

Attachment 14

Certificate of Confidentiality

June 18, 2013



CONFIDENTIALITY CERTIFICATE NO. DA-12-131

Dear Investigator:

The original Confidentiality Certificate issued to your organization is enclosed. Please keep this in a safe place. Any correspondence sent to NIDA regarding the Certificate must reference the Certificate number. Please note the Certificate expires at the end of September 2017. We are providing one more year of Certificate coverage than you requested because it has been our experience that many studies take longer to complete than initially projected. Providing an extra year will ensure coverage for subjects, and may spare you the need to formally submit a request for an extension.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information (including matters subject to reporting) and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

If you determine that the research project will not be completed by the expiration date, you must submit a written request for an extension of the Certificate three months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise me of any situation in which the certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to: Anne Jarrett, Office of Extramural Affairs, NIDA, 6001 Executive Boulevard, Room 4239, Bethesda, MD 20892 (FedEx's to Rockville, MD 20852), Phone (301) 402-6020 and fax number (301) 443-0538, e-mail address: aj99v@nih.gov .

Please visit the NIH website for Confidentiality Certificates at

<http://grants.nih.gov/grants/policy/coc/index.htm>.

Sincerely,

Mark R. Green, Ph.D.
Confidentiality Certificate Coordinator

Enclosure



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 PII. 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):

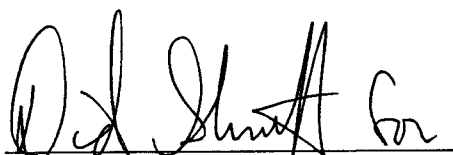
"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

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

National Institutes of Health
National Institute on Drug Abuse
Bethesda, Maryland 20892

CONFIDENTIALITY CERTIFICATE NO. DA-12-131

issued to

**BEHAVIORAL HEALTH GROUP
WESTAT**

conducting research known as

**“POPULATION ASSESSEMENT 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 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



CONFIDENTIALITY CERTIFICATE NO. DA-12-131

Dear Investigator:

The Amendment to the Confidentiality Certificate issued to your organization is enclosed. Please keep the original Certificate and Amendment in a safe place. Any correspondence sent to NIDA regarding the Certificate must reference the Certificate number. Please note the Certificate expires at the end of September 2017.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information (including matters subject to reporting) and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

If you determine that the research project will not be completed by the expiration date, you must submit a written request for an extension of the Certificate three months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise me of any situation in which the certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to: Tanya Barnett, Office of Extramural Affairs, NIDA, 6001 Executive Boulevard, Room 4246, MSC 9550, Bethesda, MD 20892-9550, Phone (301) 451-7971 and fax number (301) 443-0538.

Please visit the NIH website for Confidentiality Certificates at

<http://grants.nih.gov/grants/policy/coc/index.htm>.

Sincerely,

A handwritten signature in blue ink, appearing to read "Kate Bent".

Kate Bent, RN, Ph.D., CNS
Confidentiality Certificate Coordinator

Enclosure