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 10, 2008

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) plans to oversee cognitive testing, analysis and focus groups of the Transgender HIV Behavioral Survey for CDC/National Center for HIV, STD & TB Prevention (NCHHSTP) through an Interagency Agreement (under OMB No. 0920-0222, exp. 02/28/10). Primary testing will be conducted by RTI International. Advertising for volunteer participants will start February 15, and testing as soon as possible after that.

Under the Interagency Agreement, the QDRL will: 1) develop a protocol for data collected by RTI (e.g., moderator's guide, cognitive interview probes and specific data to collect during interviews); 2) develop a plan for data analysis to be conducted by RTI (summary of findings for each question along with a systematic review within and across respondents); 3) train interviewers and moderators on the protocol (including the script, data collection spreadsheet, and analysis strategy); 4) monitor data collection (ensure data quality; take possession of confidential data and paperwork at each data collection site; assist in conducting interviews if necessary); 5) ensure quality and completeness of the final report; review and edit drafts of the report; request additional information or re-writes if necessary; provide RTI with an outline to structure the final report; 6) house data (includes audio tapes) at NCHS; 7) participate in calls with RTI to review work, progress, data collection visits, etc.

Background Information about Cognitive Testing of Questionnaires

The methodological design of this proposed study is consistent with the design of typical cognitive testing research. The purpose of cognitive testing is not to obtain survey data, but rather to obtain information about the processes people use to answer survey questions as well as to identify any potential problems in the questions.

Data collection procedures for cognitive interviewing are quite different from survey interviewing. While survey interviewers strictly adhere to scripted questionnaires, cognitive interviewers use survey questions as starting points to begin a more detailed discussion of questions themselves: how participants interpret key concepts, their ability to recall the requested information, and the appropriateness of response categories. Because the interviews generate narrative responses rather than statistics, results are analyzed using qualitative methods. This type of in-depth analysis reveals problems in particular survey questions and, as a result, can help to improve the overall quality of surveys.

Although we rely on focus groups less commonly than individual cognitive interviews, we have found that group discussions can generate useful information about experiences and perceptions that are particularly useful in the early stages of questionnaire development.

Proposed project: Testing and Evaluation of Transgender HIV Behavioral Survey

The goal of the questions is to capture information about the proportion of transgender or gender-variant persons who were assigned a male sex at birth, but who identify, live or present as women (e.g., transgender or gender-variant persons), and who engage in sexual and drug-related HIV risk behaviors. Ultimately, data from the survey will be used to describe the prevalence in risk behaviors, HIV testing, self-reported HIV infection, and the use of HIV prevention services. Data will be used by CDC, health departments, community based organizations, community planning groups and other stakeholders to identify met and unmet needs for HIV prevention services in this population.

The primary focus of our testing will be on evaluating the interpretations male-to-female transgender persons bring to the survey questions. This includes exploring the relevance of question wording and language, the appropriateness of the response option categories, and how well the questions succeed in including eligible persons into the pilot study, while excluding ineligible persons. There will be minimal risk to the participants because they will only be verbally answering questions.

Though the final survey will be administered using Audio-CASI, it is not feasible to program the Audio-CASI until after developing the survey content, and analyzing the focus groups/cognitive interviews. Hence, the instrument will be interviewer administered using hardcopy instruments for the cognitive interview test.

The proposed questionnaire will be asked of persons assigned a male sex at birth, but who identify, live or present as women (e.g., transgender or gender-variant persons). Focus groups and cognitive interviews will be conducted by RTI International in three major cities possibly: San Francisco, CA; Chicago, IL; Atlanta, GA; Houston, TX; Los Angles, CA; or Washington, DC. Participants will be recruited by RTI with the assistance of leaders in the transgender communities where the focus groups and cognitive interviews will take place. Transgender community leaders will ask some potential participants if they are interested in participating in a cognitive interview study/focus group. Those interested will be given an advance flyer, informational letter, or both. (Attachments 1a & 1b) Participants may also be recruited from word-of-mouth.

Recruitment will focus on African American and Latino persons, because most of the funds for the survey were through the Minority AIDS Initiative (MAI). These funds were provided to learn more about the HIV epidemic among African American and Latino populations in the United States. Within these constraints, RTI hopes to recruit participants with some demographic variety (e.g. age and education).

The study will be conducted anonymously, and waived signed-informed consent will be employed. RTI will collect minimal personal identifiers in order to recruit participants. A first name and a contact telephone number for reminder calls, if available, may be used—however, no other personal identifiable data will be collected. First name and phone numbers collected as part of the recruiting and scheduling process will be destroyed within 30 days of the completed focus groups/interviews.

Focus groups and cognitive interviews will be conducted in a private room of an RTI facility or in a private room of a community-based organization or a professional facility with a one-way mirror. Focus groups and the cognitive interviews will be recorded on audio tape. An NCHS QDRL staff person will observe the focus groups and the cognitive interviews from behind a one-way mirror in an adjacent room to ensure that RTI staff are following NCHS guidelines for conducting focus groups and cognitive interviews. An RTI staff person will serve as note taker for the focus groups, and will also be seated

behind a one-way mirror in an adjacent room. Only observers specifically outlined in the informed consent form will be allowed to observe the focus groups and the cognitive interviews.

Participants will be informed of taping procedures in the informational letters, during the telephone screening process, and in the process of reviewing the waived-signed consent forms prior to the start of the focus groups and the cognitive interviews. Participants will also be informed of the observers in the adjacent room behind the one-way mirror.

RTI will conduct four focus groups with as many as 32 participants (4 groups of 8) for 90 minutes each, and conduct cognitive interviews with as many as 40 participants for 60 minutes each. The introduction to the focus groups is shown in Attachment 2, and the introduction to the cognitive interviews is shown in Attachment 3.

At the end of the focus groups/cognitive interviews, participants will be paid and provided copies of the consent form. All consent forms and audio tapes will be turned over to an NCHS staff person for safekeeping and stored in a secure travel case until they are returned to NCHS at which point tapes and materials will be transferred to secured locked storage cabinets at NCHS.

We propose paying participants $50. Our approved base incentive is $40. However we hope that the increased incentive will be sufficient to entice this hard-to-reach group of African American and Latino transgender or gender-variant persons to participate in our study. In a QDRL study conducted in 2005 to assess how well questions captured accurate information about sexual identity (heterosexual, homosexual, bisexual), a $50 incentive proved to be successful in recruiting a diverse group in order to properly test the questions.

In total, for this project, the maximum respondent burden will be 88 hours of interviewing (32 people at 90 minutes for each focus group (48 hours) plus 40 people at 60 minutes each (40 hours), 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	40	1	1	40
Focus Groups	32	1	1.5	48
Total				88

Attachments (3)
cc:
M. Moien
M. Daneshvar
S. Perryman