

TO: Office of Management and Budget (OMB)
Through: Reports Clearance Officer, DHHS
Project Clearance Chief, NIH
Project Clearance Liaison, National Institute on Drug Abuse (NIDA)

FROM: Kevin P. Conway, Ph.D.

SUBJECT: Request to Conduct Focus Groups to Support Development of E-cigarette and Hookah Questionnaire Items under OMB Control Number 0925-0675, Expiration Date 5/31/2016, Generic Clearance for Methodological Studies in the Population Assessment of Tobacco and Health (PATH) Study (NIDA)

The National Institute on Drug Abuse (NIDA) plans to conduct focus groups under OMB Control Number 0925-0675, expiration date 5/31/16, Generic Clearance for Methodological Studies in the Population Assessment of Tobacco and Health (PATH) Study (NIDA). The purpose of these focus groups is to develop new items and update current items on e-cigarette and hookah use for the PATH Study's questionnaires.

Circumstances Making the Collection of Information Necessary

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (referred to herein by TCA) became law. The TCA authorizes the Food and Drug Administration (FDA), through the Center for Tobacco Products (CTP), to regulate tobacco products, including, for example, tobacco product standards, constituents, labeling, marketing practices, advertising, and promotional activities to appeal to youth. Fulfilling the mandates of the TCA, FDA's CTP requires a solid evidence base that informs their regulatory decisions, their implementation, and subsequent assessments of their effectiveness, as well as their future regulatory decisions and actions.

Under data collection authorization of Title 42 USC 285o, NIDA is partnering with FDA's CTP to enhance this evidence base by conducting the national longitudinal cohort study known as the PATH Study. The PATH Study uses automated computer-assisted interviews (ACASI) to collect baseline and follow-up information from youth ages 12-17 and adults ages 18 and older on a number of issues, including use of existing and emerging tobacco products; attitudes and perceptions toward use of different tobacco products; knowledge of the contents of tobacco products and of the health consequences of their use; tobacco-use cessation attempts, cessation outcomes, and rates of relapse; uptake of new products, product/brand switching, and dual-and-poly-use of tobacco products; and health conditions, including those potentially related to tobacco use, particularly to the use of new and emerging products. The PATH Study is also collecting biospecimens from adults to assess biomarkers of tobacco exposure and indicators of tobacco-use related health conditions and disease processes.

Purpose and Use of the Information Collection

The objective of this methodological sub-study is to develop new and update current items in the PATH Study's questionnaires to help capture the universe of e-cigarette and hookah use behaviors in the PATH Study cohort. Specifically, its focus is on developing and updating items for: (1) accurately measuring dose and frequency of e-cigarette and hookah use; (2) describing e-cigarette and hookah devices and accessories; and (3) accurately assessing purchasing habits, modification of devices, or other behaviors associated with use of e-cigarettes and hookah. The sub-study will include eight focus groups (four e-cigarette groups and four hookah groups of approximately eight individuals each). The e-cigarette focus groups will be conducted online and the hookah groups will be conducted online and in person. The focus group moderator will ask group participants to describe and identify e-cigarette and hookah devices, accessories, and behaviors (specifically with regard to dose and frequency of use). They will also be asked for input on the wording of questions about purchasing behaviors for these devices and/or how questions can be asked to distinguish e-cigarette and hookah use behaviors from those associated with use of other types of tobacco products.

Sample Selection. The sub-study will include eight focus groups: four groups of e-cigarette users and four groups of hookah users. The e-cigarette and hookah user groups have different sample selection procedures and criteria that were created to ensure recruitment of people with sufficient experience with e-cigarettes or hookah to yield meaningful information to inform the PATH Study. Building upon extensive past experience with focus group research, the research team chose to conduct four focus groups of e-cigarette and hookah users to allow data collection to reach saturation. Saturation is the point in qualitative data analysis when new participants repeat what previous participants have said and very little new data is revealed in the focus groups. This sub-study will employ two focus groups of similar types of e-cigarette users (two groups of dual users and two groups of exclusive users) and four groups of hookah users, to increase the likelihood that saturation will be achieved. The sub-study will not hold more than four focus groups per tobacco product for a total of eight focus groups.

E-cigarette focus group sample selection. There will be a total of four e-cigarette user focus groups. Two of the e-cigarette groups will include dual e-cigarette/cigarette users, and two will include exclusive e-cigarette users. E-cigarette users will be recruited in online e-cigarette user forums and on Craigslist. Additionally, users will be recruited via fliers at tobacco shops, vapor lounges, and local college campuses. (See Attachment A for the recruitment materials, which include an on-line forums/Craigslist notice and a flyer.) To be eligible for the dual cigarette/e-cigarette user focus groups, participants must use cigarettes and e-cigarettes at least weekly for the past three months. To be eligible for the e-cigarette exclusive user focus groups, adult participants must use e-cigarettes every day or some days for at least the past three months and may not report cigarette smoking more than once a month for the past three months.

Hookah focus group sample selection. There will be a total of four hookah user focus groups. Hookah users will be recruited for both the online and in-person focus groups by way of online forums and on Craigslist; and via fliers at tobacco shops, hookah lounges, and local college campuses. (See Attachment A for the recruitment materials, which include an on-line

forums/Craigslist notice and a flyer.) Adult respondents who report any hookah use in the past three months will be eligible to participate, regardless of their other tobacco use.

The sub-study plans to recruit approximately eight individuals for each focus group. Interested participants who contact the study will be asked a series of screening questions to identify eligible e-cigarette and hookah users and verify their access to a computer and an email address to accept the email invitation to the focus group (for online groups only). (See Attachment B for the screening questionnaire.) Persons selected to participate in a focus group will be contacted by the study and scheduled for their focus group session. Individuals will be scheduled to ensure maximum diversity by age, gender, and race/ethnicity in each group.

Data Collection. All four e-cigarette user focus groups and two of the four hookah user focus groups will be held online using conferencing technology (WebEx). Use of online versus in-person focus groups opens recruitment to all regions in the United States, rather than restricting recruitment to the Washington, D.C. metro area. This may also help to identify e-cigarette and hookah use terms that are salient to users in areas outside the Mid-Atlantic region. In addition to the online focus groups, two in-person focus groups will be held with local hookah users. Half the hookah user focus groups will be held in-person because hookah use is more common than dual or exclusive e-cigarette use,¹⁻⁴ and previous experience with hookah users suggests that illegal drug use (e.g., marijuana use) or other sensitive topics may be more likely to emerge in the hookah user groups than in the e-cigarette user groups. Sensitive topics such as illegal drug use are generally better addressed in person rather than online. See Table 1 for a summary description of the sub-study’s focus groups by data collection mode and tobacco product.

The use of the Internet in data collection may result in recruitment of e-cigarette and hookah users who are not representative of all such users. However, this small-scale, qualitative study is not designed to yield conclusions that will be generalizable to all e-cigarette and hookah users. Rather, the purpose of this study is to develop new and update current items in the PATH Study’s questionnaires to help capture e-cigarette and hookah use behaviors.

Table 1. Number of focus groups by data collection mode and tobacco product use

	Number of online focus groups	Number of in-person focus groups	Total
E-cigarette exclusive users	2	---	2
Dual e-cigarette users	2	---	2
Hookah users	2	2	4
Total	6	2	8

This sub-study will employ focus groups of approximately eight people each. Focus groups will be conducted by a highly experienced moderator using moderator's guides. (See Attachments C, D, and E for the moderator's guides.) Focus groups will last approximately 1.5 hours and are structured to include time for group discussion in response to the moderator's questions. Additionally, the hookah focus groups will employ a picture of a hookah to facilitate discussion of terms associated with different parts of the apparatus. Institutional Review Board (IRB) approval was granted on 9/9/2013 by Westat's IRB (see Attachment F).

Informed consent. The informed consent process for the in-person and online groups are similar, but not identical. Westat's IRB granted a waiver of written informed consent for the online focus groups because the research is low-risk and obtaining written consent for the online focus groups poses a logistical challenge.

In-person focus group participants will review the informed consent document (see Attachment F) with the aid of the focus group moderator and sign the form before participating in the focus group. At the time of consent, the moderator will also ask permission to audio record the interview. Should an individual refuse informed consent or decline to be audio recorded, s/he will be excused from participation and thanked for his/her time.

Online focus group participants will give oral consent to participate in this sub-study. At the start of each online focus group, the focus group moderator will read informed consent language to the participants and obtain verbal consent (see Attachments C and E). At the time of consent, the moderator will also ask permission to audio record the interview. Online focus group participants will be asked to ensure that they are in a quiet, private place and able to participate without interference from others. Should an individual refuse informed consent, decline to be audio recorded, or be unable to participate in an online focus group because of his or her setting, s/he will be excused from participation and thanked for his/her time.

Incentive Payment. The sub-study will offer the Federal standard incentive of \$40.00 to each focus group participant. The payments are provided to thank the participants for their time and contributions to the study. At the completion of an online focus group, participants will receive a check for \$40.00 sent by Federal Express; at the completion of an in-person focus group, participants will receive \$40.00 in cash.

Data Analysis. The sub-study will transcribe and de-identify focus group recordings, which will then be reviewed and coded independently by at least two study researchers using the constant comparative method. In this method, codes reflect the categories from the moderator's guides and *in vivo* codes from themes that arise during the course of data analysis.⁵ Coding is done individually and later compared; conflicts in coding are then discussed and resolved by the researchers using an iterative process. The questions and topics in the moderator guides will provide the framework for data analysis (see Attachments C, D, and E).

Use of Information Technology to Reduce Burden

The PATH Study will apply new technologies to improve data quality and utility while also reducing respondent burden and controlling study costs. Online focus groups will be conducted

using WebEx. WebEx is an online conferencing technology that is a cost-effective way to hold meetings among individuals in different locations. This method of data collection will reduce participant burden, allow for participation of individuals from diverse locations in the U.S., and save time and money that would otherwise be spent to travel participants to the study site.

Efforts to Identify Duplication

Data collected for this sub-study are specific to the methodological needs of the PATH Study (i.e., to develop new and update current questionnaire items on e-cigarette and hookah use for the PATH Study's data collection). The sub-study complements a study that is requesting approval of OMB under the CTP's Generic Clearance (0910-0497) "Other Tobacco Products (OTP): A Focus Group Study." This study seeks to inform CTP's efforts to implement the provisions of the TCA related to educating the public about the harms of tobacco use. It is an exploratory study of consumers' attitudes and beliefs about non-cigarette tobacco products such as e-cigarettes and hookah, including their reasons for use; perceptions of how the products compare to conventional tobacco products; and knowledge and beliefs about health effects and addictiveness. In addition, the study seeks to explore perceived social norms regarding these products, including use and attitudes among friends and family, and other sources of information about the products. By contrast, the PATH Study's sub-study is methodological in scope and specific to its need to develop new and update existing items on e-cigarette and hookah use behaviors for its future questionnaires. The PATH Study's sub-study sample is also restricted to e-cigarette and hookah users who identify as experienced users (as opposed to new or experimental users) and includes online data collection to expand the possible recruitment pool.

Consequences of Collecting the Information Less Frequently

Little is known about e-cigarette and hookah use in the U.S., given how recently these products have appeared in the current tobacco product market. The PATH Study provides a timely opportunity to collect population-level data on use behaviors associated with these products. This methodological sub-study is planned in the spring of 2014 so that its findings will be available in time to inform the PATH Study's questionnaires for the second follow-up wave of data collection. The consequences of not conducting this methodological sub-study as described herein are that its findings would not be available to meet the PATH Study's needs for reliable and valid measures on e-cigarette and hookah use behaviors to include in its questionnaires for the second wave of data collection.

Assurance of Confidentiality Provided to Respondents

Participation in the proposed sub-study is voluntary. Personally identifiable information (PII), including names and contact information, will be collected for the purpose of selecting and scheduling eligible participants for focus groups and for sending incentives to online participants at the conclusion of the focus group. PII will not be associated with data collected during the focus group, and will be destroyed after the focus group is finished. PII for eligible individuals not selected for a focus group will be destroyed immediately. The data collection materials (Attachments A-E) used in this sub-study have been reviewed and approved by the Westat Institutional Review Board (IRB) to ensure the protection of human subjects. (See Attachment F for Westat's IRB approval letter and consent form.)

Estimates of Hour Burden Including Annualized Hourly Costs

The average annual hour burden for the proposed sub-study is presented in Table 2 for each activity (screener, consent, and focus group participation).

Table 2. Annualized hour burden estimates

Data Collection Activity	Estimates of Annual Hours Burden				
	Type of Respondent	# of Respondents	# of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Screening	Adults	90	1	10/60	15
Informed consent	Adults	64	1	4/60	4
Focus groups	Adults	64	1	90/60	96
Total					115

The estimates for hourly wage of adult respondents (Table 3) are based on the national median hourly estimate for all occupations reported in the Bureau of Labor Statistics' Occupational Employment Statistics, May 2012 National Occupational Employment and Wage Estimates United States. (See http://www.bls.gov/oes/current/oes_nat.htm.)

Table 3. Annualized cost to respondents

Data Collection Activity	Annualized Cost to Respondents						
	Type of Respondent	# of Respondent	# of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours	Hourly Wage Rate	Respondent Cost
Screening	Adults	90	1	10/60	15	\$16.71	\$251
Informed consent	Adults	64	1	4/60	4	\$16.71	\$67
Focus groups	Adults	64	1	90/60	96	\$16.71	\$1,604
Total					115		\$1,922

List of Attachments

- A. Recruitment materials
- B. Screening questionnaire
- C. E-cigarette focus group moderator's guide
- D. Hookah focus group moderator's guide – in person
- E. Hookah focus group moderator's guide – online
- F. IRB approval letter and consent form

References

1. Pearson J, Richardson A, Niaura R, Vallone D, Abrams D. e-Cigarette awareness, use, and harm perceptions in US adults. *Am J Public Health*. 2012;102(9):1758-1766. PMID: 3474361.
2. Regan A, Promoff G, Dube S, Arrazola R. Electronic nicotine delivery systems: adult use and awareness of the 'e-cigarette' in the USA. *Tob Control*. 2011;22(1):19-23. PMID: 3524053.
3. [King BA](#), [Dube SR](#), [Tynan MA](#). Current tobacco use among adults in the United States: findings from the National Adult Tobacco Survey. *Am J Pub Health*. 2012;102(11):e93-e100.
4. Primack BA, Shensa A, Kim KH, Carroll MV, Hoban MT, Leino EV, Eissenberg T, Dachtler KH, Fine MJ. Waterpipe smoking among U.S. university students. *Nicotine Tob Res*. 2013;15(1):29-35.
5. Miles M, Huberman, A. *Qualitative Data Analysis: An Expanded Sourcebook*. Sage Publications, Thousand Oaks, CA, 1994.