Supporting Statement B for Request for Clearance

Developmental Projects to Improve the National Health and Nutrition Examination Survey And Related Programs

OMB No. 0920-1208 Expiration Date: 12/31/2020

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Developmental Projects to Improve the National Health and Nutrition Examination Survey And Related Programs

Part B. Collection of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

This submission requests approval for a generic, three-year, revision for the currently approved Information Collection Request (ICR) titled Developmental Studied to Improve the National Health and Nutrition Examination Survey and related programs (OMB No. 0920-1208, Exp. Date 12/31/2020. The National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0950, Exp. Date 11/30/2021) is conducted by the Division of Health and Nutrition Examination Surveys (DHNES) within the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). This clearance covers research, projects and activities that will evaluate and improve upon survey design and operations, as well as examine the feasibility and address challenges that may arise with future cycles of the NHANES or related NCHS programs/projects.

This generic request includes a broad range of research and activities. The specific sample will be appropriate for the type of project. Samples could include groups such as incentivized volunteers; individuals in the NHANES sample who did not screen into the survey as well as potential or current NHANES participants; contractors working on NHANES or other surveys; past NHANES participants or family members; physicians, nurses or other health care providers; state or local area data retrieval personnel, participants in NCHS or other federal agency surveys or samples; members of the general public, in the US or in other countries with which we collaborate regarding health surveys or public health projects

There may be situations where NHANES will need to conduct developmental testing among groups or samples that are not nationally representative. This might occur if NHANES performs testing using subgroups of other NCHS programs, such as NHIS or among participants relevant to outside collaborators / organizations, such as local health organizations or with researchers abroad where participants do not reside in the US. On other occasions, NHANES may need to utilize samples of existing pools of volunteers from sources such as our contractor's database of volunteers, existing panel survey participants, or convenience samples. In such cases, probability or other sampling methods, deemed appropriate to the circumstance, would be used to identify participants. Circumstances where this approach has been needed in the past include: testing of equipment, technology or exam protocols/procedures; testing of questions wording or translations of questions into languages other than English; testing related to specific public health topics; or testing existing NHANES components among different age groups. It is also possible that testing might be performed to assess matters related to survey response rates, outreach and gaining cooperation efforts, adjustments to NHANES needed to ensure safety and acceptability of traditional NHANES components

administered in new ways in response to unexpected circumstances like rapidly emerging health concerns or crises such as COVID-19.

The specific universe and sampling methods will be detailed in each GenIC.

2. **Procedures for the collection of information**

The procedures for data collection will depend on the project proposed and will be described within each GenIC. It is anticipated that in-person, phone, or internet interviews or exams (administered by NCHS staff or contractors) may be used as well as self-collected data methods. Focus groups may be convened to discuss issues such as recruitment efforts, barriers to response or community outreach. Cognitive or other testing may be conducted to improve questions and data quality or to compare alternative data collection options/approaches.

Each proposed activity will submit an application to the NCHS Ethics Review Board for their review and approval, outlining the specific procedures for participant selection and consent, as applicable.

3. Methods to maximize response rates and deal with nonresponse

Specific methods to maximize response rates, if any, will be described in the individual GenIC submissions.

4. Tests of procedures or methods to be undertaken

Tests of procedures or methods related to the various current and planned NHANES surveys, or other NCHS programs is the focus of this generic request. The specific procedures to be tested will be described in the individual GenIC. However, some example descriptions of potential types of developmental projects or special studies testing are provided below.

Pilot studies – tests conducted in the NHANES Mobile Examination Center (MEC) trailers to see if examination content, often already developed or in use in other settings (such as a clinical or medical research setting), will work in the MEC environment. These tests may look into issues such as how long the exam will take, how well field staff can conduct the exam, or how well the equipment holds up after being moved from location to location. An example might include testing a hearing exam that is usually given in schools or in a doctor's office to determine if noise is a problem or if the space that was designed for this component is appropriate. Pilots could also be used to test to see if components done in the MEC environment could be deployed in alternative settings (such as in the home, at fixed sites, among other NCHS survey samples, etc.)

Feasibility studies – tests conducted to see if a proposed component can be successfully operationalized or if data collected from a procedure can be successfully stored, shipped or analyzed. Feasibility tests could also include assessing how well participants can

follow instructions provided required in the protocol and/or if participants are willing to participate in the proposed component at all. One example might be a test of whether or not 3-5 year-olds can successfully provide a urine sample in the MEC, or if a participant is willing to collect their urine for a 24-hour period at home and then drop off the collection to the NHANES field office. Another example might be a test of obtaining 24-hour blood pressure measurements at home.

Calibration studies – projects conducted to determine what range of values a machine or assessment can detect. May also include testing to assess whether or not a piece of equipment can give stable values across time after being moved from location to location, or how frequently a piece of equipment would need maintenance or adjustments in the field to give consistent readings.

Equipment testing – projects to assess or compare how well proposed equipment does or does not work, or how long a procedure using a certain piece of equipment may take, or how easy a piece of equipment is or is not to use. One example might be a test of how well a digital camera versus a special scanner takes pictures of medication bottles. Another example might be a test of how liver ultrasound machinery works,

Focus groups – projects involving conducting guided discussion about survey related issues such as field operations and logistics or to obtain feedback from individuals or groups such as survey participants (past or present) subject matters experts, or the general public.

In-person interviews – test of questions to be asked in NHANES or other NCHS program environments. This could be a test of modes or a test of how understandable a set of questions are or are not. One example might be a comparison of an in-person interview with an interview conducted remotely (such as through Skype or other teleconferencing mechanism) to see if the remote option worked well enough to be used as an alternative to an in-person option.

Self-administered interviews – tests to assess the quality of and differences in the data obtained when participants fill out interview questions for themselves as compared to when they are asked by an interviewer. Some examples include web-based surveys or mailed paper surveys that individuals complete at home. Other projects might include comparing approaches to in-person screening interviews with approaches to self-administered screening.

Usability studies – projects to assess how easy or not a computer interface or other survey platform is for individuals to use. An example might be a study to test a web-based self-administered survey verses a self–administered paper survey, or to test an interview that is done with touch screens with or without audio to see which is easier for participants.

Cognitive testing (including testing of translations) - An example might be a test of whether a question or set of questions asked in one language is understood in the same

way when translated into a different language. Or, a test of whether the intended meaning of a question is the meaning perceived by the respondent.

Incentive studies – projects involving the use of or variations in incentives to assess the impact on response rates or other levels of participation. Examples might be testing the amount of incentive, such as full incentive for arriving to the MEC on time verses partial incentive for late arrival. Or, tests to see if changes in timing, of when an incentive is given, impact participation. Such tests could also be used to assess at what point an incentive is no longer helpful with regard to increasing response rates. Incentive studies could be done among NHANES participants, among volunteers, among participants in other NCHS activities, or among the general public.

Non-response studies - Projects to test materials and procedures to improve response rates, including changes to advance materials and protocols, changes to the incentive structure, introduction of new and timely outreach and awareness procedures including the use of social media. These projects might also include activities comparing individuals who choose to participate in our surveys with others who choose not to participate, and an exploration of possible reasons for these differences.

Methodology studies – projects that involve testing which method is best suited for the purposes of the survey or projects to facilitate changing or modifying an existing method in light of new technology. An example might be projects to assess the use of devices that people can wear to assess certain health measures or indicators. Another example might be a test of multiple brands of automated blood pressure cuffs to see which ones individuals consider more comfortable while still providing accurate measurement.

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 DHNES and other:

Tala H. Fakhouri, PhD MPH Senior Health Scientist Division of the National Health and Nutrition Examination Surveys National Center for Health Statistics Centers for Disease Control and Prevention Email: tfakhouri@cdc.gov Office: 301-458-4608

2) The following person is responsible data collection activities:

David Woodwell, MPH Chief, Planning Branch Division of Health and Nutrition Examination Surveys National Center for Health Statistics Centers for Disease Control and Prevention dwoodwell@cdc.gov Phone: 301-458-4327

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

Ryne Paulose, PhD Acting Program Director Division of Health and Nutrition Examination Surveys National Center for Health Statistics Centers for Disease Control and Prevention Phone: 301-458-4484