Diabetes Education Program, the Supplemental Nutrition Assistance Program (SNAP), National Cholesterol Education Program, or Dietary Guidelines for Americans?
7. **Health disparities**: How will the data be used to assess the health and nutrition status of health of racial and ethnic minorities and under-served populations? Will the data provide information on the social determinants of health?
8. **Emerging health concern**: Is the proposed content an emerging health issue that NHANES could successfully capture in the next 1 or 2 years? Would NHANES be timely enough to provide useful or actionable information?

Section 3: Data collection

Specifications for examination, laboratory, and questionnaire content data collection are described below. Please respond to all aspects of data collection relevant to your proposal.

A. Examination Content

In this section, describe the methodology of exam content data collection and include protocols as supplementary information.

Please address the following, as they apply:

1. **Validity and reliability of the proposed methods**: Describe what is known about the validity and reliability of the method for all measurements. Is this a "gold standard" or a

standardized evidenced-based indicator, such as an FDA-approved method? The information on validity and reliability should cover the entire target age range for the proposed component. NOTE: If the method has not been validated for the specified target age, provide a justification for using a non-validated target age.

   a. For exam components that will rely on examiner assessments, indicate the inter-rater and intra-rater reliability (if unknown, state unknown).
   b. Provide references and citations, with hyperlinks to key journal articles that document how widely used the proposed method is used. Discuss potential limitations of the proposed methods.

2. **Total time and participant burden**: Estimate the total time required for the component from start to finish, including explaining the component, administering pre-test screening or exclusion questions, participant preparations (e.g., changing shoes for treadmill testing), conducting the test, completing post-examination procedures. If known, note any differences in time due to age, or a health condition. If a percentage of tests are expected to be repeated due to participant noncompliance or technician error, describe this in the proposal.
3. **Equipment/Supplies**: If equipment and specific supplies have been selected, please provide additional details, as outlined below. If equipment has not been finalized, provide current recommendations. This information is important for determining the technical feasibility of the proposal.

   a. Describe criteria used to select equipment and whether it has been used in NHANES previously, or in another large-scale health study? Is the equipment suitable for use in a mobile examination vehicle?
   b. Describe the equipment calibration and quality control (QC) procedures, hardware requirements for operation, data storage, and data transmittal, survey staff training requirements, and other technical requirements for all equipment used for this component.
      i. Is there a warranty or available service plan from the equipment manufacturer? Is on-site maintenance available throughout the U.S.?

Describe measures that will be taken to ensure that equipment problems will not interfere with ongoing survey data collection activities. Identify problems that have occurred in similar field studies, or in past NHANES and how such problems can be avoided or minimized.

c. Briefly describe the software requirements for specialized instruments or equipment. Does a 3rd party have copyright or licensure for the software? Are maintenance agreements and licenses required? What is the cost of the software? Hardware platform requirements, and any data storage requirements should also be described briefly. Be aware that current NCHS policy does not allow data to be collected, transmitted, or stored on a non-CDC network. Also, although this policy is evolving, proposers should be aware that at this time cloud-based service may not be permitted. If utilizing a cloud-based service is essential to the proposed component, at a minimum, the Federal Risk and Authorization Management Program (FedRamp) authorization will be required. Please include this information as part of your proposal.

d. Confirm that the equipment specified for use in NHANES will be available for the entire duration of data collection. Provide detailed technical descriptions, manuals, and cost information as supplementary documents.

4. **Priority of exam subcomponents:** To maintain the operational feasibility and to balance the data needs for various health and nutrition topics, we may not be able to accept all measurements proposed. If the proposal includes several independent measures or subcomponents (e.g., a muscle strength exam includes 3 assessments: grip strength, timed walk, and knee extension), then rank the subcomponents in order of priority for inclusion.

5. **Processing results, grading, and interpretation**: How will the exam data be processed? Specifically, what are the steps required for file reading, data scoring, interpretation, and preparation of results? Specify all individuals involved, the responsibilities of each entity, the timeline for each step, and for the final transfer of data to NHANES contractors.

6. **Staffing requirements**: Describe qualifications, certifications (if applicable), required training, and other competencies of staff to conduct this component in the field.
7. **Reporting results to participants**: If the results of the exam component have clinical significance for survey participants, provide an example of how to report this finding. Cite reference ranges and cut points used clinically or in other studies. If the results are not to be reported, justify the rationale for this decision.
8. **Participant experience, interest, and acceptability**: If the examination has been previously conducted in NHANES or any other large-scale health study, comment on the participant experience, including acceptability of the data collection method (including for different subgroups) and how the survey participant may benefit from receiving exam results. If the proposed exam is sensitive in nature, propose methods to maintain privacy and minimize embarrassment or discomfort during the data collection process.

B. Laboratory Content

In this section, describe the methodology of laboratory assay data collection and include protocols as supplementary information.

Please address the following, as they apply:

1. **Specimen or Sample Collection**: Provide minimum specimen or sample amount (quantity or volume), shipment and storage requirements. Describe any special collection procedures for obtaining biologic specimens (excluding blood and urine) or environmental samples.
2. **Laboratory and clinical test characteristics**: Provide the specificity and sensitivity of the proposed analytic assay method. Provide information on accuracy and precision (desirable specification for allowable total error). What is the limit of detection (LOD) and the limit of quantitation (LOQ)? What percentage of results are expected to be below the LOD/LOQ? If the same analyte was tested in a previous NHANES using a different method, was a crossover study done, or will it be done? Comment on the time frame for the analyses of the specimens, the possible impact of long-term storage on the analytes, as well as the overall lab capacity to conduct the assays.

3. **Validity and reliability of the proposed methods**: Describe what is known about the validity and reliability of the method for all measurements. Is this a "gold standard" or a standardized evidenced-based indicator, such as an FDA-approved method? The information on validity and reliability should cover the entire target age range for the proposed component. NOTE: If the method has not been validated for the specified target age, provide a justification for using a non-validated target age.
    a. For any analyte, does a standard reference material (SRM) exist (i.e., NIST standards)? Was the method tested with the SRM?
    b. Provide references and citations, with hyperlinks to key journal articles that document how widely used the proposed method is used. Discuss potential limitations of the proposed methods.
4. **Equipment/Supplies**: Provide a brief description of equipment or supplies, if known, for sample or specimen collection other than for urine or blood (e.g., vacuums to collect home dust samples). What criteria were used to select the equipment for use in NHANES? Has the equipment been used in NHANES previously, or in another large-scale study?

    a. Describe the equipment calibration, maintenance, and quality control (QC) procedures, if applicable. Include hardware requirements for operation, data storage, and data transmittal, survey, and other technical requirements for all equipment used for this component.
    b. Is there a warranty or available service plan from the equipment manufacturer? Is on-site maintenance available throughout the U.S.? Describe measures that will be taken to ensure that equipment problems will not interfere with ongoing survey data collection activities. Identify problems that have occurred in similar field studies, or in past NHANES and how such problems can be avoided or minimized.
    c. Confirm that the equipment will be available for the entire duration of data collection. Provide detailed technical descriptions, manuals, and cost information as supplementary documents.

5. **Processing results, grading, and interpretation**: How will the specimens or samples be processed? Specifically, what are the steps required for analyses? Specify all laboratories and individuals involved, the responsibilities of each entity, and the timeline for each step. The expectation is a 21-day turn-around from the time the specimens or samples are received in the lab until the results are submitted to the NHANES contractor.
6. **Staffing requirements**: Describe qualifications, certifications (if applicable), required training, and other competencies of staff to collect the specimens or samples.
7. **Total time and participant burden**: Estimate the total time required for the proposed component from start to finish, explaining the component, administering pre-test screening questions, participant involvement (e.g., urine collection in the restroom), conducting the test, completing post-examination procedures. If known, note any differences in time by age, or because of a particular health condition. If a percentage of tests are expected to be repeated due to participant noncompliance or technician error, describe this in the proposal.
8. **Reporting results to participants**: If the results of the laboratory assay have clinical significance for survey participants and the testing laboratory is CLIA certified, provide an example of how to report this finding to a survey participant. NOTE: If lab is not CLIA certified, we will not report the findings to the participant. Cite reference ranges and cut points used clinically or in other studies. If the results are not to be reported (for any reason other than the lab is not CLIA certified), justify the rationale for this decision.
9. **Participant experience, interest, and acceptability**: If the biospecimen or environmental sample has been previously collected in NHANES or any other large-scale health study, comment on what is known about the participant's experience, acceptability of the data collection protocol, and potential value of a test result. If the proposed measurement is sensitive in nature, propose methods to maintain privacy and minimize embarrassment or discomfort during the data collection process.

C. Questionnaire Content

In this section, please address the following as they apply to any proposed questions:

1. **Validity and reliability of the proposed questions**: Have the questions been validated? Identify the source of questions, administration mode, and describe other large-scale health studies that have used the questions. Summarize pertinent findings from previous studies (with references and hyperlinks) and results from known cognitive research testing used to validate questions. Address any issues related to potential differences in the validity and reliability of findings across study subgroups. Discuss the appropriateness for use in the proposed target groups, cross-cultural validation, and availability of Spanish translations.
2. **Question rationale**: Address how each question will be used. Is the question necessary to interpret a physical or laboratory measurement? State if it will be used to exclude participants from an exam, as a covariate (risk factor) in an analysis of a particular physical or laboratory measurement, or to provide a prevalence estimate. For prevalence estimation, provide the denominator variable used to calculate the estimate, as well as known current prevalence.
3. **Question priority**: To maintain a reasonable length for the NHANES interview and to balance data needs for various topics, we may have to limit the number of questions included for any given content area. When a series of questions on a particular behavior or condition are proposed (e.g., questions about milk consumption include details on current milk consumption patterns, type of milk, and summary of milk consumption over a lifetime), rank questions in order of priority for inclusion. Consider omitting questions with probable low percent responses (due rare conditions or outcomes) that may have limited analytic value.
4. **Participant burden**: Estimate the total time required for interviewer administration, counting respondent response and recording response times, regardless of possible skip patterns. If response categories are read aloud for each question, provide this information in total time.
5. **Databases, software, and IT requirements**: Briefly describe any specialized data collection instruments or data bases used during data collection. Does a 3rd party have

copyright for the data base or software, and is there a cost associated with its purchase or use? Will additional coding be required post-data collection?

6. **Visual aids**: Are any visual aids recommended? For example, a showcard with a picture or answer categories?
7. **Question placement and administration mode**: Specify whether, due to an association with a particular lab or examination measure, the proposed questions should be administered on the same date as the examination or lab collection. Comment on preference for a particular interview mode for question administration. Could the questions be administered using multiple modes, including phone, web, or self-administration?
8. **Participant privacy**: If the proposed questions are sensitive in nature, address ways to maintain privacy, minimize embarrassment and reduce item nonresponse. Are there privacy considerations for questions asked of children?
9. **Proxy reporting**: For questions that target children 16 years and under, specify whether the questions are suitable for a proxy to respond to or if they are best answered directly by a child participant. Specify age ranges where proxy reporting differs by age.

Section 4: Supplementary documentation

1. **Laboratory Assays:** Attach specifics of laboratory method in an appendix (i.e., laboratory procedure manual or manufacturer's package insert). Additionally, provide documentation on CLIA certification for the lab that will process the specimens and CLIA validation for any analytes.
2. **Equipment:** Please provide equipment specification provisions not included in the proposal, safety precautions; and dimensions of equipment, including weight and needed working space (such as wall clearance). Describe the portability of the equipment and any environmental considerations, including temperature and humidity, voltage, hardware/software, etc.

Section 5: Data disclosure and release

NCHS' mission is to release high quality data in a timely manner and to make data available on as wide a basis as practicable (public use dissemination, preferred) while protecting confidentiality. NOTE: If added disclosure risks are identified during the review process by the NCHS Disclosure Review Board process, the data access may be limited to access through the NCHS Research Data Center only.

1. Are there any possible challenges or impediments to timely data release?
2. Would any finding from the proposed measure increase the chance of reidentification of a survey participant or a particular survey location?

Section 6: Project budget

NCHS requests that all potential NHANES partners include funding source information in their proposals. Proposers agree to provide financial support for new survey content. Additionally, new survey content often requires cognitive, feasibility, or pilot testing prior to full-scale implementation in the survey (data collection, processing, interpretation, release). The sponsoring group(s) should be prepared to financially support the proposed component as well as pre-testing prior to the start of the survey, related data processing costs such as coding, reading, and any other associated activities necessary for timely data release. Depending on the complexity of the proposed content, funding may be needed as soon as FY26, and will continue throughout the data collection and production periods.

NCHS will prepare an updated cost estimate for the proposed content based on the information provided here, and additional information discussed at the time the proposal is considered for likely inclusion in the survey. Any information regarding equipment, laboratory, coding/reading/grading, and other associated costs will assist us in this endeavor.