



This document is scheduled to be published in the Federal Register on 03/11/2016 and available online at <http://federalregister.gov/a/2016-05431>, and on FDsys.gov

[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 60-day comment request

Population Assessment of Tobacco and Health (PATH) Study

SUMMARY: In compliance with the requirement of Section 3506(c) (2) (A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

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.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy

of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Kevin P. Conway, Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, NIH, 6001 Executive Boulevard, Room 5185, Rockville, MD 20852; or call non-toll-free number (301) 443-8755 or E-mail your request, including your address, to: PATHprojectofficer@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: Methodological Studies for the Population Assessment of Tobacco and Health (PATH) Study (NIDA), 0925-0675, expiration date 5/31/2016 - **EXTENSION** - NIDA, NIH, in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a request to continue the Population Assessment of Tobacco and Health (PATH) Study's conduct of methodological studies in support of improvements in the Study's approaches for data and biospecimen collection. The PATH Study is a national longitudinal cohort study of tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17; the Study conducts annual or biannual interviews and collects biospecimens from adults and youth to inform FDA's regulatory actions under

the Family Smoking Prevention and Control Act. The methodological studies under this extension will continue to enhance the approaches used by the PATH Study for data and biospecimen collections to obtain high quality and useful data; minimize respondent burden; and achieve and maintain high response, retention, and follow-up rates.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total annualized burden hours are 29,750.

Estimated Annualized Burden Hours

Data Collection Activity	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
In-person surveys	Adults	5,000	1	90/60	7,500
	Youth	3,500	1	90/60	5,250
Web 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	1,000	1	2	2,000
	Youth	1,000	1	2	2,000
Biospecimen collection	Adults	1,000	1	15/60	250
Total		20,000	20,000		29,750

Dated: March 7, 2016.

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Project Clearance Liaison.

NIDA, NIH

[FR Doc. 2016-05431 Filed: 3/10/2016 8:45 am; Publication Date: 3/11/2016]