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 Electronic Nicotine Product and Social Media 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 inform changes and/or improvements of items on (1) exposure to tobacco-related content on social media sites and (2) use of e-cigarette and other electronic nicotine products, both for use in the PATH Study's Wave 4 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 use of tobacco products, particularly new and emerging products. The PATH Study is also collecting biospecimens from adults to assess biomarkers of tobacco exposure and potential indicators of harm related to tobacco use.

Purpose and Use of the Information Collection

Given that the electronic nicotine product marketplace and social media technology are rapidly evolving, it is important to explore concepts and terminology in these domains to inform item development for the PATH Study's Wave 4 questionnaires. This sub-study is intended for that purpose, to conduct focus groups on the use of electronic nicotine products and of social media sites that have tobacco-related content. The sub-study includes 13 focus groups: three groups of dual e-cigarette and cigarette users; three groups of electronic nicotine product polyusers (those who use two or more different electronic nicotine products); three groups of users who modify their electronic nicotine products; and four groups of social media users.

Electronic nicotine product focus groups. These nine groups will address concepts and terminology around: (1) patterns of use among dual users of cigarettes and e-cigarettes; (2) patterns of use among electronic nicotine product polyusers (those who use different electronic nicotine products, such as e-cigarettes and e-hookahs, or different devices, such as disposable and rechargeable); and (3) the modification of electronic nicotine product devices. Focus group moderators will ask participants to describe and identify their electronic nicotine products, behaviors, and modifications. They will also ask for input on the terminology used to refer to varying electronic nicotine product types. All nine of the electronic nicotine product focus groups will be held with adults ages 18 and up.

Social media focus groups. These four groups will explore concepts and terms associated with social media featuring tobacco products and messaging. Moderators of these groups will ask participants about their social media use, exposure to tobacco-related content, and whether they consider this content to encourage or discourage tobacco use. Two of the social media focus groups will be held with youth ages 12-15, and two with young adults ages 18-24.

Sample Selection. The sub-study will include a total of 13 focus groups: nine groups of electronic nicotine product users and four groups of social media users. Focus group facilities will advertise the sub-study to solicit participation, with the goal of recruiting approximately eight to ten individuals for each focus group. In order to meet participation goals, the facilities will invite 10 individuals for each group.

Focus group facilities will recruit participants using their own internal recruiting database, as well as newspaper ads, fliers, and Craigslist ads. Facilities will adapt recruiting strategies as needed to ensure adequate participation. Interested participants who contact the sub-study will be asked a series of screening questions to determine their eligibility. (See Attachment B for screening questionnaire.) No youth will be screened without permission from a parent or guardian. 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. Recruitment screeners can be found in Attachment A.

The focus groups will be conducted in person at research facilities in Denver, CO; Chicago, IL; Boston, MA; Portland, ME; and Rockville, MD. Conducting focus groups at multiple locations across the country facilitates recruitment of diverse participants from different geographic

regions where use patterns and terminology may also vary. In addition, these five locations allow the PATH Study to reduce costs by taking advantage of existing facilities.

Electronic nicotine product focus group sample selection. There will be nine focus groups with electronic nicotine product user. Three of these will be with dual e-cigarette/cigarette or other tobacco product users, three with polyusers of electronic nicotine products, and three with users who modify their electronic nicotine product devices. These focus groups will be conducted in Denver, CO, Chicago, IL, and Boston, MA.

Social media focus group sample selection. There will be four social media focus groups, two with youth (aged 12-15) and two with young adults (aged 18-24). Participants will be eligible if they report that they have a social media account and have seen content related to electronic nicotine products and/or other tobacco products. For young adults, a mix of tobacco users and non-users will be recruited. Tobacco use will not be a criterion for youth participation. Youth participants cannot be screened or participate in the focus group without the signed consent of a parent or guardian and the assent of the youth. The parent or guardian must accompany the youth until the focus group begins. Youth and their parent or guardian may participate in focus groups as long as they are in different groups. The focus groups will be conducted in Portland, ME and Rockville, MD.

Table 1. Number of focus groups by topic and location

Location	Dual Users Focus Group	Polyusers Focus Group	Modifications Focus Group	Social Media Focus Group	Total
Denver, CO	1	1	1	-	3
Chicago, IL	1	1	1	-	3
Boston, MA	1	1	1	-	3
Portland, ME	-	-	-	2	2
Rockland, MD	-	-	-	2	2
Total	3	3	3	2	13

Data Collection. Focus groups will include approximately eight to ten people each. They will be conducted by an experienced moderator using moderator's guides. (See Attachment B for the moderator guides.) Focus groups will last approximately 1.5 hours and will be structured to include time for group discussion in response to the moderator's questions. Additionally, the social media focus group will employ a card sort of pictures of social media posts related to tobacco to facilitate discussion of how these posts encourage or discourage tobacco use. Institutional Review Board (IRB) approval was granted on July 6, 2015 by Westat's IRB (Attachment C).

All focus groups will be audio-recorded with the participants' consent. The audio-recordings will only be accessible to project staff directly working on the project and no names or other personally identifying information (other than the participants' voices) will be included on the audio recordings.

Informed consent. Focus group participants will review the informed consent document (Attachment D) 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.

Youth participants cannot participate in a focus group without the signed informed consent of a parent or guardian and the assent of the youth. Youth will be assured that participant confidentiality means that neither parents nor authorities will have access to any information from the focus group. After obtaining permission/assent, parents will be excused from the room before the focus group begins (parental permission and youth assent forms are in Attachment D).

Incentive Payment. Focus groups under this sub-study are estimated to be 90 minutes in length, which compares to the 60 minutes that is typical for cognitive interviewing. An incentive of $50 is proposed for adult focus group participants and of $30 for youth, which for adults is $10 more and for youth is $5 more than the Federal government's standard remuneration for cognitive interviews. The incentive payments are proposed to thank participants for the 90 minutes of their time and for their contributions to the focus group session. Participants will receive the incentive at the completion of the focus group. The parents and guardians of youth participants will be offered $10.00 in remuneration for travel expenses; note that the parents and guardians will transport their youth to the session, provide written permission for their youth's participation, and wait as their youth participates in the session. They will not participate in the session with the youth or in a different session at the same time as the youth. The $10.00 remuneration offered to parents and guardians of youth is strictly to offset travel expenses incurred for transporting the youth to and from the focus group session.

Data Analysis. The sub-study will use qualitative methods to analyze the focus group recordings, which will be transcribed and de-identified before being reviewed and coded. The focus group transcripts will be analyzed using NVivo qualitative software to help identify common themes that both reflect the categories of the moderator's guides and arise during the course of data analysis. Questions and topics in the moderator guides will provide the framework for data analysis (Attachment B) and serve as the guide to organize the findings and recommendations on items for the PATH Study's Wave 4 questionnaires.

Use of Information Technology to Reduce Burden

The focus group sub-study will utilize technology to facilitate recruitment and the scheduling process while also reducing participant burden and controlling study costs. Recruitment efforts will use email communications when possible because many individuals prefer to communicate via email so they can respond when it is convenient. Using email for recruitment and scheduling

can help to reduce participant burden and save time and money that would otherwise be spent conducting telephone calls, leaving voice messages, and making call-backs.

Efforts to Identify Duplication

Data collected for this sub-study are specific to the needs of the PATH Study to develop and improve items on electronic nicotine product use and exposure to tobacco-related content on social media sites for the Wave 4 instruments. In an effort to maximize the utility of data collected, minimize burden on participants, and comply with HHS standards, the PATH Study collaborates with other tobacco-related data collections supported by the Federal government and reviewed by OMB. NIH and FDA coordinate with the Assistant Secretary for Planning and Evaluation (ASPE) at HHS and with program leads on tobacco-related studies within NIH (e.g., NCI) and at HHS sister agencies (e.g., CDC, SAMHSA) to harmonize questionnaire development activities among tobacco-related data collection efforts. The PATH Study welcomes the feedback of HHS program leads on its focus group plans, and specifically for this sub-study, has sought to incorporate recommended changes, comments, and suggestions by HHS program leads into the final version of this document for OMB review and approval.

Consequences of Collecting the Information Less Frequently

This sub-study is planned for August – September of 2015 so that its findings will be available in time for use in the development of the PATH Study's Wave 4 questionnaires for the fall of 2016. The consequences of not conducting this sub-study as described herein are that its findings on the domains of electronic nicotine products and tobacco-related social media would not be available in time to inform item development for the Wave 4 questionnaires. This could ultimately affect the relevancy, timeliness, quality, and utility of the PATH study data.

Assurance of Confidentiality Provided to Participants

Participation in the focus groups is voluntary. Personally identifiable information (PII), including names and contact information, will be collected for the purpose of selecting and scheduling eligible participants for the focus groups. These data will be securely stored in password protected files to which only project staff will have access, and will be destroyed after the study is finished. Names provided by participants on consent and incentive receipt forms will be stored in locked cabinets, separate from data. 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. Data collection materials (Attachments A, B, D, and E) used for this sub-study have been reviewed and approved by the Westat Institutional Review Board (IRB) to ensure the protection of human subjects. (See Attachment C for Westat's IRB approval letter.)

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

Activity name	Type of Participant	Number of Participants	Number of Responses per Participant	Average Burden per Response (in hours)	Total Annual Burden Hours
Adult Screening	Adult	660	1	10/60	110
Parent Screening	Parent	60	1	2/60	2
Youth Screening	Youth	60	1	8/60	8
Adult Consent	Adult	110	1	4/60	7
Parent Permission	Parent	20	1	4/60	1
Youth Assent	Youth	20	1	4/60	1
Adult Focus Groups	Adult	110	1	86/60	158
Youth Focus Groups	Youth	20	1	86/60	29
Total					316

The estimates for hourly wage of adult participants (Table 3) are based on the national median hourly estimate for all occupations reported in the Bureau of Labor Statistics' Occupational Employment Statistics, May 2014 National Occupational Employment and Wage Estimates United States. (See http://www.bls.gov/oes/current/oes_nat.htm.) The estimates for hourly wage of youth participants (Table 3) are based on the federal minimum wage established in 2009. See http://www.dol.gov/dol/topic/wages/minimumwage.htm.

Table 3. Annualized cost to participants

Activity	Type of Participant	Number of Participants	Number of Responses per Participant	Average Burden per Response	Total Annual Burden Hours	Hourly wage rate	Respondent Cost
Adult Screening	Adult	660	1	10/60	110	$17.09	$1,880
Parent Screening	Parent	60	1	2/60	2	$17.09	$34
Youth Screening	Youth	60	1	8/60	8	$4.45	$36
Adult Consent	Adult	110	1	4/60	7	$17.09	$120
Parent Permission	Parent	20	1	4/60	1	$17.09	$17
Youth Assent	Youth	20	1	4/60	1	$4.45	$4
Adult Focus Groups	Adult	110	1	86/60	158	$17.09	$2,700

Activity	Type of Participant	Number of Participants	Number of Responses per Participant	Average Burden per Response	Total Annual Burden Hours	Hourly wage rate	Respondent Cost
Youth Focus Groups	Youth	20	1	86/60	29	$4.45	$129
Total							$4,920

List of Attachments

Attachment A. Recruitment Screeners

A-1. Electronic Nicotine Product (ENDs) Recruitment Screener

A-2. Social Media Recruitment Screener

Attachment B. Moderator Guides

B-1. Modifications Moderator Guide

B-2. Polyuse and Dual Use Moderator Guide

B-3. Social Media Moderator Guide

B-4. Social Media Card Sort Images

Attachment C. IRB Approval Letter

Attachment D. Consent, Permission and Assent Forms

D-1. Adult Electronic Nicotine Product (ENDs) Consent Form

D-2. Adult Social Media Consent Form

D-3. Parent Permission and Youth Assent Forms