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

October 25, 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 evaluate the Blood Donor History Questionnaire for the Office of the Assistant Secretary for Health (OASH).

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: Blood Donor History Questionnaire Evaluation Study

Before every donation of blood, potential donors are asked questions about their medical history, high-risk behavior, and potential exposure to transfusion of transmissible diseases. These questions ensure that donation procedure is safe for the donor and ensure that the donated product is safe and effective for the patient. FDA has required or recommended that certain information be obtained about donors' health history in its regulations or guidance documents. FDA's five overlapping layers of safety include: 1) donor eligibility; 2) donor deferral and registries; 3) infectious disease testing; 4) quarantine of unsuitable product; and 5) investigation of adverse events.

An evaluation study of the Blood Donor History Questionnaire is needed to determine the interpretive and cognitive processes used by potential donors when responding to donor form deferral questions and specifically to examine the response processes to better understand the implications of a policy change regarding blood donor deferral policy for Men who have Sex with Men (MSM).

The Blood Donor History Questionnaire that we are evaluating appears as Attachment 1. The testing procedure will conform to the cognitive interviewing techniques that have been described in our generic OMB clearance package.

As many as one hundred 60-minute cognitive interviews may be conducted with adults aged 18 years and over who have ever thought about giving blood, have been deferred from giving blood for any reason, or who have successfully given blood in the past, and men aged 18 years and over who have had sexual contact with another man at least once in their life. In addition, we hope to recruit respondents with demographic variety (particularly in terms of education, race/ethnicity, and income). Only individuals who agree to be audio taped will be eligible to participate in the study.

We plan to recruit respondents through advertisements and flyers, flyers distributed at blood donation centers and Lesbian Gay Bisexual Transgender (LGBT) centers, staff at blood donation centers and LGBT community centers, and by word-of-mouth. The advertisement/flyer used to recruit respondents aged 18 years and over who have ever thought about giving blood, have been deferred from giving blood for any reason, or who have successfully given blood in the past appears as Attachment 2a. The flyer distributed at blood donation centers and staff at blood donation centers used to recruit potential blood donors aged 18 years and over appears as Attachment 2b. The advertisement/flyer used to recruit men aged 18 years and over who have had sexual contact with another man at least once in their life appears as Attachment 2c.

Cognitive interviews will be conducted by QDRL staff and may be conducted in the QDRL, blood donation centers, community centers, or mutually agreeable location in the greater Washington, DC and Baltimore areas and possibly another location outside of the Washington, DC and Baltimore area which will be determined at a later time by the Blood Donor Evaluation Study Workgroup. Interviews conducted in blood donation centers will be conducted after the individual has either donated blood or they have been deferred.

The study will be conducted anonymously. QDRL Staff will collect <u>minimal</u> 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.

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.

We propose paying respondents $50 for their participation, which is $10 over our standard payment. Given the recruitment is targeted, i.e., blood donors and men to have sex with men (MSM) we hope the extra $10 above our $40 standard payment will increase participation, reduce the number of cancelations, and maximize time and travel in a particular location.

At the end of the interviews, participants will be paid and provided with copies of all papers they signed.

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.

In total, for this project, the maximum respondent burden will be 100 hours of interviewing in addition to travel time. 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) Other questionnaire testing	100	1	1	100

Attachments (2)
cc:
M. Moien
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DHHS RCO