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

National Health Interview Survey (NHIS) Follow-up Health Study

Supporting Statement B

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1. Respondent Universe and Sampling Methods

The National Health Interview Survey (NHIS) (OMB No. 0920-0214, Exp Date 12/31/2023) is a continuous annual survey of the non-institutionalized, civilian population of the United States. Each single year and any combination of consecutive years comprise a nationally representative sample of the U.S. population. NHIS collects survey data from one adult age 18 and older (the Sample Adult) and about one child, if applicable, per household. In 2019, data were collected from over 32,000 Sample Adults.

This project proposes to invite adults from a convenience sample of 2021 NHIS households in selected geographic areas in 9 states to participate. These areas have been selected with the goal of achieving sample dispersion among urban and rural areas. This pilot study has been limited to a small number of states to ensure an efficient use of resources. We will recruit until 900 NHIS Sample Adults agree to be contacted to schedule an appointment. NHIS Sample Adults who did not respond for themselves or did not complete the NHIS entirely in English, will not be eligible for this pilot study. Additional exclusion criteria for specific components of the health exam are specified in the Home Visit Questions (Attachment 1j).

2. Procedures for the collection of information

Invitation to participate

At the end of the NHIS interview, in households selected for this study, the interviewer will describe the study and invite the Sample Adult to participate. Specifically, the interviewer will request permission to give the Sample Adult's contact information to the project staff scheduling the appointments and collecting the data for the study; respondents who refuse will be asked why (Attachment 1c). If the NHIS interview is in person, the Field Representative (FR) will offer the Sample Adult a copy of the brochure during this process (Attachment 1d). If the NHIS interview is over the phone, the FR will mail the brochure to Sample Adults who agree to be contacted.

Scheduling

If the Sample Adult agrees to be contacted, and provides at least a phone number (providing an email address and permission to text is optional), then project staff will use a multi-mode approach, which includes phone calls, emails, and texts to schedule the appointment (Attachment 1e). If project staff are unable to reach the respondent by those methods, they will mail a letter and brochure asking respondents to contact the central scheduling number. (Attachments 1f).

Once contact is made with the respondent via phone, the staff will record and respond appropriately to any participant questions, concerns and reasons for refusal. They will then screen the respondents who agree to participate for COVID-19 risk using the CDC-recommended COVID screening questions and schedule accordingly (Attachment 1e). The project staff will also provide instructions about what to do to prepare for the visit (Attachment 1e). Finally, the project staff will ask how (phone/text/email) the respondent would prefer to receive the appointment reminder.

Project staff will send the reminder approximately 24 hours prior to respondents' appointment (see Attachment 1e). If the health representative can reach the respondent by phone, s/he will reiterate the COVID screening questions and reschedule if necessary (Attachment 1e).

Screening, identification verification, and consent

On the day of the scheduled visit, the health representative will visit the respondent's home, after following the COVID-19 safety protocols described in Attachment 1b Part 2. If someone answers the door, then the health representative will ask for the respondent by name. If the respondent is not at home or is not available to participate in the study when the health representative arrives at the home, and this is the health representative's first visit to the home, then the scheduling process will start again from the beginning. If the respondent is not home or is unavailable and this is not health representative's first visit to the home, then no further attempts will be made to schedule the respondent, and the case will be classified as a non-respondent.

If the respondent is available when the health representative arrives at the home, the health representative will screen the respondent again for COVID-19 and reschedule if necessary (Attachment 1e).

If the respondent answers no to all the COVID-19 screener questions, (Attachment 1e) then the health representative will request to see a photo ID in order to verify the identity of the participant. The health representative will not record the ID in any way. Once the Sample Adult's identity is verified, the health representative will offer the respondent a surgical mask and reiterate that NCHS recommends that SAs wear a face mask during the visit. The respondent can still participate even if s/he wears a different mask or refuses to wear any mask.

The health representative will then provide the respondent with a hard copy of the Measurement and Lab Test Explanation handout, the COVID Serology handout and the informed consent form (Attachments 1g and 1h) and ask the respondent to read them. If

the respondent is unable to read it themselves then the health representative will read both documents out loud. As shown in Attachment 1h, the participant will be informed that taking part is voluntary and there is no penalty if they refuse. If they choose to participate, they don't have to do every part and can stop at any time. After providing written consent, the NHIS respondent becomes a Follow-up Health Study participant.

Exam

Once consent has been obtained, the health representative will ask the participant to provide a urine sample (Attachment 1i). If the participant is unable to provide a specimen, the health representative will encourage the participant to drink some water and try again later in the visit. The health representative will measure the participant's height, weight, waist circumference, blood pressure, and resting heart rate (Attachment 1i). The health representative will also collect a venous blood sample (Attachment 1i). The health representative will also record any concerns or reasons for study component refusal that the participant provides, and will administer a short survey about the participant's study experience which includes a question about what concerns, if any, the participant had about participating (Attachment 1i). This questionnaire is designed to gather information that can be used to improve the recruitment, scheduling, and exam procedures in future iterations of this project.

After completing the exam, the health representative will give the participant a paper report of their height, weight, waist circumference, blood pressure and resting heart rate to keep as well as a $75 prepaid card (Attachment 1j). The health representative will also read the Blood Pressure Statement out loud. A participant with a high blood pressure needs to know immediately so they can call for a medical appointment. In contrast, there is no combination of height, weight, and waist measurement that warrants immediate clinical action. Reading out loud will ensure that participants, especially those who cannot read, hear what their blood pressure is and what it could mean to their current health. The health representative will then leave the home and immediately prepare and ship the biospecimens to the lab.

Specimens will be labeled with a unique specimen ID. That ID will only be linked to study participants within the study's secure IT environment. The specimen ID will not be linked to any NCHS public use files. The receiving laboratory will not have access to any PII. The lab will perform specimen analysis and run the blood and urine tests listed in the Measurements and Lab Test Explanation handout (Attachment 1h). The blood and urine specimens will be stored at the lab for seven days, after which they will be destroyed.

Quality Control

All data collected from the participants will be entered into encrypted laptop computers. Built-in quality control checks, such as hard and soft edits, will be programmed into the instrument to maximize the accuracy and consistency of the data.

The study will employ experienced, certified phlebotomists to serve as the health representatives. They will have passed background checks and have documented

experience including a minimum of 100 verifiable successful venipuncture draws. For those states requiring licensure, the phlebotomists will maintain appropriate licenses.

All phlebotomists working on this study will complete training requirements for safety, privacy and confidentiality. In addition, their training will cover all procedures related to the home visit, including the standardized protocol for anthropometric and blood pressure measurements; biospecimen collection and shipping; using the encrypted laptops to record health exam data and paradata; and administering the participant survey. The phlebotomists will be required to have experience in conducting all exam procedures, the training will review safety protocols and the protocol for handling adverse medical events, and specimen collection scenarios that may impact specimen quality.

Field observations will be done throughout the survey by both NCHS staff and contractors to monitor field staff performance and case management. Equipment calibration and on-site inspections will be performed and documented regularly.

All confidential data will be securely electronically transmitted between the contractor and NCHS using the CDC Secure Access Management System (SAMS). Extensive review will be conducted regularly to verify the completeness, consistency, and analytic usefulness of the data.

Estimation Procedures

The program plans to use the following approaches to estimation.

The first step of the analysis will be to evaluate patterns of response. We will calculate overall response rates taking into account all the steps of nonresponse, as well as agreement and participation rates at each step of the process (recruitment, scheduling, and the exam itself). We will also calculate completion rates for each exam component (anthropometrics, blood pressure measurement, urine collection, blood collection). This evaluation will also include the calculation of conditional rates, such as the refusal and no-show rate among participants who scheduled appointment and conditional completion rates of each step in the process among those who made it to the previous step in the process. Since all respondents and non-respondents to this study will have participated in the NHIS main interview, to the extent sample sizes permit, we will also be able to evaluate response rates by demographic characteristics such as age group, sex, urbanicity, race and Hispanic origin, health conditions such as cardiovascular disease and diabetes, and health care access and utilization variables such as whether or not the respondent has health insurance coverage or a usual source of health care. The goal of this analysis is to assess how demographic factors, health, and health care access and utilization are related to the likelihood of participation.

The second step of the analysis will focus on participant concerns and reasons for refusal as they are potentially related to nonresponse bias, cost, and data quality. Specifically, the second step will involve the calculation of percentage of participants at each stage who express particular types of concerns and give particular reasons for refusals. This analysis will also be repeated by demographic and health characteristics, to learn whether

concerns and reasons for refusal differ across groups. These data will be recorded mostly verbatim during the recruitment, scheduling, and exam process and coded after the completion of data collection.

The third step of the analysis will be to calculate summary statistics related to other possible challenges to high response rates and high-quality data. This includes the mean time between interview and first contact attempt, first contact attempt and exam among those who at least start the exam; percentage of exams with a variety of types of problems and challenges (also recorded during the exam); and the percentage of blood and urine samples collected that could be analyzed for any/all analytes.

Finally, non-response bias assessments will be conducted using NHIS health and demographic data. While the power to detect differences will be limited by the small sample size of this pilot study, this analysis should provide provisional information about the differences between participants and non-participants.

The results of the evaluation of the pilot data will be used to develop recommendations for a larger field test or full-scale implementation.

3. Methods to maximize response rates and deal with nonresponse

Schedulers and health representatives will be trained in a variety of strategies to gain cooperation, and avert and convert refusals including

- Gaining potential participant trust by providing clear, thorough, succinct answers to questions about the purpose, goals, and logistics of the study
- Reducing potential participant skepticism about the study by addressing common participant concerns
- Increasing potential participant motivation to participate in the study by explaining how the study will benefit the participant, the CDC, and the nation

In addition, health representatives will be trained in allying participant fears, putting participants at ease, and encouraging participation in each study component

Other methods to maximize response include:

- Offering potential participants a choice of mode of contact for scheduling the appointment
- Follow-up efforts including the mailing of a letter and brochure (Attachment 1f)
- Flexible home exam scheduling options including evenings and weekends
- Telephone, text, or email reminders (as chosen by the participant) before scheduled appointments
- Use of monetary incentives as appropriate, as explained in Supporting Statement A
- Providing test results from the examination
- Proactively calling participants to reschedule broken appointments

4. Tests of procedures or methods to be undertaken

Wherever possible, exam protocols were adapted from those used in previous studies. The weight measurement was adapted from the one used in the highly successful 2014 Health Measures at Home Study. The urine collection protocol was adapted from the ones used in the highly successful 2017 NHANES Longitudinal Survey and Population Assessment of Tobacco and Health (PATH) study. The blood collection protocol was adapted from the one used in the PATH study.

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

1) The following person was consulted in the statistical aspects of the design of this study:

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2) The following person is responsible for the data collection activities:

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3) The following person is responsible for the analysis of this project:

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