U.S. Department of Transportation

Privacy Impact Assessment

National Highway Traffic Safety Administration (NHTSA)

Office of Vehicle Safety Research (OVSR)

Responsible Official

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Executive Summary

The mission of the National Highway Traffic Safety Administration (NHTSA) is to save lives, prevent injuries, and reduce the economic costs of road traffic crashes through education, research, safety standards, and enforcement activity. Subchapter V of Title 49 of the United States Code (U.S.C.) authorizes the Secretary of Transportation to conduct "motor vehicle safety research, development, and testing programs and activities, including activities related to new and emerging technologies that impact or may impact motor vehicle safety." 49 U.S.C. 30182. Pursuant to § 1.95 of Title 49 of the Code of Federal Regulations (CFR), the Secretary has delegated this authority to the National Highway Traffic Safety Administration (NHTSA).

NHTSA's Office of Vehicle Safety Research (OVSR) conducts research at the NHTSA Vehicle Research and Test Center (VRTC) in East Liberty, Ohio. Research programs covered by this assessment support NHTSA's mission by examining how drivers interact with current production driver-assistive and advanced technologies. The research is conducted by NHTSA VRTC staff with the support of its on-site support services contractor, Transportation Research Center, Inc. (TRC). This Privacy Impact Assessment (PIA) is being conducted because in the context of this research, NHTSA and its contractor, TRC, collect, process, and maintain Personally Identifiable Information (PII) on members of the public.

What is a Privacy Impact Assessment?

The Privacy Act of 1974 articulates concepts for how the federal government should treat individuals and their information and imposes duties upon federal agencies regarding the collection, use, dissemination, and maintenance of personally identifiable information (PII). The E-Government Act of 2002, Section 208, establishes the requirement for agencies to conduct privacy impact assessments (PIAs) for electronic information systems and collections. The assessment is a practical method for evaluating privacy in information systems and collections, and documented assurance that privacy issues have been identified and adequately addressed. The PIA is an analysis of how information is handled to—i) ensure handling conforms to applicable legal, regulatory, and policy requirements regarding privacy; ii) determine the risks and effects of collecting, maintaining and disseminating information in identifiable form in an electronic information system; and iii) examine and evaluate protections and alternative processes for handling information to mitigate potential privacy risks.[1]

Conducting a PIA ensures compliance with laws and regulations governing privacy and demonstrates the DOT's commitment to protect the privacy of any personal information we collect, store, retrieve, use and share. It is a comprehensive analysis of how the DOT's electronic

[1]Office of Management and Budget's (OMB) definition of the PIA taken from guidance on implementing the privacy provisions of the E-Government Act of 2002 (see OMB memo of M-03-22 dated September 26, 2003).

information systems and collections handle personally identifiable information (PII). The goals accomplished in completing a PIA include:

- *Making informed policy and system design or procurement decisions. These decisions must be based on an understanding of privacy risk, and of options available for mitigating that risk;*
- *Accountability for privacy issues;*
- *Analyzing both technical and legal compliance with applicable privacy law and regulations, as well as accepted privacy policy; and*
- *Providing documentation on the flow of personal information and information requirements within DOT systems.*

Upon reviewing the PIA, you should have a broad understanding of the risks and potential effects associated with the Department activities, processes, and systems described and approaches taken to mitigate any potential privacy risks.

Introduction & System Overview

NHTSA's OVSR conducts research and safety testing of motor vehicles and motor vehicle equipment, as well as research studies on driver behavior and performance. The purpose of the latter is to understand driver behavior and how it relates to crashes. With new technologies, NHTSA studies how drivers understand and use the technologies and assess whether the technologies can be implemented safely and, if relevant, produce a reduction in crashes or injuries. NHTSA conducts research and testing at its VRTC and as well as through contracts with research organizations. In the conduct of this research, NHTSA and/or its contractors collect, process, and maintain PII about members of the public.

Participant Selection

Experimental research studies in OVSR conducted at VRTC begin with NHTSA personnel identifying a research need and developing a study plan. In accordance with the Paperwork Reduction Act (PRA), all studies that involve the collection of information from 10 or more people are reviewed and approved by the Office of Management and Budget (OMB). As part of this process, all study procedures, including a description of the information that will be collected from participants, are published in the Federal Register and opened for public comment. In addition to clearance from OMB, experimental research studies in OVSR must comply with all regulations in NHTSA Order 700-5 (Appendix A) on the protection of human research subjects. These regulations include a clause that all research studies at NHTSA involving human subjects must be reviewed and approved by an Institutional Review Board (IRB) that has received a Federalwide Assurance (FWA) from the Department of Health and Human Services (HHS).

Following the receipt of PRA and IRB clearances, TRC staff begin recruiting participants for the study. Participants in the research studies are adults, typically aged 25 years or greater. Potential participants are recruited by the contractor on behalf of NHTSA, using various methods including, but not limited to: online or print newspaper advertisements; online advertisements or postings on social media platforms; targeted mailings to registered vehicle owners; or flyers posted in locations where participants are likely to see them.

Potential participants respond to recruitment efforts by visiting a secure website to access and respond to initial screening questions used to assess their eligibility for participation in the study. At this stage, the research team obtains only the minimum amount of information necessary to determine eligibility. This is based on the specific inclusion/exclusion criteria of the study. It is also used to determine suitability (e.g., a potential participant's ability to travel to the research site multiple times, if that is what the study requires). Finally, participants may be asked questions necessary to assign them to appropriate experimental groups. Participants are asked to provide demographic information (e.g., age, sex, driving experience and history) necessary for the appropriate analysis of study data. Contact information is obtained to allow research staff to maintain contact with candidate participants to complete the recruitment process. For individuals who do not meet enrollment criteria based on responses to the initial screening questions, the research team retains only non-identifying information, such as sex or age.

Individuals whose responses to initial screening questions meet the enrollment criteria are e-mailed a link to a secure website used to present a second set of screening questions that address driver license information, driving experience and history, as well as general health and ability to drive for the duration of the test protocol without need for assistive equipment and without health concerns. The software used to present screening questions is programmed to record responses to individual vehicle and driving related questions, but for health questions only record a summary indication of whether an individual meets or does not meet the study participation criteria. Information related to specific medical conditions the candidate/participant may have or medications they take is not recorded.

Screening question response data are reviewed by the research team and a determination is made whether the individual meets the study participation criteria. Those respondents meeting the criteria are contacted by e-mail or phone to schedule an appointment for study participation.

Upon arriving for study participation, individuals undergo the informed consent process. This process involves participants reading and/or listening to a research team member explain the consent form. The consent forms are written in plain language, and they tell participants that their participation in the study is voluntary and explain their rights as research participants. The forms also detail the purpose of the study, whether there are any risks (or benefits), the duration of the study, and any compensation participants will receive for their participation (Social Security number is not obtained for payment and tax reporting purposes). The forms describe the steps taken by the research team to ensure participants' data is kept private and identify the

personnel who will have access to their data (i.e., the contractor's research team and NHTSA personnel only). All consent forms used in experimental research studies in OVSR are approved by an independent commercial IRB and NHTSA's Office of Chief Counsel. If potential participants agree to enrollment, they sign the consent form. Once participants sign the consent form, they are considered to be enrolled in the study.

Study Participation

OVSR research studies involving human subjects may take place in a variety of settings. Information may be collected from participants in person (e.g., at a laboratory where participants may complete computerized or paper-based tasks, questionnaires, or drive in a computer-based driving simulator), online (e.g., a web-based questionnaire), or by mail, telephone, or e-mail (e.g., paper-based or phone-based surveys).

Typically, an individual's participation in the study is limited to a single interaction. For example, the participant may complete a single session in person in which the individual drives an instrumented vehicle over a specified course and protocol or drives in a computer-based driving simulator. Some studies require multiple visits or observation over a period of days while driving an instrumented vehicle. During the study period, the study team may collect a variety of information from or about participants, including, but not limited to: name, address, telephone number, driver's license number, date of birth, sex, and demographic data; responses to questions about traffic safety attitudes, beliefs, or behaviors; performance on computer-based driving simulators; information from in-vehicle sensors and cameras; or participants' driving records. Individuals may be selected to be representative of the general population or of specific groups, including, but not limited to: drivers of particular types of vehicles or drivers having experience with certain vehicle technologies.

In all studies, participants are made aware of the duration of the study and the duration of their active participation in the study during the informed consent process.

Post-Study Activities

After participants complete their participation in the study, they are provided compensation. Cash payment is typically provided by TRC at the end of the participant's final visit to VRTC.

Administrative data about participants (e.g., name, address, contact information) are separated from study data (e.g., driving performance metrics) and stored in separate files. The two files are linked via a unique identifier assigned to each participant. All data is protected using appropriate technical (e.g., encryption), administrative (e.g., password-protected access to a limited set of users), and physical safeguards.

Study Termination

After the study ends, administrative data is destroyed at a pre-determined date; these data include participants' names, addresses, etc., and all other PII. After study completion, VSR receives a

report from the contractor detailing the study results in aggregate, in which no participants can be uniquely identified, as well as a de-identified data set which contains no PII.

Information about specific research studies conducted by OVSR covered under this PIA is provided in Appendix B.

Fair Information Practice Principles (FIPPs) Analysis

The DOT PIA template is based on the fair information practice principles (FIPPs). The FIPPs, rooted in the tenets of the Privacy Act, are mirrored in the laws of many U.S. states, as well as many foreign nations and international organizations. The FIPPs provide a framework that will support DOT efforts to appropriately identify and mitigate privacy risk. The FIPPs-based analysis conducted by DOT is predicated on the privacy control families articulated in the Federal Enterprise Architecture Security and Privacy Profile (FEA-SPP) v3[2], sponsored by the National Institute of Standards and Technology (NIST), the Office of Management and Budget (OMB), and the Federal Chief Information Officers Council and the Privacy Controls articulated in Appendix J of the NIST Special Publication 800-53 Security and Privacy Controls for Federal Information Systems and Organizations[3].

Transparency

Sections 522a(e)(3) and (e)(4) of the Privacy Act and Section 208 of the E-Government Act require public notice of an organization's information practices and the privacy impact of government programs and activities. Accordingly, DOT is open and transparent about policies, procedures, and technologies that directly affect individuals and/or their personally identifiable information (PII). Additionally, the Department should not maintain any system of records the existence of which is not known to the public.

Prior to the initiation of data collection, and in accordance with the PRA, these collections are posted for public comment and reviewed and approved by the Office of Management and Budget (OMB). As part of this process, all study procedures—including the specific information that will be collected from participants and the forms used to collect this information—are published by OMB on reginfo.gov. Prior to submission to OMB, the public is notified of the proposed collection through a Federal Register notice and is given 60 days to provide comments through an electronic docket at regulations.gov. After addressing any comments received during the comment period, NHTSA submits a second Federal Register notice notifying the public that the collection is being submitted to OMB and invites public comment to be sent directly to OMB.

NHTSA also informs the public that their PII is collected and stored through this Privacy Impact Assessment, which is published on the DOT website. This document identifies the information

[2] http://www.cio.gov/documents/FEA-Security-Privacy-Profile-v3-09-30-2010.pdf

[3] http://csrc.nist.gov/publications/drafts/800-53-Appdendix-J/IPDraft_800-53-privacy-appendix-J.pdf

collection's purpose, storage, and use of the PII. The PIA is available at https://www.transportation.gov/privacy.

Additionally, all potential participants are advised of what information about them will be collected during the informed consent process. They are also made aware that participation is voluntary, who will have access to their data, how their data will be used and protected, the rights they have as participants (e.g., that they may withdraw from the study at any time without loss of any compensation to which they were entitled), and the purpose of the study.

Individual Participation and Redress

DOT provides a reasonable opportunity and capability for individuals to make informed decisions about the collection, use, and disclosure of their PII. As required by the Privacy Act, individuals should be active participants in the decision-making process regarding the collection and use of their PII and they are provided reasonable access to their PII and the opportunity to have their PII corrected, amended, or deleted, as appropriate.

Prior to enrollment in a study, potential participants can obtain information from several sources to make informed decisions about the collection, use, and disclosure of their PII.

First, individuals can view publicly-available materials required by the PRA regarding the kinds of information collected from participants. These materials include documents submitted to OMB as part of the clearance process. They are published online[4] and searchable by OMB control number, agency, and study details. Details of the information collection request are also published twice in the Federal Register[5] and searchable by study title, agency, and other study details.

Second, during the informed consent process, potential participants are provided with the information necessary to make an informed decision about their decision to participate in the study, including information about the collection and use of their PII. Consent forms used in this process are reviewed and approved both by NHTSA's Office of Chief Counsel and an IRB. Per federal regulations on the protection of human subjects (45 C.F.R. § 46[6]), during the informed consent process, the research team provides potential participants with a statement that their participation in the study is voluntary and that refusal to participate or discontinuing participation at any time will involve no penalty or loss of benefits to which they were otherwise entitled. The research team also informs participants whether any data already collected about them will be retained and analyzed even if participants decide to withdraw and whether the research team will honor participants' requests to have all of their data destroyed or excluded from analysis upon withdrawal. Additionally, during the informed consent process, the research team tells potential

[4] http://www.reginfo.gov/public/do/PRAmain

[5] http://federalregister.gov

[6] http://www.ecfr.gov

participants whether there are any circumstances under which their participation may be terminated early by the research team.

The informed consent process also communicates to participants the specific information that will be collected about them during the study, who will have access to their data, and how their data will be used and protected. Participants are informed that their data will be reported only in aggregate and that no identifiable information about them will be published in the public domain without their explicit consent. Participants are given contact information for a research team member who can answer additional questions about the study and the contact.

NHTSA will submit an information collection request (ICR) for any collections of information subject to the PRA. Approved collection instruments will include a PRA Burden Statement which includes language addressing the voluntary nature of the collection. DOT will not collect information subject to the PRA from more than nine individuals until OMB has issued an authorized information collection number. [7]

Purpose Specification

DOT should (i) identify the legal bases that authorize a particular PII collection, activity, or technology that impacts privacy; and (ii) specify the purpose(s) for which it collects, uses, maintains, or disseminates PII. The PII contained in PTB is utilized for transit subsidy usage reconciliation, reporting for the agency, monitoring, and tracking participant usage.

Title 23, United States Code, Section 403 authorizes the Secretary to conduct research and development activities on all aspects of highway and traffic safety systems and conditions, including those relating to driver, passenger, motorcyclist, and pedestrian characteristics, as well as on human behavioral factors and their effect on highway and traffic safety and evaluations of the effectiveness of highway and traffic safety countermeasures.

Accordingly, OVSR conducts research studies on behaviors and attitudes in highway safety, focusing on drivers, passengers, pedestrians, and motorcyclists, and uses those studies to develop and refine countermeasures to deter unsafe behaviors and promote safe alternatives. Potential participants are provided with information about the purpose of the study, and the purpose for which any PII is collected, during the informed consent process. PII about study participants is only used or disclosed under the terms specified in the consent form, and PII collected from participants as part of these research studies supports these purposes and is limited to that which is relevant and necessary to support a given research topic. Some PII may be collected to facilitate administrative aspects of the study (e.g., the collection of participants' addresses in order to send compensation), while other PII may be necessary to obtain information about consented participants from external sources (e.g., the collection of driver's license numbers in order to obtain driving records or vehicle registration information from a State department of

[7] OMB maintains a list of ICRs at – http://www.reginfo.gov/public/do/PRAMain

motor vehicles), to derive variables necessary for interpretation of the study results (e.g., date of birth in order to obtain age in months), to assign participants to experimental groups (e.g., sex), or to accurately interpret study data (e.g., race, amount of education). In the course of these research studies, the research team collects the minimum amount of information from participants necessary to conduct the study for the purposes authorized under 23 U.S.C. § 403.

Data Minimization & Retention

DOT should collect, use, and retain only PII that is relevant and necessary for the specified purpose for which it was originally collected.

Any PII collected from participants as part of these research studies is limited to that which is relevant and necessary to support the purpose for which it was collected. The collection of some kinds of PII is necessary for successful administration of the study; for example, it is sometimes necessary to collect participants' names and mailing addresses to send them study-related communications or compensation after the study is complete. The collection of other PII may be necessary to obtain archival data about consented participants, such as driving records, from external sources. In most studies, it is necessary to collect demographic information about participants (e.g., date of birth, sex, race, amount of education) to derive study variables, assign participants to the appropriate experimental groups, or accurately interpret other study data. In the course of these research studies, the research team collects the minimum amount of information from participants necessary to conduct the study for the purposes authorized in 23 U.S.C. § 403.

PII collected during the research study is stored separately from the participants' responses. In a typical study, name, address, driver's license number, sex, and age would be stored in one electronic data file, while study data like driving performance and eye glance behavior information or responses to questionnaires would be stored in a separate file.

Once the research is complete, any electronic data files containing data containing PII are destroyed. Only the files containing non-attributable study data is retained by NHTSA.

Deliverables required under the research study contract that are submitted to OVSR are considered Federal records; these include Final or Interim Reports and non-attributable datasets that do not contain PII about study participants.

Files created by NHTSA's contractors during a research study that contain PII but are not submitted to NHTSA are not considered Federal Records. Some of these files, like documentation of informed consent, are required by Department of Health and Human Services regulation, 45 CFR 46.115(b), to be retained for 3 years after the study's completion. After this time, they are destroyed by the contractor. Other files created by the contractor that may contain PII are destroyed at a time agreed upon in advance by the NHTSA Contracting Officer's Representative (COR) and the Contractor. Typically, these files are destroyed immediately after

verification that all aspects of the study that require the PII have been completed (e.g., the research report has been approved by NHTSA for publication).

Use Limitation

DOT shall limit the scope of its PII use to ensure that the Department does not use PII in any manner that is not specified in notices, incompatible with the specified purposes for which the information was collected, or for any purpose not otherwise permitted by law.

Potential participants can obtain information about the way their PII will be used from several sources. First, for any studies that require approval from OMB in accordance with the Paperwork Reduction Act, all study procedures— including a description of the specific information that will be collected from participants and the forms used to collect this information—are published twice in the Federal Register and subject to the public comment process. Materials submitted to OMB as part of the clearance process are also published online.[8] These documents are searchable by OMB control number, agency, and other study details. During the informed consent process, potential participants are made aware of what PII will be collected and the ways in which it will be used.

Any PII collected during a research study is used only for those purposes of which the participant is made aware via the informed consent process, as is specified in all required notices. Additionally, depending on the study protocols, PII about study participants is destroyed immediately after data collection has ended, all participants have been compensated, or archival data to be used in the study has been received from external sources. No identifiable information is retained longer than it is needed to fulfil the purpose for which it was collected. Data transmitted from contractors to OVSR for future use will not be associated with any identifier and will not be reidentified.

Data Quality and Integrity

In accordance with Section 552a(e)(2) of the Privacy Act of 1974, DOT should ensure that any PII collected and maintained by the organization is accurate, relevant, timely, and complete for the purpose for which it is to be used, as specified in the Department's public notice(s).

OVSR ensures that the collection, use, and maintenance of PII collected about study participants is relevant to the purposes for which it is to be used and, to the extent necessary for those purposes, that it is complete and up-to-date. Whenever possible, PII about study participants is collected directly from the individuals themselves (e.g., name, address) because self-reported information is assumed to be accurate. We attempt to minimize the need for any manual entry by the contractor of PII or study data about participants (e.g., transferring hard-copy paper information into a computer database) because of the increased opportunity for inaccuracies.

[8] http://www.reginfo.gov/public/do/PRAMain

Instead, whenever possible, data is collected via automated means, such as electronic entry of PII by participants themselves.

Additionally, during the data collection period, the research team completes periodic "spot checks" to ensure that the correct study data is being assigned to the correct participant, and to check for completeness or missing data. These internal data quality checks ensure that PII about participants is accurate and complete.

Security

DOT shall implement administrative, technical, and physical measures to protect PII collected or maintained by the Department against loss, unauthorized access, or disclosure, as required by the Privacy Act, and to ensure that organizational planning and responses to privacy incidents comply with OMB policies and guidance.

PII collected about study participants is safeguarded in accordance with applicable rules and policies, including all applicable DOT automated systems security and access policies. For information collected, stored, or transmitted electronically, OVSR uses systems that meet or surpass best practices for information security and data protection of PII. In all studies, participants' PII is stored on computers in encrypted form. Electronic exchanges of PII (e.g., driving records from a State BMV to NHTSA VRTC) occur via password-protected and encrypted data transmission protocols.

OVSR also ensures that information collected or stored electronically is protected by administrative controls. Names and passwords are required to access NHTSA secure networks and computers and access is limited to personnel directly involved in a study.

PII is also protected using physical safeguards. If any PII is collected in hard-copy (paper) form, those copies are stored in locked cabinets or a safe to which only study personnel have access.

Electronically-stored recruitment information containing PII about participants is kept in a separate file or database from the files or databases that store study data. Unique identifier codes are created and assigned to each participant. One electronic database contains PII about participants (e.g., name, address) and their unique identifier code, and a separate database contains information collected from or about participants for the study purposes (e.g., driving performance data, eye glance location and duration data) in which participants are identified only by the unique identifier code.

Accountability and Auditing

DOT shall implement effective governance controls, monitoring controls, risk management, and assessment controls to demonstrate that the Department is complying with all applicable privacy protection requirements and minimizing the privacy risk to individuals.

NHTSA is responsible for identifying, training, and holding personnel accountable for adhering to NHTSA privacy and security policies and regulations. NHTSA follows the Fair Information

Practice Principles as best practices for the protection of information associated with OVSR reports. In addition to these practices, policies and procedures will be consistently applied, especially as they relate to the protection, retention, and destruction of records. Moreover, all OVSR projects undergo a Privacy Threshold Assessment (PTA). The PTA is an analytical tool used by DOT to determine the scope of privacy risk management activities that must be executed to ensure that DOT initiatives do not create undue privacy risks for individuals. The PTA determines whether the initiative creates privacy risk for individuals that must be further analyzed, documented, or mitigated, and determines the need for additional privacy compliance documentation.

NHTSA staff also complete mandatory annual security and privacy awareness training, as well as acknowledgement of system rules of behavior. The NHTSA Security and Privacy Officers conduct regular periodic security and privacy reviews of the system consistent with the Office of Management and Budget Circular A-130, Managing Information as a Strategic Resource.

Research team personnel receive clear guidance in their duties as they relate to the handling of PII, and only the minimum number of personnel have access to participants' PII. Further, IRBs require yearly review of all ongoing studies. Finally, oversight from the NHTSA COR throughout the process ensures that privacy controls are being implemented correctly by the Contractor.

Responsible Official

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Approval and Signature

Claire W. Barrett
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Appendix A: Order 700.5, Protection of Human Subjects, Human Surrogates, and Animal Subjects in NHTSA Conducted, Sponsored or Regulated Research

U.S. Department
of Transportation

ORDER #: 700-5

Date of Issuance: November 8, 2006

National Highway
Traffic Safety
Administration

Subject: PROTECTION OF HUMAN SUBJECTS, HUMAN SURROGATES AND ANIMAL SUBJECTS IN NHTSA CONDUCTED, SPONSORED OR REGULATED RESEARCH

PARAGRAPH:

1. PURPOSE. This Order establishes policy and procedures for the use and protection of human subjects, human surrogates and animal subjects in research performed, funded or regulated, in whole or in part, by the National Highway Traffic Safety Administration (NHTSA).

2. EFFECT ON OTHER DIRECTIVES. This Order supersedes NHTSA Orders 700-1, dated November 4, 1981 (Subject: Protection of the Rights and Welfare of Human Subjects in NHTSA-Sponsored Experiments), 700-3, dated June 30, 1980 (Subject: Human Use Review Panel), and 700-4, dated April 24, 1979 (Subject: Ethical Use of Human Surrogates in NHTSA-Sponsored Experiments). This Order is intended to set forth minimum requirements for the protection of human subjects, human surrogates and animal subjects in NHTSA conducted, sponsored or regulated research. It does not prevent entities conducting covered research from applying more rigorous review procedures or extending additional protections to research subjects, whether pursuant to institutional policy or state or local laws or regulations.

3. REFERENCES. The policy and procedures detailed in this Order incorporate by reference certain requirements of 45 C.F.R. Part 46 (the Department of Health and Human Services' (HHS) Policy for Protection of Human Research Subjects) and 49 C.F.R. Part 11 (Department of Transportation (DOT) Policy for Protection of Human Subjects), primarily pertaining to the

process for establishing an Institutional Review Board (IRB).

4. DEFINITIONS.

   a. "Animal Subject" means a live, vertebrate animal used as an integral part of a test, experiment, or other evaluation procedure.

   b. "Certification" means an official statement by a contractor or funding recipient to NHTSA, affirming that research involving human subjects or human surrogates has been reviewed and approved by an Institutional Review Board (IRB) provided for in a current HHS-Approved Assurance, and will be subject to continuing review by the IRB. Certification as it relates to human research subjects and human surrogates is different than the Certification of Humane Care and Use of Animal Research Subjects required under this policy as it relates to use of animal subjects.

   c. "Certification of Humane Care and Use of Animal Research Subjects" is the official set of assurances set forth in Appendix A that must be executed by an officer of the contractor or funding recipient authorized to bind the entity conducting the research prior to the commencement of any research activity covered under this policy involving animal subjects.

   d. HHS-Approved Assurance" means a current assurance appropriate for the research in question, on file with the Office for Protection from Research Risks, HHS, and approved for federal-wide use by that office.

   e. "Human Subject" means a living individual about whom an investigator conducting research obtains:

      (1) Data through intervention or interaction with the individual; or

      (2) Identifiable private information, which includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for its collection to constitute research involving human subjects.

   d. "Human Surrogate" means a deceased person or portion thereof used as an integral part of a test, experiment, or other evaluation procedure.

5. POLICY.

   a. Human Subjects and Human Surrogates

      (1) No research activity performed, funded or regulated, in whole or in part, by NHTSA may involve

human subjects or human surrogates unless:

(a) The research has been reviewed and approved by an Institutional Review Board ("IRB"), established in accordance with the requirements of 49 C.F.R. Part 11 and 45 C.F.R. Part 46, with a current assurance appropriate for the research in question approved by and on file with the Office for Protection from Research Risks, HHS;

(b) The IRB that initially reviewed and approved the research will subject it to continuing review at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third-party observe the consent process and research; and

(c) Prior to commencement of the research, the contractor or funding recipient submits to NHTSA a certification of IRB review and approval, and of continuing IRB review, and, unless NHTSA already has a copy of its current assurance on file with HHS, a copy of the applicable assurance, which shall be retained by the program office overseeing the research.

(2) This policy does not apply to research activity involving adult human subjects in which the only involvement of these subjects is in connection with the use of educational tests, survey procedures, interview procedures or observation of public behavior, *unless*:

(a) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to subjects; and

(b) Any disclosure of human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) This policy applies to all research activity with children involving survey or interview procedures or observations of public behavior, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

b. Animal Subjects

(1) No research activity performed, funded or regulated, in whole or in part, by NHTSA may involve animal subjects unless the contractor or funding recipient involved in the research has submitted to NHTSA the Certification of Humane Care and Use of Animal Research Subjects set forth in Appendix A, executed by an officer of the contractor or funding recipient authorized to bind the entity conducting the research; and

(2) The contractor or funding recipient planning to conduct the research has identified in its proposal the following information:

(a) The species and approximate number of animal subjects to be used;

(b) The rationale for involving animals, and the appropriateness of the species and numbers used;

(c) A complete description of the proposed use of the animals;

(d) A description of procedures to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and thatanalgesic, anesthetic, and tranquilizing drugs will be used where appropriate to minimize discomfort and pain to animals;

(e) A description of any euthanasia methods to be used; and

(f) The education, training and experience of all animal health professionals who will be supervising the use of the animals and all treatments, drugs and procedures administered to such animals.

6. RESPONSIBILITIES.

a. The Senior Associate Administrator for the program responsible for the research involving human subjects, human surrogates or animal subjects shall:

(1) Prior to the approval of the research, notify the Administrator in writing of the proposed research;

(2) With respect to research involving human subjects or human surrogates, prior to the commencement of the research, ensure that the program office involved has obtained from the entity performing the research a certification of IRB review and approval satisfying the requirements of this Order and, unless NHTSA already has a copy of the current assurance on file with HHS, a copy of the applicable assurance;

(3) With respect to research involving animal subjects, prior to the commencement of the research, ensure that the program office involved has obtained from the entity performing the research a properly executed Certification of Humane Care and Use of Animal Research Subjects (see Appendix A).

b. The Director, Contracts and Procurement, shall ensure that each NHTSA solicitation, contract, cooperative agreement or grant that involves or may involve human subjects, human surrogates or animal subjects, contains the appropriate special contract provision set forth in Appendix B.

7. APPENDICES. Following and appended are the documents referenced in this Order.

   a. Appendix A - Certification of Humane Care and Use of Animal Research Subjects

   b. Appendix B - Special Provisions For Contracts or Assistance Agreements Involving the Use of Human Subjects, Human Surrogates or Animal Subjects

Gregory A. Walter
Senior Associate Administrator for
Policy and Operations

APPENDIX A

CERTIFICATION OF HUMANE CARE AND USE OF ANIMAL RESEARCH SUBJECTS

It is the policy of the National Highway Traffic Safety Administration that all research using animal subjects performed, funded or regulated, in whole or in part, by the agency be performed in accordance with the following Principles:

I. The transportation, care, and use of animals should be in accordance with applicable Federal laws, guidelines, and policies.

II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, and the good of society.

III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in animals.

V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. In any case, veterinary care shall be provided as indicated.

VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.

IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard

to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

I certify that, in conducting research using animal subjects, all involved researchers and personnel will adhere to the Principles on Humane Care and Use of Animal Research Subjects set forth above.

Signature **Date**

Name

Title

Contractor/Funding Recipient

NHTSA Contract or Agreement Number

APPENDIX B

SPECIAL PROVISIONS FOR CONTRACTS AND ASSISTANCE AGREEMENTS INVOLVING THE USE OF HUMAN SUBJECTS, HUMAN SURROGATES AND ANIMAL SUBJECTS

Protection of Human Subjects (Special Provision)

The [contractor/funding recipient]* shall comply fully with 49 C.F.R. Part 11, DOT's regulation governing Protection of Human Subjects, and with NHTSA Order 700-5, which sets forth the Agency's policies and procedures for the protection of human subjects participating in research supported directly or indirectly by NHTSA, including through contracts, grants and cooperative agreements.

Protection of Human Surrogates (Special Provision #_)

The [contractor/funding recipient]* shall comply fully with NHTSA Order 700-5, which sets forth the Agency's policies and procedures for the protection of human surrogates used in research supported directly or indirectly by NHTSA, including through contracts, grants and cooperative agreements.

Humane Care and Use of Animal Research Subjects (Special Provision #_)

The [contractor/funding recipient]* shall comply fully with NHTSA Order 700-5 which sets forth the Agency's policies and procedures for the humane care and use of animal subjects used in research supported directly or indirectly by NHTSA, including through contracts, grants and cooperative agreements.

*Select "contractor" if the funding instrument is a contract or "funding recipient" if the funding instrument is a grant or cooperative agreement.

Appendix B: Research Studies Covered Under This PIA

Driver Interaction with Driver-Assistance Technologies

System Manager Contact Information: Elizabeth Mazzae, elizabeth.mazzae@dot.gov , 937-666-3314

Date of DOT Chief Privacy Officer Adjudication of Privacy Threshold Assessment (PTA): 4/13/2020

System Overview:

The objective of this research is to learn about drivers' use of and behavior while interacting with certain advanced driver-assistance system (ADAS) technologies. This research will help NHTSA to better understand the current state of implementation of ADAS technologies, how drivers interact with them, and how they may be useful for improving driving safety. The research will involve on-road, semi-naturalistic driving experimentation in which participants who are members of the general public will drive government-owned, instrumented production vehicles equipped with the ADAS technologies. Participants will include licensed drivers aged 25 to 65 who are healthy and able to drive without assistive devices. Participants will be recruited using print and online newspaper advertisements as well as using letters mailed to registered owners of the vehicle models of interest. Study participation will be voluntary and monetary compensation will be provided. Staff from NHTSA's Vehicle Research and Test Center will carry out the research with support from the on-site support services contractor, Transportation Research Center, Inc. (TRC). The results of this research study will be described in a report provided to NHTSA after the study is complete.

Research staff will recruit individuals with two different levels of experience with advanced driver assistance technologies: Individuals with no experience and individuals who own specific vehicle make/models equipped with the ADAS feature(s) being studied. Individuals who do not have experience with these technologies will be reached via advertisements (print and online). Individuals with experience driving one of the two specific vehicle models equipped with the features of interest will be registered owners identified via data from the State of Ohio's Bureau of Motor Vehicles (BMV). Owners of the vehicles of interest will be contacted by U.S. mail through a postcard containing the study description and an invitation to participate.

Individuals interested in participation will respond to the advertisement or mailing by completing Question Set 1, Interest Response Form either in print (vehicle model-of-interest owners only) or online via a secure website.

The information participants will provide at this time is:

- Self-report of a valid U.S. driver license
- Sex
- Date of birth (mm/dd/yy)
- Driving frequency
- Personally-owned vehicle model and characteristics

- Advanced driver assistance system feature use experience
- Contact information:
  - Residential address
  - E-mail address
  - Phone number

Question Set 1 will ask participants to verify whether they currently possess a valid U.S. driver license, but will not ask for the actual number at this time. The research team will review the response data and will determine whether the individual meets the initial study participation criteria. Those meeting the criteria, will move on to the next step (Question Set 2).

Individuals meeting the criteria associated with Question Set 1, Interest Response Form will be sent an e-mail message containing a web link for accessing Question Set 2 via a secure website. The website will present the questions and record responses to individual vehicle and driving related questions, while recording only a summary indication of whether an individual meets the health question requirements.

Response data will be reviewed by the research team and a determination will be made whether the individual meets the study participation criteria. Those respondents meeting the criteria, will be contacted by e-mail or phone to schedule an appointment for study participation.

The information participants will provide at this time will relate to the participant's:

- Ability to read, write, and speak English without assistance
- Vision
- Hearing
- Ability to drive an automatic transition without assistance
- Medical issues impacting the ability to drive continuously for 3 hours
- Household members who work or are retired from an automotive manufacturer
- Criminal convictions in the last 3 years
- Driver license number
- Day and times available for participation
- Contact information
  - E-mail address
  - First and last name
  - Street address
  - Phone number

Participants' driver's license numbers will be used to determine whether a candidate participant has more than 2 points on their driving.

In summary, participants must meet the following requirements in order to participate:

- Be aged 25-65 years

- Drive at least 11,000 miles annually
- Hold a valid U.S. driver license
- Have no uncorrected vision or hearing problems
- Be in good general health, able to drive a production passenger vehicle continuously and safely for a period of 3 hours and without the need for assistive devices
- Currently have no more than 2 points on their driving record
- Have no recent criminal convictions
- Self-report they are able to read, write, speak, and understand English
- Be willing to drive to NHTSA's Vehicle Research and Test Center and spend up to approximately 4 hours participating in a research study
- Not have anyone in their household who works in or is retired from any automotive manufacturer, which may constitute a conflict of interest with the research

Enrolled study participants will drive a government-owned instrumented vehicle on public roadways in normal traffic during daytime hours. Vehicle instrumentation will include video cameras for recording the driver eye glance and hand locations and the road scene. Information such as vehicle location, speed, and control inputs will also be recorded.

The research team will review video and engineering data to extract descriptive information associated with driving behavior and system use such as frequency of system use and timing of responses to system prompts.

A post-drive questionnaire will be administered using a tablet computer immediately following completion of the study drive. There will be two versions of the questionnaire with both having the same questions but referring to the specific vehicle and ADAS features the participant drove with in the study.

Participants' responses to scale-based questions will be combined for analysis. Responses to open-ended questions will be qualitatively summarized and described in the technical report without reference to individual participants.

For the observational driving study and the post-drive questionnaire, NHTSA plans to provide cash payment at the rate of $50 per hour for study participation. Such compensation is consistent with normal experimental practice to compensate participants for their time and encourage participation in research studies. Participants will not need to provide SSN or bank account information to receive compensation.