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

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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. 06/30/2015) plans to conduct research to evaluate the Uniform Donor History Questionnaire for CDC's Office of Blood, Organ, and other Tissue Safety (BOOTS).

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: Cognitive testing of the Uniform Donor History Questionnaire

Before every organ and tissue donation, individuals most knowledgeable about the donor are asked to provide information about the potential donor including questions on their medical history, sexual history, travel history, etc. These questions ensure that the donated organs and tissues are safe for the recipient.

The Uniform Donor History Questionnaire has never been cognitively tested or qualitatively validated. An evaluation study of the Uniform Donor History Questionnaire is needed to determine the interpretive and cognitive processes used by individuals when responding to questions about the donor. The goal of the cognitive testing is to develop a standardized questionnaire that could be used across all organ or tissue procurement organizations.

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

Prior to the start of conducting cognitive interviews, Dr. Stephanie Willson, principal investigator on the project will receive training from the Living Legacy Foundation or a similar organ or tissue procurement organization on how to specifically conduct interviews with individuals who are asked to respond to questions about the donor's medical history, sexual history, travel history, etc. Dr. Willson will also observe interviews conducted by organ or tissue procurement organizations with individuals who have lost a loved one within a 24 hour period.

In evaluating the Uniform Donor History Questionnaire, Dr. Willson plans to conduct 60-minute interviews with 45 respondents aged 18 years and older. Interviewing will occur in three rounds of 15. This iterative approach builds flexibility into the study. As Dr. Willson gains insight into how people understand the questions, she can fine tune the investigation and explore relevant, and potentially unforeseen, issues. To accomplish this goal, analysis will be performed at the end of each round and then inform the next.

Round 1

The first round of cognitive testing will be used to obtain an overview of how the questionnaire performs. The goal is to capture general issues and gain an overview of interpretations and difficulties that might create response error. As many as fifteen 60-minute cognitive interviews may be conducted in the QDRL with respondents 18 years and over from the general population with a range of demographic characteristics. Only individuals who agree to be audio taped will be eligible to participate in the study. We plan to recruit respondents 18 years and over through advertisements & flyers (Attachment 2a), and word-of-mouth.

Round 2

The second round of testing will begin to focus on respondents who have experienced the recent loss of a loved one. Interviewing people in a state of grief will begin to illuminate how the questionnaire performs under more realistic conditions. As many as fifteen 60-minute cognitive interviews may be conducted in the QDRL with respondents 18 years and over who have lost a loved one in the past 12 months. Only individuals who agree to be audio taped will be eligible to participate in the study. We plan to recruit respondents 18 years and over who have lost a loved one in the past 12 months through advertisements & flyers (Attachment 2b), and word-of-mouth. At the conclusion of the interview respondents will receive two handouts to assist individuals in locating bereavement services: 1) the Maryland Grief/Loss Therapists (Attachment 3a); and 2) Support Resources: Local and National Support Groups produced by the Living Legacy Foundation of Maryland (Attachment 3b).

Round 3

The third, and final, round will evaluate how the questionnaire performs under the most realistic scenarios possible. Within the first 24 hours of losing a loved one, people are in a state of shock. This frame of mind has been shown to affect memory and response patterns. With that in mind, as many as 15 cognitive interviews will be conducted with respondents who are historians for "Donors in Spirit" – those who wanted to donate but cannot donate due to illness such as certain cancers or HIV. Interviews would occur within roughly 24 hours of losing the loved one. Recruitment of respondents will be done in coordination with procurement centers local to the DC/Baltimore metro area that are willing to assist with recruitment, e.g., the Living Legacy Foundation. Procurement Centers will read a statement about QDRL's study (Attachment 2c). If the respondent is interested in participating in the validation study, the Procurement Center will contact Dr. Willson to set-up an appointment to meet the respondent. Upon meeting the

potential respondent, Dr. Willson will explain the study in more detail. If the respondent agrees to participate in the study and agrees to be audio recorded, the respondent will be asked to read the Waived Signed Informed Consent form. At the conclusion of the interview, respondents will receive four handouts which Procurement Centers routinely provide to the historians of "Donors in Spirit" to assist with next steps and to assist individuals in locating bereavement services. The four handouts include: 1) Maryland Grief/Loss Therapists (Attachment 3a); 2) Support Resources: Local and National Support Groups produced by the Living Legacy Foundation of Maryland (Attachment 3b); 3) What to do when a love one dies: A survivor's checklist (Attachment 3c); and 4) What Now? Practical Help After the Death of a Love One, produced by the Living Legacy Foundation of Maryland (Attachment 3d). Respondents who express the need for additional help will be referred to the family services coordinator at the procurement organization.

Finally, because iterative methodology is designed to be responsive to emergent findings, the sample and recruitment plan may be altered as indicated by findings at the end of round one and/or round two.

The study will be conducted 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.

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.

We propose paying participants $40, which is our standard payment. At the end of the interviews, participants will be paid and provided with copies of all papers they signed. Participants in rounds 2 & 3 will be given the materials as described in the Round 2 and Round 3.

In total, for this project, the maximum respondent burden will be 45 hours of interviewing in addition to travel time. The burden is already accounted for in the generic clearance. An updated burden table for this genIC project is shown below:

Projects	**Number of Participants**	**Number of Responses/ Participant**	**Average hours per response**	**Response burden**
QDRL Interviews				
2) Other questionnaire testing	45	1	1	45

Attachments (3)
cc:
M. Moien
T. Richardson
DHHS RCO