

## **Attachment 4**

### **NIH Privacy Act and System of Records Notice**

## The Privacy Act

The Population Assessment of Tobacco and Health (PATH) Study contract (N01DA-16-5582) incorporates in Section H, Special Contract Requirements, Article 11, The Privacy Act (Article H.11). (The full text of Article 11 appears below.) Article 11 references the applicable Privacy Act System of Records (09-25-0200), which is listed in the contract in Section J, the List of Attachments, and incorporated in full in Attachment 5. This document can also be accessed at <http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm>.

### **ARTICLE H.11. PRIVACY ACT, HHSAR 352.224-70 (January 2006)**

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement: (a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: [http://www.access.gpo.gov/nara/cfr/waisidx\\_06/45cfr5b\\_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html).

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: <http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm>.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

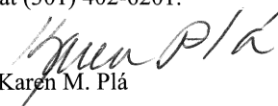
**DATE:** October 1, 2012  
**TO:** Kevin P. Conway, Ph.D.  
Deputy Director, Division of Epidemiology, Services, and Prevention Research, NIDA  
**FROM:** NIH Privacy Act Officer  
**SUBJECT:** Applicability of the Privacy Act: "Population Assessment of Tobacco and Health (PATH) Study (NIDA)"

This memo revises the August 1 memo for generic clearance of cognitive testing to include clearances for methodological studies and formative/topic-based research. The purpose of the cognitive testing is to determine baseline data collection activities and follow-up information on tobacco-use patterns, trends in risk perceptions and attitudes regarding harmful constituents. The two remaining clearances will differ in focus but the context of the PATH study will remain the same. The PATH study is designed to establish a population-based framework for monitoring and evaluating the behavioral and health impacts of regulatory provisions by the Food and Drug Administration in order to guide effective policy decisions. The study will collect longitudinal survey data from a cohort of approximately 59,000 current, former, and never tobacco product users in the U.S., ages 12 years and older.

I have determined that the Privacy Act will apply to this data collection, which involves the collection of personally identifiable information related to tobacco initiation, cessation and relapse behaviors. The first contact with potential research participants will occur in response to flyers or advertisements. Interested persons will call a listed telephone number and provide contact information. Gender, age and educational level will be asked to determine study eligibility. Face-to-face, telephone and self-administered interviews will be scheduled and video/audio taped. Minimal demographic information (e.g., gender, age, and race/ethnicity) will be obtained for all scheduled participants.

Although recruitment data will be maintained in separate, encrypted files, with password protection and access limited to authorized personnel, a crosswalk will link the participant ID with the individual's personally identifiable information. The data collection sheet will be separated from the consent forms, so that no demographic information can be associated with the individual's name. Signed consent forms will be stored separately from participant data. Upon completion of the cognitive testing, methodological studies and formative/topic-based research, the hard copy data (e.g., interview notes and recordings) will be stored in locked files at the Westat contractor facility.

The data collection is covered by NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic, and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD". If you have any questions, please contact my office at (301) 402-6201.

  
Karen M. Plá

Enclosure  
cc: Genevieve deAlmedia-Morris, NIDA PRA Liaison