

Attachment 12

**PATH Study
Certificate of Confidentiality**



CONFIDENTIALITY CERTIFICATE NO. DA-12-131

issued to

BEHAVIORAL HEALTH GROUP
WESTAT

conducting research known as

“POPULATION ASSESSMENT OF TOBACCO AND HEALTH
OR PATH STUDY”

In accordance with the provisions of section 301(d) of the Public Health Service Act (42 U.S.C. § 241 (d)), this Certificate is issued in response to the request of the Principal Investigator, Andrew Hyland, Ph.D., Behavioral Health Group, Westat, 1600 Research Boulevard, RB 4121, Rockville, MD 20850-3129, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Hyland is primarily responsible for the conduct of this research, which is funded by NIDA contract# HHSN271201100027C.

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are employed by or associated with Behavioral Health Group, Westat and its research sites, contractors, or cooperating agencies and
2. have in the course of their employment or association access to information that would identify individuals who are the subjects of the research project known as “Population Assessment of Tobacco and Health or PATH Study,”

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

The research began on September 19, 2011 and is expected to end on September 30, 2017.

The purpose of this national, longitudinal cohort study is to examine the epidemiological and health consequences of tobacco-product use among the U.S. civilian, non-institutionalized population ages 12 years and older.

Study subjects’ identities are protected by linking unique study ID numbers assigned to sampled households and individuals with personal identifiers. Survey data with study IDs are separated from materials with personally identifiable information (PII) through data collection, transmission, storage, processing, analysis, and reporting. Data are collected on encrypted laptop computers. Study data are identified and retrieved by study ID numbers only. Hard copy consent forms with participant names and all PII are maintained in secure

areas separate from the research data. They are identified only by study ID number and are stored in locked files. Biospecimens are coded and shipped for analysis by qualified laboratories. No reports or analysis files will contain PU. Individuals will not be identified in any publication or presentation, and analytic findings will be reported as aggregate statistics only.

A Certificate of Confidentiality is needed because biologic samples and sensitive information concerning study subjects' drug and alcohol use, and sexual orientation/attraction is collected during the course of the study. The Certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological and social consequences.

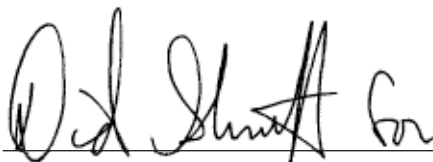
As provided in section 301(d) of the Public Health Service Act 42 U.S.C. 241(d):

“Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.”

This Certificate does not protect you from being compelled to make disclosures that: (1) have been consented to in writing by the research subject or the subject's legally authorized representative; (2) are required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or regulations issued under that Act; or (3) have been requested from a research project funded by NIH or DHHS by authorized representatives of those agencies for the purpose of audit or program review.

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire at the end of September 2017. The protection afforded by this Confidentiality Certificate is permanent with respect to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect.

Date: 8/31/2012



Nora D. Volkow, M.D.
Director



AMENDMENT NO. 1

CONFIDENTIALITY CERTIFICATE NO. DA-12-131

issued to

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OR PATH STUDY”

In accordance with the provisions of section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)), this Amendment to the original Certificate is issued in response to the request of the Principal Investigator, Andrew Hyland, Ph.D., Behavioral Health Group, Westat, 1600 Research Boulevard, RB 4121, Rockville, MD 20850-3129, to protect the privacy of research subjects by withholding their identities from all persons not connected with the research. Dr. Hyland is primarily responsible for the conduct of this research, which is supported by NIDA contract# HHSN271201100027C.

Under the authority vested in the Secretary of Health and Human Services by section 301 (d), all persons who:

1. are employed by, or associated with Behavioral Health Group, Westat and its research sites, contractors, and cooperating agencies and
2. have in the course of that employment or association access to information that would identify individuals who are the subjects of the research project known as, “Population Assessment of Tobacco and Health or PATH Study,”

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

The purpose of this Amendment is to amend the protocol to include changes in the recruitment and informed consent processes, incentives to study subjects, and the survey instruments. The Certificate will expire September 30, 2017. All other aspects of this research project remain unchanged.

Date: 6/6/13



Nora D. Volkow, M.D.
Director