

Attachment 15

NIH Privacy Act 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.

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>.



DATE: June 14, 2016

TO: Kevin P. Conway, Ph.D.
Deputy Director
Division of Epidemiology, Services, and Prevention Research,
National Institute on Drug Abuse, NIDA

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: "Population Assessment of Tobacco and Health (PATH) Study (NIDA) – Fourth Wave of Data Collection"

I have reviewed the NIDA submission to the OMB referenced above. NIDA is partnering with the Food and Drug Administration (FDA) to conduct the PATH study through Westat, the prime contractor. The PATH study will collect baseline and follow-up information on tobacco-use patterns, trends in risk perceptions, and attitudes regarding harmful constituents using audio-computer assisted-interviews (ACASI). The data will be drawn from a cohort of approximately 49,210 civilian, non-institutionalized youth aged 12 to 17, and adults aged 18 and older.

NIDA will use the data collected to generate research hypotheses regarding relationships between tobacco exposure and use, health conditions, and the onset and progression of disease processes. In so doing, NIDA will further its mission to understand substance abuse and addiction.

The PATH study will conduct two (2) different interviews as a means to collect information; the parent interview and the adult and youth extended interview. The parent interview will focus on gaining information about the youth respondent's life that may be associated with tobacco use, and includes questions on parental supervision, parental risk perceptions of tobacco use, school performance, and tobacco use by youth. The adult and youth extended interview will collect information related to attitudes and beliefs regarding harmful constituents, risk perceptions, environmental factors, family and peer influences, general health, health effects and demographics (e.g., date of birth, gender, race, ethnicity, household income, pregnancy status as well as sexual identity, orientation, and attraction).

Data will be identified by unique numbers assigned to each respondent and will be maintained in separate, encrypted tables, with password protection and access limited to authorized personnel. The ID numbers will link the respondent's extended interview responses with his or her own biospecimens. Crosswalks that match these numbers to personally identifiable information (PII) will be stored in secure, encrypted files accessible only to authorized staff whose roles on the study necessitate access. Authorized users will have access to research data free of PII only behind a secure data firewall that will not permit downloading or printing of data.

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NIDA will not have access to identifying information, and personal identifiers will not be included in the data received by NIDA. Westat will transfer all data for the PATH study and associated products and documents to NIDA at the time final data files are compiled, and will not retain any records of the data.

I have determined that the Privacy Act will apply to this data collection. It will involve the collection of personal information such as name, phone number, date of birth, address, phone number, blood and urine sample, and information related to tobacco initiation, cessation and relapse behaviors, all of which will be retrieved by a unique identifier.

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 questions, please contact me at (301) 402-6201.



Celeste Dade-Vinson
NIH Privacy Act Officer

Enclosure

cc: Genevieve deAlmeida-Morris, NIDA PRA Liaison (w/o enclosure)