[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; comment request:

Methodological Studies for the Population Assessment of Tobacco and Health (PATH) Study

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 26, 2012, Vol. 77, No. 227, p. 70451 and allowed 60-days for public comment. Two comments were received in support of this request. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: Title*:* Cognitive Testing of Instrumentation and Materials for Population Assessment of Tobacco and Health (PATH) Study. Type of Information Collection Request: New. Need and Use of Information Collection:

The PATH study will establish a population-based framework for monitoring and assessing the behavioral and health impacts of regulatory provisions implemented as part of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) by the Food and Drug Administration (FDA). NIDA is requesting generic approval from OMB for methodological studies to improve the PATH study instrumentation and data collection procedures. These methodological studies will support ongoing assessment and refinement of the PATH study's design, and highlight ways to improve study implementation, data collection procedures, and techniques for retention and followup. Data collection methods to be used in these methodological studies include: in-person and telephone surveys; web and smartphone/mobile phone surveys; and focus group and individual in-depth qualitative interviews. Biospecimens may also be collected from adults.

Frequency of Response: Annual [As needed on an on-going and concurrent basis]. Affected Public: Individuals. Type of Respondents*:* Youth (ages 12-17) and Adults (ages 18+). Annual Reporting Burden: See Table 1. The annualized cost to respondents is estimated at: $371,284. There are no capital, operating or maintenance costs.

Table 1. Estimated Annual Reporting Burden Summary - Methodological Studies for the PATH Study

Data Collection Activity	Type of Respondent	Number of Respondents	Responses Per Respondent	Hours Per Response	Annual Hour Burden
In-person and telephone surveys	Adults	5,000	1	90/60	7,500
	Youth	3,500	1	90/60	5,250
Web and smartphone/mobile phone surveys	Adults	5,000	1	90/60	7,500
	Youth	3,500	1	90/60	5,250
Focus groups and individual in-depth qualitative interviews	Adults	1000	1	2	2,000
	Youth	1000	1	2	2,000
Biospecimen collection	Adults	1,000	1	15/60	250
TOTAL		20,000			29,750

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Blvd., Room 5185; Rockville, MD 20852, or call non-toll free number 301-443-8755 or email your request, including your address to: PATHprojectofficer@mail.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: February 19, 2013.

Glenda J. Conroy
Executive Officer (OM Director), National Institute on Drug Abuse (NIDA)

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