



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; Comment Request

Cognitive Testing of Instrumentation and Materials for the 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.

PROPOSED COLLECTION: *Title:* Cognitive Testing of Instrumentation and Materials for Population Assessment of Tobacco and Health (PATH) Study. *Type of Information Collection Request:* Generic Clearance. *Need and Use of Information Collection:* The PATH study will establish a population-based framework for monitoring and evaluating 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 cognitive testing of the PATH study's instrumentation, materials to support data collection (e.g., advance mailings, reminder letters, etc.), consent forms, and methods of administration (e.g., computer assisted personal interviews [CAPI], audio computer assisted self-interviews [ACASI], web-based interviews). Cognitive testing of these materials and methods will help to ensure that their design and content are valid

and meet the PATH study's objectives. Additionally, results from cognitive testing will inform the feasibility (scientific robustness), acceptability (burden to participants and study logistics) and cost of the information collection to help minimize its estimated cost and public burden.

Frequency of Response: Annual [As needed on an on-going and concurrent basis]. *Affected*

Public: Members of the public. *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: \$11,861. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Table 1 Estimated Annual Reporting Burden Summary - Cognitive Testing of Instrumentation and Materials for the PATH Study

Instruments/Documents to be Tested	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses Per Respondent	Average Burden Hours Per Response*	Estimated Total Annual Burden Hours Requested
Materials to Support Data Collection	Adult	100	1	1 ³⁰ / ₆₀	150
Assent Forms	Youth	98	1	2	196
Consent Forms	Adult	98	1	2	196
PATH Study Questionnaires	Youth	40	1	2	80
	Adult	130	1	2	260
TOTAL		466			882

*Calculations include one hour of travel time per respondent.

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.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans 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 E-mail 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 60-days of the date of this publication.

Signed _____
David Shurtleff, Acting Deputy Director, NIDA

Dated: May 17, 2012

Certified to be A True Copy

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