



[BILLING CODE 4140-01-P]

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB review; 30-day comment request;

#### 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 for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 6, 2014, pages 7206-7207, and allowed 60-days for public comment. One public comment was received. 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.

**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](mailto:OIRA_Submission@omb.eop.gov) or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT 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.

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: Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Boulevard., Room 5185; or call non-toll-free number (301)-443-8755; or E-mail your request, including your address to: [PATHprojectofficer@mail.nih.gov](mailto:PATHprojectofficer@mail.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

**PROPOSED COLLECTION:** Population Assessment of Tobacco and Health (PATH) Study – Second Wave of Data Collection -0925-0664–Revision- National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a revision request (OMB 0925-0664, expires 11/30/2015) for the Population Assessment of Tobacco and Health (PATH) Study to conduct the second wave of data collection. The PATH Study is a large national longitudinal cohort study on tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17. The PATH Study conducts annual interviews and collects biospecimens from adults to help inform the development, implementation, and evaluation of tobacco-product regulations by FDA in meeting its mission under the Family Smoking Prevention and Tobacco Control Act (TCA) to

regulate tobacco products, including tobacco-product advertising, labeling, marketing, constituents, ingredients, and additives. The longitudinal design of the PATH Study enables it to measure and report within-person changes and between-person differences in tobacco product use behaviors and health effects within the cohort over time. These data will help to inform regulatory decisions and actions by FDA.

OMB approval is requested for 3 years. There are no capital, operating, or maintenance costs to report. There are no costs to respondents other than their time. The total estimated annualized burden hours are 56,939. Factors accounting for the difference between the baseline and Wave 2 total hours include the following: (1) Wave 2 does not have a screening phase; (2) as indicated in Supporting Statement B, a 86 percent response rate for adult interviews and a 90 percent response rate for youth interviews are projected for Wave 2; and (3) fewer biological samples will be collected in Wave 2.

#### Estimated Annualized Burden Hours

Type of Respondent and Instrument	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours per Response	Estimated Total Annual Burden Hours Requested
Adults – Extended Interview	27,113*	1	1	27,113
Adults – Baseline youth respondents who age into adult cohort – Consent for Extended Interview	2,295	1	2/60	77
Adults – Baseline youth respondents who age into adult cohort – Extended Interview	1,990*	1	68/60	2,255
Adults – Baseline youth respondents who age into the adult cohort – Consent for Biological Samples	1,990	1	4/60	133
Adults – Biospecimen Collection: Urine	11,373	1	10/60	1,896
Adults – Biospecimen Collection: Blood	896	1	18/60	269
Adults – Tobacco Use Form	12,269	1	4/60	818
Adults – Follow-up/Tracking Participant Information Form	33,615	2	8/60	8,964
Youth – Extended Interview	10,537**	1	32/60	5,620

Type of Respondent and Instrument	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Burden Hours per Response	Estimated Total Annual Burden Hours Requested
Youth – Shadow youth who age into youth cohort – Assent for Extended Interview	2,338	1	2/60	78
Youth – Shadow youth who age into youth cohort – Extended Interview	2,105**	1	42/60	1,474
Parent Interview	10,748	1	14/60	2,508
Parents of Shadow youth who age into youth cohort – Parent Permission and Consent for Parent Interview	2,338	1	2/60	78
Parents of Shadow youth who age into youth cohort – Parent Interview	2,147	1	17/60	608
Parents of youth – Follow-up/Tracking Participant Information Form for Youth	14,165	2	8/60	3,777
Adults – Follow-up/Tracking Participant Information Form for sample Shadow youth (completed by parents)	4,772	2	8/60	1,273

\* Estimated total number of adult extended interview respondents is 27,113 adults from Wave 1 + 1,990 youth from Wave 1 who turn 18 by Wave 2 = 29,103.

\*\* Estimated total number of youth extended interview respondents is 10,537 youth from Wave 1+ 2,105 shadow youth who turn 12 by Wave 2 = 12,642.

Dated: June 25, 2014.

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