

**Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB#: 0925-0648 Exp., date: 05/2021)**

**TITLE OF INFORMATION COLLECTION:** Stakeholder Feedback Survey on PATH Study

**PURPOSE:**

The Population Assessment of Tobacco and Health (PATH) Study at the National Institute on Drug Abuse (NIDA) seeks to collect qualitative customer feedback from PATH Study data users and tobacco research community. The findings from this survey will help improve the access and use of the PATH Study data and development and design of future PATH Study data collections and dissemination products.

The PATH Study is a national cohort study designed to generate longitudinal epidemiologic data on tobacco use behaviors including patterns of use, attitudes, beliefs, exposures, and related health outcomes. This study is a collaboration between the NIH NIDA and the U.S. Food and Drug Administration (FDA) Center for Tobacco Products and began in 2011. Wave 1 of the questionnaire and biospecimen data collection began on 2013 with annual data collections through Wave 4, which began in 2016. The PATH Study transitioned to biennial data collection starting with Wave 5 in 2018 and will continue with Wave 6 and 7 in 2021 and 2023, respectively. The multi-wave design allows for the detailed longitudinal assessment of participants’ patterns of tobacco product use, tobacco product exposures, tobacco-related attitudes and beliefs, and tobacco-related health outcomes, and provides critical evidence to inform FDA’s regulatory actions under the Family Smoking Prevention and Tobacco Control Act (FSPTCA) to protect the Nation’s public health and reduce its burden of tobacco-related morbidity and mortality. The PATH Study data is available as a public use data file that is available for download and also as restricted use files, which require permission to access the data through a Virtual Data Enclave at Inter-university Consortium for Political and Social Research (ICPSR) at the University of Michigan.

**DESCRIPTION OF RESPONDENTS:**

The target respondents will be current and former users of the PATH Study data (both public use and restricted use files), as well as the tobacco research community who are currently on the listservs used as standard dissemination channels for the PATH Study announcements. The web survey links will be sent to the target respondents and will be open for 2-3 weeks during March 2021.

**TYPE OF COLLECTION:** (Check one)

- |  |  |
|--|--|
| <input type="checkbox"/> Customer Comment Card/Complaint Form          | <input checked="" type="checkbox"/> Customer Satisfaction Survey |
| <input type="checkbox"/> Usability Testing (e.g., Website or Software) | <input type="checkbox"/> Small Discussion Group                  |
| <input type="checkbox"/> Focus Group                                   | <input type="checkbox"/> Other: _____                            |

**CERTIFICATION:**

I certify the following to be true:

1. The collection is voluntary.

2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: Heather Kimmel, PhD, Project Director and COR of the PATH Study

To assist review, please provide answers to the following question:

**Personally Identifiable Information:**

1. Is personally identifiable information (PII) collected? [ ] Yes [X] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [X] No

**Gifts or Payments:**

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [X] No

**ESTIMATED BURDEN HOURS and COSTS**

Category of Respondent	No. of Respondents	No. of Responses per Respondent	Time per Response (in hours)	Total Burden Hours
Individuals	450	1	15/60	113
<b>Totals</b>		450		<b>113</b>

**COST TO RESPONDENT**

Category of Respondent	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost
Individuals	113	\$29	\$3277
<b>Totals</b>			<b>\$3277</b>

\* The wage rate is the mean hourly wage of \$29.05 in the United States for Education and Health Services sector as reported in BLS December 2020. Average hourly and weekly earnings of all employees on private nonfarm payrolls by industry sector, seasonally adjusted: <https://www.bls.gov/news.release/empsit.t19.htm>.

**FEDERAL COST:** The estimated annual cost to the Federal government is \$22,640

The annualized cost to the federal government for the customer feedback survey is presented in the table below. The customer feedback survey is conducted by off-site contractors from ICPSR with oversight, management, scientific direction, and analyses by federal and in-house contractor staff at NIH/NIDA. This effort is funded by FDA through an Interagency Agreement to NIH/NIDA using tobacco user fees assessed under the authority of the FSPTCA (PL 111-31, June 22, 2009).

Staff	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
NIH Federal Oversight	GS 13/10	\$134,798	5%		\$6740
NIH In-house Contractor		\$138,000	5%		\$6,900.00
Contractor Cost					
Off-site contractors					\$9,000
Travel					
Other Cost					
<b>Total</b>					\$22,640

\*the Salary in table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2021/general-schedule/>.

**If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:**

**The selection of your targeted respondents**

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?  
 Yes       No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

We will be reaching out to the PATH Study data users using a database of former and current PATH Study data users. As this database is managed by ICPSR, ICPSR will be sending the web survey link to former and current PATH Study data users. Additionally, the web survey link will be shared to the following listservs, which are standard dissemination channels for the PATH Study announcements:

- Center for Coordination of Analytics, Science, Enhancement, and Logistics in Tobacco Regulatory Science (CASEL)
- FDA/ Center for Tobacco Products (CTP) social media
- Society for Research on Nicotine & Tobacco (SRNT) listservs
- College on Problems of Drug Dependence (CPDD) listserv
- The NIH Tobacco and Nicotine Research Interest Group (TANRIG) listserv

The survey will also be available to anyone via link on the ICPSR's PATH Study Data Series website.

**Administration of the Instrument**

1. How will you collect the information? (Check all that apply)
  - Web-based or other forms of Social Media
  - Telephone
  - In-person
  - Mail
  - Other, Explain
2. Will interviewers or facilitators be used?  Yes  No

**Please make sure that all instruments, instructions, and scripts are submitted with the request.**