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

<table>
<thead>
<tr>
<th>Instruments/Documents to be tested</th>
<th>Type of respondent</th>
<th>Estimated number of respondents</th>
<th>Estimated number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Estimated total annual burden hours requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials to Support Data Collection ................................</td>
<td>Adult ..................</td>
<td>100</td>
<td>1</td>
<td>1 3:40</td>
<td>150</td>
</tr>
<tr>
<td>Assent Forms ..................................................................</td>
<td>Youth .................</td>
<td>96</td>
<td>1</td>
<td>2</td>
<td>196</td>
</tr>
<tr>
<td>Consent Forms ..................................................................</td>
<td>Adult ..................</td>
<td>98</td>
<td>1</td>
<td>2</td>
<td>196</td>
</tr>
<tr>
<td>PATH Study Questionnaires ...........................................</td>
<td>Youth .................</td>
<td>40</td>
<td>1</td>
<td>2</td>
<td>80</td>
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<tr>
<td>Total ...........................................................................</td>
<td></td>
<td>466</td>
<td></td>
<td></td>
<td>882</td>
</tr>
</tbody>
</table>

* Calculations include one hour of travel time per respondent.

FOR FURTHER INFORMATION CONTACT: 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 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 60-days of the date of this publication.

Dated: May 17, 2012.

David Shurtleff,
Acting Deputy Director, NIDA.

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Center for Scientific Review Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6). Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.