Template for NHANES Biospecimen Program Proposals to Use Serum, Plasma, and Urine Specimens

General information: Proposals should generally be limited to a maximum of 10 single-spaced typed pages (not including cover page, tables, and figures) using at least a size 10 point font. **Please adhere to the most recent Federal Register Notice which contains more detailed instructions for each section.**

Title Page:

- **Project Title** (Provide a title that includes a brief description of the proposed analyte, general age range to include, and planned survey years)
- **Principal Investigator** (List the name, institution, address, phone number, and e-mail of the principal investigator; for CDC investigators, the investigator's Collaborative Institutional Training Initiative (CITI) expiration date must be included)
- **Laboratory Name** (List the name and address of the institution where the proposed laboratory analysis would be performed)
- **Additional Investigators** (List all additional investigators included in the project including name, institution, address, phone number, and e-mail; for CDC investigators, the investigator's Collaborative Institutional Training Initiative (CITI) expiration date must be included)

Proposal Components:

1. **Specific Aims** (List the broad objectives; describe concisely and realistically what the study is intended to accomplish, and state the specific hypotheses to be tested.)
2. **Background and Public Health Significance** (Describe the public health significance, scientific merit and practical utility of the assay, the background of the proposal, identifying gaps in knowledge that the project is intended to fill, and the importance of the study in terms of the broad, long-term objectives and public health relevance. Include a justification for the need for a nationally representative sample.)
3. **Study Design and Methods** (Include a detailed description of laboratory methods, including validity and reliability, the volume of specimen and number of specimens requested, justification for pristine specimens vs. surplus specimens, and methods for handling and storing the specimens, including freezer conditions. Provide a rationale for the chosen survey years and age groups. Provide a concise analytic plan that includes how survey design and survey weights will be used and how missing data will be handled.)

4. **Clinical Significance or Results** (Include a discussion of the potential clinical significance of the results and whether there is evidence that results of the test would provide grounds for medical intervention even if many years have passed since the examination of the participant and collection of the sample. Any test with results that are clinically significant, and would require reporting to the participant, is not appropriate for testing on the stored serum, plasma, or urine samples and will not be approved.)
5. **Qualifications** (Provide a brief description of the Principal Investigator's expertise in the proposed area, including publications within the last three years.)
6. **Period of Performance** (Please provide an estimated timeline for completion of the project. Substantial progress must be made in the first year, and the project should be completed within a reasonable time period.)
7. **Funding** (Please include the source of funding and the current status of the funding)