DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

January 12, 2011

Margo Schwab, Ph.D.
Office of Management and Budget
725 17th Street, N.W.
Washington, DC 20503

Dear Dr. Schwab:

The staff of the NCHS Questionnaire Design Research Laboratory (QDRL) (OMB No. 0920-0222, exp. 03/31/2013) plans to conduct research to 1) test Spanish language versions of questions for the National HIV Behavioral Surveillance (NHBS) system for CDC, National Center for HIV, Hepatitis, STD, and TB Prevention (NCHHSTP, Division of HIV/AIDS Prevention (DHAP), and 2) to begin development of an A-CASI sexual identity question proposed for the National Health Interview Survey (NHIS). The English testing version testing of this protocol was explained in a letter written to you on November 22, 2010, and approved on December 21, 2010. The Spanish language version protocol is exactly the same as the English version protocol with the exception that there is a combined 3 in 1 telephone screener in addition to the individual screeners. The 3 in 1 screener was developed for locations where all three targeted groups may be present.

We propose to start advertising for volunteer participants as soon as we receive clearance and to start testing as soon as possible after that.

Background Information about Cognitive Testing of Questionnaires

The methodological design of this proposed study is consistent with the design of typical cognitive testing research. As you know, the purpose of cognitive testing is to obtain information about the processes people use to answer survey questions as well as to identify any potential problems in the questions. The analysis will be qualitative.

Proposed project: National HIV Behavioral Surveillance (NHBS) system, and questions regarding sexual identity for the National Health Interview Survey (NHIS) – Spanish Language Testing

Purpose 1: To test questions for the National HIV Behavioral Surveillance

The National HIV Behavioral Surveillance (NHBS) system was initiated by the Centers for Disease Control and Prevention (CDC) to help state and local health departments establish and maintain a surveillance system to monitor selected behaviors and to have access to prevention services among groups at highest risk for HIV infection. Findings from NHBS are used to enhance understanding of risk and testing behaviors and to develop and evaluate HIV prevention programs. The NHBS is administered in both English and Spanish.

NHBS activities are implemented in data collection cycles focusing on different risk groups of interest: men who have sex with men (MSM), injecting drug users (IDUs) and heterosexuals at high risk of HIV infection (HET). NHBS uses a slightly different

questionnaire for each of these three groups. The questionnaires for the 3 groups appear in Attachment 1a, b, and c. The three questionnaires (Attachment 1a, b, & c) are modified from the NHBS CAPI instrument. The first questionnaire (Attachment 1a) targets men who have sex with men (MSM). This questionnaire focuses on demographic characteristics of this group, their HIV risk and exposure, and use and knowledge of antiretroviral medications. The second questionnaire (Attachment 1b) targets injecting drug users (IDU). This questionnaire focuses on demographic characteristics of this subgroup, as well as their drug use, their network of peers, their HIV risk and exposure, and use and knowledge of antiretroviral medications. The third questionnaire (Attachment 1c) targets heterosexuals at high risk of HIV infection (HET). This questionnaire focuses on demographic characteristics of this subgroup, as well as their drug use, their network of peers, their HIV risk and exposure, and use and knowledge of antiretroviral medications.

We propose to recruit as many as 60 adults (aged 18 years and older) to adequately test each version of the NHBS instrument:

1) We plan to evaluate the MSM questionnaire using 20 cognitive interviews. In order to receive the MSM questionnaire in the NHBS, respondents must meet the following criteria. They must be at least 18 years of age, they must have been assigned the male sex at birth, and must live and present themselves as male, and they must have engaged in oral or anal sex with a male sex partner at least once in their lifetime. Cognitive interviews will be conducted in community centers in the greater Washington, DC and Baltimore areas. Respondents will be recruited through staff at community centers, flyers distributed at community centers (see Attachment 2a), and word-of-mouth. The specific telephone screener to be used for verifying eligibility of those who respond through staff/flyer/word-of-mouth is shown in Attachment 3a and Attachment 3d.

2) We plan to evaluate the IDU questionnaire using 20 cognitive interviews. In order to receive the IDU questionnaire in the NHBS, respondents must meet the following criteria. They must be at least 18 years of age, they must be male or female (i.e. cannot be transgendered) and they must have injected drugs in the past 12 months. Cognitive interviews will be conducted in drug abuse and needle exchange centers and community centers in the greater Washington, DC and Baltimore areas. Respondents will be recruited through staff at needle exchange centers and community centers, flyers distributed at needle exchange centers and community centers (see Attachment 2b), and word-of-mouth. The specific telephone screener to be used for verifying eligibility of those who respond through staff/flyer/word-of-mouth is shown in Attachment 3b and Attachment 3d.

3) We plan to evaluate the HET questionnaire using 20 cognitive interviews. In order to receive the HET questionnaire on the NHBS, respondents must meet the following criteria. They must be at least 18 years of age, they must be male or female (i.e., not transgendered), they must either be low educated (i.e. high school education or less or be living in poverty), they must have engaged in vaginal or anal sex with an opposite sex partner in the past 12 months, and they cannot have injected drugs in the past 12 months. Cognitive interviews will be conducted in community centers in the greater Washington, DC and Baltimore areas. Respondents will be recruited through staff at community centers, flyers distributed at community centers (see Attachment 3c), and word-of-mouth. The specific telephone screener to be used for verifying eligibility of those who respond through staff/flyer/word-of-mouth is shown in Attachment 3c and Attachment 3d.

4) Additionally, because the NHBS focuses on HIV risk and exposure, and the use and knowledge of antiretroviral medications, we must recruit respondents for all risk groups (i.e., MSM, IDU, and HET) who have tested HIV positive and HIV negative.

QDRL is aware of the fact that these high risk groups are not mutually exclusive and that there will likely be numerous respondents who could be recruited to all three. It is our expectation that testing will illustrate whether or not and to what extent this is problematic for survey data quality.

Purpose 2: To begin development of an A-CASI sexual identity question

A primary difficulty in designing a sexual identity question for a national population survey is that the construct of sexual identity (as opposed to a more objective construct, such as behavior) is a complex concept; respondents' conceptions of the construct itself can vary dramatically depending on demographic characteristics (e.g., race/ethnicity, gender, age), socio-cultural context and geographic location. QDRL has conducted multiple evaluations using cognitive interviewing methods on various sets of questions designed to capture information on sexual identity. Analysis consistently shows that the questions produce measurement error due to problems with respondent comprehension of terminology as well as the use of labels that are not consistent with the way respondents identify themselves. Analyses of survey data support these conclusions. Lack of understanding key terms and unsuitable use of labels results in high levels of responses in non-substantive categories such as 'something else', 'don't know', and refused. As a result, responses that are not analyzed have higher prevalence than the responses of interest. Additionally, depending on how questions are worded, estimates vary and do not always make theoretical sense. For example, estimates from NHANES show twice as many gay men than bisexual men, while NSFG estimates show an equal proportion. Also of concern is the fact that the percent of the population responding in the non-substantive categories varies across demographic and socioeconomic statuses, which further reduces the ability to interpret the data. It is believed that developing an A-CASI sexual identity question, with help screens to clarify concepts for respondents, will resolve many of these interpretive problems.

For this project, a proposed sexual identity question which was developed from previous cognitive testing studies has been placed in each DHAP questionnaire. This question will be examined using traditional cognitive interviewing techniques. The QDRL recognizes that this is only one step in the development process. Given the timing and content of the DHAP project, it was logical to begin this developmental work with this package. Other rounds of interviewing will be required to complete and test a final A-CASI sexual identity question.

Cognitive Interviews

Cognitive interviews will be conducted by QDRL staff and an individual respondent for 90 minutes each. Respondents will be informed of audio taping procedures during the screening process, and in the process of reviewing the consent forms prior to the start of the interview. Only individuals who agree to be audio taped will be eligible to participate in the study.

Due to the sensitive nature of the questions as well as the small and unique targeted populations, the NCHS QDRL is requesting approval to conduct the study anonymously. QDRL Staff will collect minimal personal identifiers. A first name and a contact telephone number for scheduling and reminder calls, if available, may be used—however, full name, address and home telephone number, will not be collected. The QDRL routinely collects this information in order to 1) pay respondents through the use of the approved cash payment receipt form, and 2) to acquire informed consent. It is the QDRL's belief that the collection of these identifiers would put the respondent at risk of potential harm resulting from a breach of confidentiality because the majority of the targeted population is such a small and unique

community.

Respondents who decide to participate will be asked to read the waived signed Informed Consent form which allows for the audio taping of the interview. The interviewer will witness the reading of the waived signed Informed Consent form. In addition, prior to the start of the interview the interviewer will turn on the tape recorder and respondents will be asked to verbally acknowledge that they have agreed to participate in the research study and that they have agreed to be audio taped. If the respondent decides to turn off the audio tape anytime during the interview, they will be asked for consent to retain the interviewing materials and the portion already taped. The interviewer will get verbal consent from the respondent to do so prior to turning off the tape.

Interviews will begin with an overview about the purpose of the study. The QDRL interviewer will follow the interview protocol, but will also ask emergent probes to better understand the question-response process. Examples of the sorts of probes that may be asked at the interviewer's discretion include:

- Could you tell me what [term] means to you?
- Why did you answer that way?
- In your own words, could you tell me what you think this question is asking?
- Was this question easy or hard to answer? Why?
- How sure are you about your answer?

Interviewers may use some or all of these probes, depending upon the content of the interview and how much information the respondents reveal without being prompted. In some interviews, probes will be administered throughout the interview, and for others they will be administered after completing the questionnaire.

We propose paying participants $50, which is $10 over our standard payment. Given the length of the cognitive interview (90 minutes vs. our traditional 60 minute interview), that the targeted population is small and unique, and given the sensitive nature of the questions we hope the extra $10 above our $40 standard payment will encourage respondents to participate in the study. In total, for this project, the maximum respondent burden will be 90 hours of interviewing in addition to travel time.

After the interview, respondents will be given the thank-you letter signed by the Director of NCHS, a copy of the informed consent document, and $50.

Because the interviews contain sensitive information and the respondent's voice will be on the tape, the respondent will <u>not</u> be asked for Special Consent for Expanded Use of Video and Audio Recordings which would allow QDRL staff to play the tape at conferences as part of a presentation, for students, or for other people who write survey questions.

Extreme care will be taken with all tapes and paperwork from the interviews conducted off-site. Tapes and identifying paperwork will be stored in a secured travel case until returned to NCHS, at which point they will be transferred to the usual secured locked storage cabinets.

An updated burden table for this project is shown below:

Projects	**Number of Participants**	**Number of Responses/ Participant**	**Average hours per response**	**Response burden**
QDRL Interviews				
2) NCHS Surveys	60	1	1.5	90

Attachments (3)
cc:
M. Moien
C. Walker
S. Perryman