

**Supporting Statement B
for
Request for Generic Clearance for
Cognitive Interviews and Focus Groups for the
Population Assessment of Tobacco and Health
(PATH) Study (NIDA)**

October 7, 2015

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B. STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods

Cognitive interviews and focus groups are qualitative methods that are used to assess new and emergent concepts, to inform measure development, and to identify potential issues in the wording or phrasing of questions that may lead to inaccurate or inconsistent responses. For the PATH Study, focus groups are important for exploring tobacco-related concepts (e.g., emerging tobacco products and product use behaviors), consumer language used to describe various tobacco products, and the beliefs and attitudes people have about using such products. Cognitive interviews involve the detailed consideration of how participants interpret key concepts, their ability to recall the requested information, and the appropriateness of response categories. Cognitive interviews and focus groups play an essential role in the development and revision of questionnaire items that are included in the PATH Study's instruments and materials.

Data collection procedures for cognitive interviews and focus groups are qualitative in nature. In focus groups, trained moderators use moderator guides and probes to engage participants in a discussion of emerging, novel, or potentially unfamiliar concepts, terms, and phrases. In cognitive interviews, words, images, questions, and response options are presented to an individual to elicit open-ended responses, followed by tailored probing to engage the individual in discussing the meaning of the item. Both methods generate open-ended verbal responses rather than statistical estimates, and results are analyzed using qualitative methodologies.

Sampling for cognitive interviews and focus groups is purposive and nonrandom, although every effort is made to recruit participants who are demographically diverse, such as by age, gender, and race/ethnicity. The purpose of the particular substudy, such as to probe attitudes about use of a specific tobacco product, also affects sample selection. However, most of the substudies under this Generic Clearance will seek to recruit a variety of participants, including current and former tobacco users, users of a diverse range of tobacco products (e.g., cigarette,

pipe, cigar, hookah, and e-cigarette users), and individuals ages 12 years and older.

Cognitive interviews and focus groups are important sources of information for the PATH Study that can help to improve its instruments and data collection protocols with a small sample of respondents before fielding to the entire cohort. In this way, the PATH Study is able to reduce potential sources of non-sampling error and minimize respondent burden associated with questionnaire items that are unclear or ambiguous.

B.2 Procedures for the Collection of Information

Recruitment. Recruitment for cognitive interviews and focus groups will normally be by means of advertisements (e.g., Craigslist, newspapers, or flyers posted in public locations), which can be an effective means to attract diverse numbers of potential participants.¹ The advertisement or flyer may include the topic area or theme, estimated time involved, incentive amount, and other information about the cognitive interview or focus group session, including the types of respondents sought to participate. Occasionally, church groups, employers, and/or social or service organizations will be contacted directly to help recruit potential participants. In such cases, a flyer will be provided to a contact person to post in a prominent location or distribute to members of the organization. Each substudy request submitted under this Generic Clearance will include any advertisements, introduction email messages, or scripts that are planned for fielding calls from potential participants.

Screening and Scheduling Procedures. In response to flyers or advertisements, interested persons will call a listed telephone number, and usually leave contact information (name and telephone number) on voicemail. The responsible contact person, labeled the Project Recruiter, will call the person back, give a brief description of the nature of the study (e.g., face-to-face interview, self-

¹ For cognitive interview and focus group sessions in the Washington, DC area, NIDA's contractor typically will directly recruit participants. For sessions outside of this area, the contractor may engage focus group facilities to recruit participants using the approaches and materials approved by OMB for a given substudy.

administered or in-depth interview, focus group), where the interview or group will take place, video/audio taping procedures, and the incentive to be offered for completing an interview or group. First, the recruiter will determine through a brief series of questions whether the participant possesses the desired characteristics (e.g., gender, age, and educational level). If the participant does meet the selection criteria and agrees to complete a cognitive interview or focus group, he/she will be scheduled for an interview or group. Telephone numbers and minimal demographic information (e.g., gender, age, and race/ethnicity) are obtained for all scheduled participants. For those callers who are ineligible for the study (e.g., because they are in the PATH Study cohort, are under 12 years old, or are non-tobacco users) or no longer interested after hearing a description of the research, no identifying information will be retained. Recruitment data will be maintained in separate, encrypted files, with password protection and access limited to authorized personnel. Any hard-copy data will be stored in locked files at the contractor's facilities.

Methods for Cognitive Interviews. After an interview is scheduled, the participant will usually travel to the location of the activity (whether contractor office or another location). On rare occasions, a participant may be unable to travel to the intended location (e.g., an individual may be housebound or have limited mobility). In such cases, the interview may be conducted in his/her home or at a location normally frequented by the participant, such as a senior center. To reduce the number of "no shows" for cognitive interviews, participants scheduled more than a week in advance will receive a reminder telephone call by the recruiter a day or two prior to the scheduled interview.

When the participant arrives, he/she will be greeted by a project coordinator/representative or the interviewer. The participant will then be brought to the interview room and asked to read a consent form. The consent forms and, as needed, parent permission and youth assent forms, will be included with each request submitted to OMB under this generic clearance. In the rare instance that the participant consents to the cognitive interview, but not to recording it, the session will be carried out but not recorded. If the participant consents to record the interview but changes his/her mind while the session is being recorded, the interviewer will stop the recording equipment, but will ask

the participant for consent to retain the interviewing materials and the portion already recorded. If the participant does not give oral consent, the entire recording will be destroyed immediately after the interview.

The interview will begin with the interviewer reading a more detailed explanation of the purpose and the procedures to be used. Interviewing procedures vary depending on the specific technique to be applied. The selection of technique is determined by the nature of the project, or the stage of development of the questionnaire or set of questions under study. The most commonly used method is the concurrent think-aloud interview with interviewer probing. In these interviews, participants are presented with questions and response categories, and asked to think aloud about how and why they answered as they did. The interviewer usually probes extensively to ascertain the degree of comprehension and the recall processes involved.

If possible, the cognitive interview will be conducted in the mode intended for the instrument. For an ACASI interview, for example, the participant would complete items on a computer with a headset and an interviewer would ask questions about his/her experience with the laptop computer and about the content of the items they answered, and an interviewer may observe the participant as he/she interacts with the computer.

During the conduct of a cognitive interview, if the interviewer observes emotional stress in the participant (e.g., in response to questions that elicit thoughts related to experiences of personal trauma), he/she will stop the interview and ask if the participant would like to take a break, terminate the interview, or continue.

Methods for Focus Groups. If a participant is scheduled, he/she will travel to the location of the activity (whether contractor office or another location). When participants arrive they will be greeted by staff working on the project and directed to the interviewing location, where they will be greeted individually by the focus group moderator. Participants will be seated around a table.

The moderator will introduce the study and outline the elements of consent. Participants will be asked to complete a consent form. Once the forms have been completed, they will be returned to the focus group moderator. In the rare instance that consent is not granted and an individual cannot participate, he or she will be excused and receive the agreed upon incentive. The moderator will lead the group's semi-structured discussions based on the focus group protocol, with the moderator posing questions and topics for discussion and probing participant responses as needed. The protocol will be included in the substudy memo submitted to OMB under this Generic Clearance.

Incentives. As described in section A.9, substudies under this Generic Clearance will offer an incentive to participants as a thank you for their participation. They will be asked to sign a receipt form indicating receipt of the remuneration. Immediately following the interview or focus group, the data collection sheet will be separated from the consent form, so that no demographic information will be associated with the individual's name. Signed consent forms will be stored separately from any data collected from the participant. Again, specific steps to be taken by each project will be specified in the substudy request submitted to OMB under this Generic Clearance.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

Advertisements in local newspapers and flyers can attract a large pool of potential participants. Direct contact to solicit support from community centers, church groups, employers, and/or social or service organizations will be explored as possible recruitment methods. Incentives will be offered to thank participants for their time and contributions to the cognitive interview or focus group session. To minimize missed appointments, substudy staff will make a reminder call to participants before the scheduled session. According to staff at the Questionnaire Design Research Laboratory (QDRL) of the National Center for Health Statistics (NCHS), the “show rate” for on-site scheduled interviews has generally been between 80 and 90 percent, across a wide range of studies.

B.4 Tests of Procedures or Methods to be Undertaken

This substantive revision request is for a 3-year approval to conduct cognitive interviews and focus groups under the PATH Study's Generic Clearance for Cognitive Interviews and Focus Groups (OMB number 0925-0663) to inform the development and refinement of questionnaire items and materials. These qualitative methods have been used routinely to enhance the content and quality of population-based surveys, such as by the National Center for Health Statistics Questionnaire Design and Research Laboratory, the Census Bureau, the Bureau of Labor Statistics, and by private research organizations over the past 20 years. The PATH Study successfully used cognitive interviews and focus groups for these purposes for Waves 1, 2, and 3 of data and biospecimen collection; the Study refined its specific techniques for Waves 2 and 3, based on experience with cognitive interviews and focus groups for a previous wave.

B.5 Individuals Consulted on Statistical Aspects and Individuals Analyzing Data

Consultants from the prime contractor's instrument design, evaluation, and analysis group will provide statistical and technical expertise on the substudies conducted under this Generic Clearance (see Attachment 5).