

ATTACHMENT 10
CERTIFICATE OF CONFIDENTIALITY

CONFIDENTIALITY CERTIFICATE

Number: AA-076-2010

Issued to

National Institute on Alcohol Abuse and Alcoholism (Bethesda, MD; Lead PI: Dr. Bridget Grant)

**Westat, Inc. (Rockville, MD; Contractor: Dr. David Maklan)
New York State Psychiatric Institute (New York, NY; Sub-study
Coordinator/Subcontractor to Westat: Dr. Deborah S. Hasin)**

conducting research under or using

National Epidemiologic Survey on Alcohol and Related Conditions-III (NESARC-III) Data

[For its users and collaborators contingent upon their approval by a National Institute on Alcohol Abuse and Alcoholism's Data Access Committee]

HHSN275200900007C

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, Bridget Grant, Ph.D., to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Grant is primarily responsible for the conduct of this research, which is supported by the National Institute on Alcohol Abuse and Alcoholism.

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

1. are enrolled in, employed by, or associated with the National Institute on Alcohol Abuse and Alcoholism

Division of Intramural Clinical and Biological Research

National Institutes of Health and its 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 pertaining to the project known as "National Epidemiologic Survey on Alcohol and Related Conditions-III (NESARC-III) Data,"

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.

NESARC-III will serve the purpose of fulfilling a variety of NIAAA data needs from a single

source of data on the magnitude of deleterious alcohol use levels, alcohol use disorders, and their associated disabilities and consequences in the U.S. general adult population, while providing valuable baseline against which to gauge trends in the prevalence of such disorders and associated disabilities over the past decade. NESARC-III includes collecting saliva samples.

A Certificate of Confidentiality is needed because potentially illegal or sensitive use of addictive substances or other sensitive information will be 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.

Measures to be taken to protect confidentiality include confidentiality training for research staff, restricted access to study records, use of codes instead of recognizable names, publication only of grouped data, and other steps to protect privacy.

Beginning date for this research: December 1, 2010. The research is expected to end on November 30, 2018.

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 on November 30, 2018. The protection afforded by this Confidentiality Certificate is permanent with respect to subjects who participate in the research during the time the Certificate is in effect.



Kenneth R. Warren, Ph.D.

Acting Director

National Institute on Alcohol Abuse and Alcoholism



Date