

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

National Institutes of Health
National Institute on Alcohol Abuse & Alcoholism
5635 Fishers Lane, Room 3108, MSC 9304
Bethesda, Maryland 20892-9304

Dana Hunt, Ph.D.
ABT Associates Inc.
55 Wheeler Street
Cambridge, MA 02138

Dear Dr. Hunt:

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, "Arrestee Drug Abuse Monitoring Project." Please note that the Certificate expires on February 28, 2011. We have provided one more year of Certificate coverage than you requested since many studies take longer to complete than initially projected. Providing an extra year ensures 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.

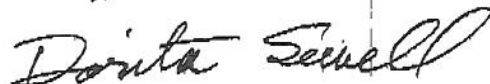
If you determine that the research project will not be completed by the expiration date, February 28, 2011, you must submit a written request for an extension of the Certificate three months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding 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 Dorita Sewell, Ph.D., Confidentiality Certificate Coordinator, Office of Science Policy and Communications, National Institute on Alcohol Abuse and Alcoholism/NIH, 5635 Fishers Lane, Room 3108, Rockville, MD 20852; 301-443-2890, Fax 301-480-1726; dsewell@mail.nih.gov.

Sincerely,



Dorita Sewell, Ph.D.
Confidentiality Certificate Coordinator

Enclosure

cc: Ms. Marianne Beauregard
Vice President

CONFIDENTIALITY CERTIFICATE**Number: AA-31-2007****Issued to****ABT Associates Inc.****conducting research known as****Arrestee Drug Abuse Monitoring Project**

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, Dana Hunt, Ph.D., to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Hunt is primarily responsible for the conduct of this research, which is supported by the Office of National Drug Control Policy.

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 ABT Associates Inc. 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 "Arrestee Drug Abuse Monitoring Project,"

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 project is to monitor drug trends of several kinds among arrestees in 10 counties. About 5000 arrestees are expected to participate.

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.

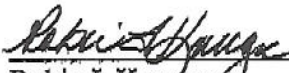
This research begins on October 1, 2006, and is expected to end on February 28, 2011.

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 February 28, 2011. 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.



Robin I. Kawazoe
Acting Deputy Director
National Institute on Alcohol Abuse and Alcoholism



Date