

Supporting Statement B for:

**The Population Assessment of
Tobacco and Health (PATH) Study (NIDA) –
Generic Clearance for Methodological Studies**

OMB No. 0925-0675, Expiration Date: 5/31/2016

Reinstatement without Change

Yellow highlights indicate changes to submission from prior approval.

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TABLE OF CONTENTS

A.	COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS	
B.1	Respondent Universe and Sampling Methods.....	1
B.2	Procedures for the Collection of Information.....	1
B.3	Methods to Maximize Response Rates and Deal with Nonresponse.....	1
B.4	Test of Procedures or Methods to be Undertaken.....	2
B.5	Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....	2

LIST OF ATTACHMENTS

Attachment 1. Examples of methodological studies to inform the PATH Study

Attachment 2. List of consultants

Attachment 3. Certificate of Confidentiality

Attachment 4. NIH Privacy Act and System of Records Notice

Attachment 5. Privacy Impact Assessment

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods

Each methodological substudy submitted to OMB under this reinstatement without change request for the PATH Study's Generic Clearance for Methodological Studies (0925-0675; expiration May 31, 2016) will continue to serve its purpose, to improve the PATH Study's methods for data and biospecimen collection. Requests will describe the substudy's purpose, a description of the sample, sampling plan, and the recruitment approach. Racially and ethnically diverse samples of male and female adults, aged 18 or older, and youth aged 12-17 will be recruited to participate in these methodological substudies. The objectives of a given substudy under this Generic Clearance will drive how participants are selected for it. Substudies that seek to statistically represent populations or subgroups will use the types of complex probability sample designs developed for the main PATH Study. Other substudies, including those for cognitive interviews and focus groups, will use purposive and nonrandom selection methods.

Examples of Methodological Substudies to Inform the PATH Study that illustrate the scope of the sampling approaches to be used (based on the specific purpose), are listed below:

- Web-ACASI Comparison: To examine the equivalence of Web and ACASI data. Probability sample of adults (non-PATH Study participants) would respond by ACASI at time 1, and be randomly assigned to respond either by Web or ACASI at time 2. Brief, cost-efficient, psychometrically sound mode of data collection at follow-up.
- Collection of biospecimens via the mail and in-person: To examine the equivalence of urine specimens gathered via the mail and in-person. Probability sample of adults (non-PATH Study participants) would be randomly assigned to two groups. One group would be asked to provide a urine specimen in person and another to send it via the mail. Brief, cost-efficient, psychometrically sound procedures would be used to compare

the effectiveness and efficiency of the two approaches for gathering urine specimens for laboratory analysis.

- Psychometric properties of PATH Study Questionnaires: To examine the psychometric properties, such as test-retest reliability, of PATH Study questionnaires. Probability sample of adults and youth (non-PATH Study participants) would be interviewed and re-interviewed within 10- 14 days of the initial interview. Brief, cost-efficient, psychometrically sound direct assessment of the psychometric properties of data gathered with the PATH Study questionnaires.
- Comparison of self-reports with CO or Cotinine: To examine the validity of self-reported tobacco use among PATH Study respondents Probability sample of adults (non-PATH Study participants) would be interviewed and asked to provide a urine sample or breathe into a mechanism to obtain biomarkers of tobacco use. Brief, cost-efficient, psychometrically sound assessment of the validity of data gathered with the PATH Study questionnaires.

B.2 Procedures for the Collection of Information

Data collection procedures for substudies under this reinstatement request will continue to vary and will include telephone discussions, in-person interviews, group discussions, web-based interviews, and web-based focus groups. See exemplar listing above for scope of data collection approaches to be included in this generic. **Each methodological substudy submitted to OMB under this Generic Clearance will detail the purpose, timeline, recruitment strategy, informed consent and confidentiality procedures, plans for the incentive payment, and data collection and analysis plans. Each substudy will provide estimates of annualized hourly burden and annualized cost for substudy participants. Finally, each substudy will include its individual approval of the prime contractor's Institutional Review Board (IRB).**

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

Methodological substudies submitted under this Generic Clearance will continue to use different methods to recruit and retain respondents. In general, reminder telephone calls, e-mails, and letters will be used to maximize response rates for surveys, focus groups, individual qualitative interviews, and biospecimen collection. These will be used to encourage potential respondents to keep their appointments. More specific information will be described in the methodological substudy memo submitted OMB under this Generic Clearance.

B.4 Tests of Procedures or Methods to be Undertaken

This reinstatement request for the PATH Study's Generic Clearance for Methodological Studies will continue its plans to pre-test drafts of substudy instruments, materials, and procedures with 9 or fewer individuals prior to finalizing them for submission in a substudy memo to OMB for its review and approval.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The PATH Study will continue to seek the advice from one or more experts to help inform the development, scope, and methods of the individual substudies submitted under this Generic Clearance. Depending on the nature of the substudy, different individuals may be consulted. A list of individuals who may consult on one or more of these substudies to be submitted under this Generic Clearance request is presented in Attach2.List of consultants. The specific individuals who consult on a substudy will be included in the substudy memo submitted to OMB.