



National Institutes of Health  
National Institute of Mental Health  
6001 Executive Boulevard  
Bethesda, Maryland 20892

6/25/2010

Westat, Inc.  
Dr. Doreen De Leonardis  
1600 Research Blvd.  
Rockville, MD 20850

Dear Dr. Leonardis,

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, 'Investigates the Use and Feasibility of Speed Warning Systems'. Please note that the Certificate expires on 12/31/2011.

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, 12/31/2011, 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:

Olga Boikess  
Certificate of Confidentiality Coordinator  
National Institute of Mental Health  
6001 Executive Boulevard  
Room. 8222, (MSC 9653)  
Bethesda, MD 20892  
Telephone: 301-443-3877  
Fax: 301-443-7264

Sincerely,

  
Olga Boikess

**CERTIFICATE OF CONFIDENTIALITY**

**CC-MH-10-113**

**issued to**

**Westat, Inc.**

**conducting research known as**

**Investigates the Use and Feasibility of Speed Warning Systems**

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, Dr. Doreen De Leonardis, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Leonardis is primarily responsible for the conduct of this research, which is supported by the National Highway Traffic Safety Association.

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 Westat, Inc. and their 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 Investigates the Use and Feasibility of Speed Warning Systems

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 behavioral research project investigates the feasibility of using an in-vehicle speed monitoring system on a voluntary population of drivers, with particular emphasis on at-risk drivers with a history of speeding.

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 subjects will be assigned a code number and identifying information and records will be kept in locked files at the Institution.

This research is currently underway and is expected to end on 12/31/2011.

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 the National Institutes of Health (NIH) or the Department of Health and Human Services (DHHS) by authorized representatives of those agencies for the purpose of audit or program review.

**CERTIFICATE OF CONFIDENTIALITY**

**CC-MH-10-113**

**issued to**

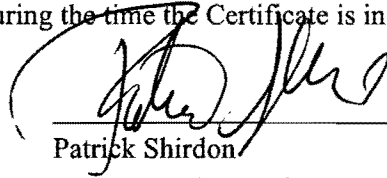
**Westat, Inc.**

**conducting research known as**

**Investigates the Use and Feasibility of Speed Warning Systems**

This Certificate does not represent an endorsement of the research project by the DHHS. This Certificate is now in effect and will expire on 12/31/2011. 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.

Date: 6/25/2010



Patrick Shirdon

Associate Director for Management

National Institute of Mental Health