



Appendix E

Certificate of Confidentiality Documentation



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

National Institute on Alcohol
Abuse and Alcoholism
6000 Executive Boulevard
Rockville, MD 20892-7003

DEC 23 1997

Jennifer Harper Ogle, M.S.
National Highway Traffic
Safety Administration
Traffic Safety Programs Office
of Research and Traffic Records
Attn: Paul Tremont (NTS-31)
400 7th St. SW
Washington, D.C. 20590

Dear Ms. Ogle:

Enclosed is the Certificate of Confidentiality prepared for you by the Department of Health and Human Services. This Certificate provides the assurance of confidentiality specified in Section 301(d) of the Public Health Service Act. All subjects enrolled during the time the Certificate is in effect are covered in perpetuity. Subjects enrolled prior to the Certificate's issuance are not protected under the terms of the Certificate. This Certificate has been issued for the duration of the project. However, because IRB approval has been given for only one year, please forward to the Institute subsequent IRB approvals as received.

Each subject should be told about the existence of this Certificate. The limitations of the Certificate's protection should also be mentioned. In addition, subjects should be offered a copy of the Certificate if they wish one.

If any questions arise regarding confidentiality or other human subject protection matters, do not hesitate to contact the Institute. We are pleased to send this authorization, and we fully anticipate that you will proceed with your research as specified.

Sincerely yours,

Lura J. Abbott, M.S.
CDR, USPHS
Confidentiality Assurance Officer
Office of Planning and Resource Management
National Institute on Alcohol
Abuse and Alcoholism

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

National Institute on Alcohol
Abuse and Alcoholism
6000 Executive Boulevard
Rockville, MD 20892-7003

CONFIDENTIALITY CERTIFICATE

issued to:

Individuals Responsible for the Research Entitled
"Quantitative Properties of the Association Between Driving
Speeds and Crash Probability"

Contract Number: DTKH22-97-C-03141

Conducted by:

Texas Transportation Institute
Texas A&M University
College Station, Texas 77843

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

Under authority vested in the Secretary of Health and Human Services by Section 301(d) of the Public Health Service Act (42 U.S.C.), all persons who:

1. are employed by Texas Transportation Institute, Texas A&M University, College Station, Texas 77843 or its contractors and cooperating agencies; and
2. have, during the course of that employment, access to information which would identify individuals who are subjects of the research on alcohol and drug abuse in the study entitled: "Quantitative Properties of the Association Between Driving Speeds and Crash Probability"

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, with the exceptions and limitations set forth below.

The objective of this pilot study is to develop a method and framework for collecting data to determine quantitative relationships between

speed and crash risks, given an array of variables such as driver characteristics (including drinking before driving), roadway characteristics, vehicle characteristics, weather conditions, and traffic conditions. The two major focus areas of this Pilot Study are 1) to determine the feasibility of using new technologies to obtain accurate pre-crash speeds for a group of test vehicles, and 2) to determine the quantitative properties that can be used to explain relationships between driving speed and crash risk, and 3) to determine the feasibility of equipping a fleet of approximately 2000-4000 vehicles to acquire data on travel speeds and speed limits.

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."

The following conditions apply to the protection provided under this Certificate:

- (1) This Certificate does not authorize Texas Transportation Institute, Texas A&M University, College Station, Texas 77843 or its contractors and cooperating agencies to refuse to reveal information concerning research subjects if the following condition exists:
 - (a) The subject (or, if he or she is legally incompetent, his or her guardian) consents in writing to disclosure of identifying information.

This Certificate requires that there be no disclosures of identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects, except as provided for in paragraph (1), above.

- (3) The Confidentiality Certificate does not govern the voluntary disclosure of identifying characteristics of research subjects.


This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services.

All research subjects in the project will be given a fair, clear explanation of the protection this certificate affords, and of the limitations and exceptions to the protection and will be given a copy of this Certificate, except when to do so would put them at risk.

- (6) This Certificate is effective upon issuance and will expire on January 1, 2000, or sooner if the holder is notified of

cancellation in accordance with the procedures set out in 42 C.F.R. § 2a.8. The protection afforded by this Confidentiality Certificate is permanent with respect to subjects who participate in the research during any time the Certificate is in effect.

- (7) This research project may also be subject to special rules for the confidentiality of alcohol and drug abuse patient records, under sections 544 and 548 of the Public Health Service Act (42 U.S.C. §§ 290dd-3 and 290ee-3), and implementing regulations at 42 C.F.R. Part 2, which restrict voluntary disclosures of information from covered patient records.



 Mary C. Ruffour, M.D., M.P.H.
 Deputy Director
 National Institute on
 Alcohol Abuse and Alcoholism

12/18/97
 Date