



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institute of Mental Health
6001 Executive Boulevard
Bethesda, MD 20892

2/2/2016

National Academy of Sciences (NAS)
Ms. Laura Aiuppa
500 5th St, NW
Washington, DC 20001

Dear Ms. Aiuppa,

Enclosed is the Confidentiality Certificate, protecting the identity of research subjects in your multi-site project entitled "Evaluation of the Department of Veterans Affairs Mental Health Services."

Please note that the Certificate expires on 12/31/2019.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information 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, 12/31/2019, you must submit a written request for an extension of the Certificate three (3) 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:

Eugene Kane III, M.P.H.
National Institute of Mental Health
6001 Executive Boulevard
Suite 6110 MSC 9669
Bethesda, MD 20892

Sincerely,

Approved Date: 02/02/2016



Eugene Kane III, M.P.H.
Certificate of Confidentiality Coordinator
National Institute of Mental Health

Enclosure



CONFIDENTIALITY CERTIFICATE

CC-MH-16-158

issued to

National Academy of Sciences (NAS)

conducting research known as

"Evaluation of the Department of Veterans Affairs Mental Health Services"

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, Ms. Laura Aiuppa, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Ms. Laura Aiuppa is primarily responsible for the conduct of this research.

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 National Academy of Sciences (NAS) 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 "Evaluation of the Department of Veterans Affairs Mental Health Services,"
3. 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.

This research study will investigate barriers to the Veterans Affairs (VA) mental health care by comparing Veterans who use the VA health system for mental health care with VA-eligible Veterans who have not elected to use the VA health system for mental health care.

A Certificate of Confidentiality is needed because 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.

All personally identifiable information (PII) will be processed and stored within Westat's FISMA High Enclave accessible only to Westat project staff. Secure passwords will be required in order to enter the FISMA High Enclave environment and sign onto the server. The Survey Management System is designed to operate within this enclave. A unique personal identifier will

be assigned to each record on the sample frame file. Westat will create another Survey ID for data collection purposes and maintain a crosswalk between the sample file unique personal identifier and the Survey ID in a linking file. This will allow a linkage between the Survey ID and survey data with the unique personal identifier and other sample frame variables provided. The linking file will remain stored within the FISMA High Enclave. A de-identified analytic data set that includes survey data only will be delivered to VA at the end of the project. No data will be retained by IOM.

This research begins on 12/12/2014 and is expected to end on 12/31/2019.

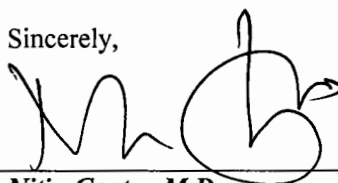
As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

"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 12/31/2019. 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 the time the Certificate is in effect.

Sincerely,

A handwritten signature in black ink, appearing to read 'Nitin Gogtay', written over a horizontal line.

Signed Date: 2/2/2016

Nitin Gogtay M.D.
Director of Clinical Research
National Institute of Mental Health