

Attachment 9

Targeted Methodological Studies

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As part of the preparation efforts to implement the full longitudinal study of all examined adults from NHANES 2007-2014, up to 750 participants may be asked to participate in targeted methodological studies, if resources permit and if tracing and participation in the field feasibility test is successful. Collectively, these projects are represented in line 6 of the burden table in Supporting Statement A.12 Estimates of Annualized Burden Hours and Costs. The average burden for these methodological study respondents is one hour.

The aims of these projects are to test the feasibility of additional proposed methods and procedures for inclusion in the NHANES Longitudinal Study. These targeted methodological studies will be conducted with volunteers who are not from the NHANES cohort, or past NHANES participants who are not part of the potential NHANES Longitudinal Study sample (e.g., past NHANES participants from the 1999-2006 cycle). A change Request, either non-substantive or full revision, as appropriate, will be submitted for clearance for each targeted methodological test with specific sample and protocol described

Examples of anticipated methodological studies include:

- Evaluation of additional bio-specimen collection procedures

We may conduct field tests to assess new procedures to collect additional bio-specimens in the NHANES Longitudinal Study, such as additional blood samples collected via dried blood spots or venous blood samples via phlebotomy. The primary objectives of the methodological tests will be to evaluate whether it's operationally feasible to collect, process, store, and transfer the proposed additional samples in a home exam environment, to compare the validity, reliability, and operational effectiveness among different sample collection methods, and to refine the operational design in key areas of standardized protocols and equipment selection, delivering training, cost-effectiveness, and feasibility.

- Cognitive testing for questionnaire items

For new and updated questions, we may conduct cognitive testing to understand how they may be interpreted by respondents, to evaluate the impact of different response options on answer choices, and to assess respondents' comprehension for specific terms and concepts. We may collaborate with other cognitive lab such as NCHS's Collaborating Center for Question Design and Evaluation Research (CCQDER) or Westat's Instrument Design Evaluation and Analysis Services to conduct the testing. The cognitive testing will be conducted in English and Spanish, an in-depth interview will be given to each participant to collect his/her responses to the questionnaires, including the participant's understanding of the wording of the questions and the decision process the participant went through in answering these questions. The results from the testing will be used to assess and improve the instruments' validity, and determine the feasibility of inclusion in the NHANES Longitudinal Study.

- Protocol tests for additional exam components

When additional exam components are proposed for the longitudinal study, we may conduct tests to evaluate its operational feasibility. For example, fundus photos have been used to detect glaucoma, retinopathy and macular degeneration. Recent advances in technology

suggested the potential of collecting fundus photos in a home setting using portable, hand-held digital cameras. If proposed and resources permit, we may conduct feasibility studies to verify the use of the camera by examiners with none or little medical background, within the home environment. We may also test to verify the validity and reliability of the photos against research standards.