U.S.Department of Transportation
Privacy Impact Assessment

National Highway Traffic Safety Administration (NHTSA)
Office of Behavioral Safety Research (OBSR) Research Studies

Responsible Official
Rory Austin
Acting Office Director
Office of Behavioral Safety Research (OBSR)
202-366-5592
rory.austin@dot.gov

Reviewing Official
Claire W. Barrett
Chief Privacy & Information Asset Officer
Office of the Chief Information Officer
privacy@dot.gov

CLAIRE W BARRETT Digitally signed by CLAIRE W BARRETT
Date: 2019.06.10 15:57:12 -04'00'

Executive Summary

The mission of the National Highway Traffic Safety Administration (NHTSA) is to save lives, prevent injuries, and reduce traffic-related health care and other economic costs. The agency develops, promotes, and implements effective educational, engineering, and enforcement programs with the goal of ending preventable tragedies and reducing economic costs associated with vehicle use and highway travel. To support NHTSA's mission, and in accordance with United States Code Title 23, Chapter 5, NHTSA's Office of Behavioral Safety Research (OBSR) 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.

To carry out these research studies, NHTSA OBSR contracts with universities and other research partners. This Privacy Impact Assessment is being conducted because NHTSA OBSR's contractors collect, process, and maintain Personally Identifiable Information (PII) on members of the public on behalf of NHTSA.

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 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.*

[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).

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 Office of Behavioral Safety Research (OBSR) conducts research studies on behaviors and attitudes relevant for highway safety, focusing on drivers, passengers, pedestrians, and motorcyclists. The purpose of these studies is to identify and measure behaviors associated with crashes or injuries and to develop and refine countermeasures to deter unsafe behaviors and promote safe alternatives. To conduct these studies, NHTSA contracts with universities or other research partners who collect, process, and maintain Personally Identifiable Information (PII) about members of the public on behalf of NHTSA.

Participant Selection

Experimental research studies in OBSR begin with NHTSA personnel identifying a research need, developing a study plan, and selecting a contractor to perform the study. These contractors are typically research firms, universities, or non-profit organizations. Once a contractor is selected, in accordance with the Paperwork Reduction Act, all studies that involve the collection of information from ten 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 OBSR 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 these clearance processes, NHTSA's contractors begin recruiting participants for the study. Potential participants may be recruited using the contractor's own existing database of previously-consented participants, or participants may be recruited by the contractor on behalf of NHTSA, using various methods. These materials are distributed by State, community, or other organizations, and include, but are not limited to: flyers posted in locations where participants are likely to see them; address-based mailings; or invitations handed out directly to potential participants.

When potential participants respond to recruitment efforts, the contractor may ask them initial screening questions to confirm their eligibility for 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). For individuals who do not enroll in the study, the research team retains only non-identifying information, such as sex or age. This limited nformation about the entire pool of individuals may be used to identify potentially eligible or interested in participating in a study and, in some cases, to evaluate the potential for bias resulting from refusals. Participants in research studies include adults and children.

Following any initial screening questions, potential participants undergo the informed consent process. This process involves participants reading and, if in-person, 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 they will receive for their participation. The forms describe the steps taken by the research team to ensure participants' data is kept private and 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 OBSR are approved by an IRB and NHTSA's Office of Chief Counsel and received an FWA. If potential participants agree to enrollment, they sign the consent form. A parent or guardian is also required to sign if the participant is under the age of majority (typically, age 18).

Once participants (and their guardian, if applicable) sign the consent form, they are considered to be enrolled in the study. At this point, the research team typically asks participants to provide contact information necessary for payment or communication during the course of the study. All participants must provide their name. If the study requires contacting participants at a later date for follow-up, participants must provide contact information (mailing address, telephone number, or e-mail address). Some contractors ask participants to provide their mailing address or Social Security number for payment and tax reporting purposes. In this case, participants may also elect to waive compensation if they do not want to disclose their mailing address or Social Security Number. Participants may also be asked to provide demographic information (e.g., age, sex, or ethnicity) that may be necessary for the appropriate analysis of study data. Finally, participants may be asked questions necessary to assign them to appropriate experimental groups (e.g., prior diagnoses of a chronic medical condition) or to confirm their eligibility.

Study Participation

After participants have provided contact, demographic, or other information, the research study typically begins. Research studies conducted by contractors on behalf of OBSR may take place in a variety of settings. Information may be collected from participants in-person (e.g., at a laboratory where participants complete computerized or paper-based tasks or drive in a computerized driving simulator), online (e.g., a web-based driver training program or a web-based questionnaire), or by mail, telephone, or e-mail (e.g., paper-based or phone-based surveys).

Often, an individual's participation in the study is limited to a single interaction. For example, the participant may complete an online questionnaire about traffic safety-related attitudes, beliefs, or behaviors, or the participant may complete a single session in-person on a computerized driving simulator. In other studies, however, an individual's participation in the study may consist of multiple interactions with the study materials or research team, as when participants complete an online driver training course and then a follow-up online test of retention six months later or when participants must return for multiple training sessions. Some studies require that an individual's participation in the study is ongoing throughout the duration of the study, as when participants drive vehicles outfitted with sensors, GPS, and video devices to collect continuous information about driving performance. Finally, some studies involve the collection of information about study participants from archival sources of data. For example, participants may provide their driver's license number so that the research team can obtain their driving records from a State DMV six months after a driver education course. Critically, 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.

During the study period, OBSR's contractors may collect a variety of information from or about participants, including, but not limited to: name, address, telephone number, Social Security number, driver's license number, date of birth, sex, race; social, economic, and demographic data; performance on behavioral or psychological tests or trainings; responses to questions about traffic safety attitudes, beliefs, or behaviors; performance on computerized 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: individuals with diseases or other medical conditions, healthy individuals as controls, drivers of particular types of vehicles, parents and other caregivers, health care practitioners, members of law enforcement, and demographic sub-groups as applicable, such as age, sex, or geographic location. All participants and the information collected about them are treated in accordance with the guidelines for a given population. For example, for research studies that involve children, the research team obtains the child's affirmative agreement to participate in the research. Mere failure to object to participating is not construed as assent. The research team also obtains consent from the child's parents or guardian.

Post-Study Activities

After participants complete their active participation in the study, they are usually compensated. This may occur at the end of their visit to a laboratory, via cash sent to them in the mail, or by some other means. Once compensation is distributed to all participants, and once any archival data about participants is received from external sources (e.g., a State DMV), administrative data about participants (e.g., name, address, SSN) are separated from study data (e.g., accuracy on a psychological test, speed in a driving simulator) 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, SSNs, etc., and all other PII. After study completion, OBSR 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. At no point in the research study process do OBSR personnel take possession of study participants' PII. The information garnered from the reports is used to develop and refine countermeasures to deter unsafe behaviors and promote safe alternative.

Information about specific research studies conducted by OBSR 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].

[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

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 Paperwork Reduction Act, 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 send 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 collection's purpose, storage, and use 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 should provide 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 be 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 in order to make informed decisions about the collection, use, and disclosure of their PII.

Firstly, individuals can view publicly-available materials required by the Paperwork Reduction Act 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.

[4] https://www.reginfo.gov/public/do/PRAMain

[5] https://federalregister.gov

Secondly, 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 that has received a FWA. 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 withdrawl. Additionally, during the informed consent process, the research team tells potential 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 information of the IRB that approved the study..

NHTSA will submit an information collection request (ICR) for any collections of information subject to the Paperwork Reduction Act (PRA). Approved collection instruments will include a PRA Burden Statement which includes language addressing voluntary nature of the collection. [7] DOT engage in any collection of information subject to the PRA until OMB has issued an authorized information collection number.[8]

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.

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.

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

[7] *Sample PRA Burden Statement* – "Under the Paperwork Reduction Act, a federal agency may not conduct or sponsor, and a person is not required to respond to collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control number. The OMB Control Number for this information collection is 2127-XXXX. Public reporting for this collection of information is estimated to be approximately XX minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are voluntary. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Information Collection Clearance Officer, National Highway Traffic Safety Administration, 1200 New Jersey Ave, S.E., Washington, DC, 20590."

[8] OMB maintains a list of ICRs at - https://www.reginfo.gov/public/do/PRAMain

Accordingly, OBSR 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 archival information about consented participants from external sources (e.g., the collection of driver's license numbers in order to obtain driving records from a State DMV), 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, OBSR's contractors collect the minimum amount of information from participants necessary to conduct the study for the purposes authorized by 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. DOT should retain PII for only as long as necessary to fulfill the specified purpose(s) and in accordance with a National Archives and Records Administration (NARA)-approved record disposition schedule. Forms used for the purposes of collecting PII shall be authorized by the Office of Management and Budget (OMB).

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 in order to send them 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) in order to derive study variables, assign participants to the appropriate experimental groups, or accurately interpret other study data. In the course of these research studies, OBSR's contractors collect 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, Social Security Number, driver's license number, and age would be stored in one electronic data file, while study data like performance on a cognitive test, performance on a driving simulator, number of crashes in a 6-month period, or responses to survey questions on traffic safety attitudes and behaviors would be stored in a separate file.

Once the study is complete—data collection has ended, the OMB approval is discontinued, participants are compensated, and any archival data has been obtained from external sources is destroyed, including the electronic file containing PII. Only the file containing non-attributable study data is retained. The contractor sends OBS non-attributable data file at the end of a study. No PII relating to study participants is provided to OBSR.

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

The disposition of these records is dictated by the appropriate NARA-approved record disposition schedule. NHTSA OBSR is currently in the process of identifying whether an existing schedule applies or whether a new schedule must be created for Federal records generated by these studies.

Files created by NHTSA's contractors during a research study that contain PII but are not submitted to NHTSA and 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 three 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 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., payment has been distributed to all participants).

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.[9] 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 OBSR 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).

OBSR 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, SSN) because self-reported information is assumed to be accurate. In research studies conducted by contractors on behalf of OBSR, we attempt to minimize the need for any manual entry by the contractor of PII or

[9] https://www.reginfo.gov/public/do/PRAMain

study data about participants (e.g., transferring hard-copy paper information into a computer database) because of the increased opportunity for inaccuracies. Instead, whenever possible, data is collected via automated means, such as electronic entry of PII by participants themselves, automatic collection of test accuracy via a computer-administered test, or automatic collection of information about a computerized driving simulator.

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, OBSR ensures that contractors provide detailed information about the technology environments, data management systems, or web-hosted data collection systems used during the study. These systems are expected to meet or surpass best practices for information security and data protection of PII. Contractors are encouraged to reference the NIST Special Publication 800-53 Revision 4, "Security and Privacy Controls for Federal Information Systems and Organizations," to obtain information about the preferred level of security controls. For example, a contractor's technology environment may be protected by a firewall with malware and intrusion prevention services, as well as anti-virus and spyware tools. In all studies, participants' PII is stored on contractors' computers in encrypted form. Electronic exchanges of PII (e.g., driving records from a State DMV to the contractor) occur via password-protected and encrypted data transmission protocols.

OBSR also ensures that information collected or stored electronically is protected by administrative controls. Names and passwords are required to access contractors' 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, in locked rooms to which only study personnel have access.

Importantly, electronically-stored PII about participants is kept in a separate file or database from the files or databases that store study responses. Unique identifier codes are created and assigned to each participant. One electronic database contains PII about participants (e.g., name, address, SSN) and their unique identifier code, and a separate database contains information collected from or about participants for the study purposes (e.g., survey responses, accuracy or reaction time on a cognitive test, performance on a driving simulator, number of crashes or violations in a specified time period) 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 OBSR 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 OBSR 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 inititative 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 Contracting Officer's Representative (COR) throughout the process ensures that privacy controls are being implemented correctly by the Contractor.

Responsible Official

Rory Austin
Acting Office Director
Office of Behavioral Safety Research (OBSR)

Approval

Claire W. Barrett
Chief Privacy & Information Asset Officer
Office of the Chief Information Officer

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

**National Highway
Traffic Safety
Administration**

ORDER #: 700-5
Date of Issuance: November 8, 2006

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 that

analgesic, 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

Hazard Perception & Distracted Driving Training Intervention for Teens (RAPT) Research Study

System Manager Contact Information: Christine Watson, christine.watson@dot.gov, 202-366-7345

Date of DOT Chief Privacy Offier Review of Privacy Threshold Assessment (PTA): 12/11/2018

System Overview: The goal of this research study is to determine whether a driver training protocol administered to teen drivers in two states reduces their number of crashes and violations within the 6-month period following training. NHTSA's contractor (Traffic Injury Research Foundation, TIRF)

will be working with DMVs in two States to identify eligible study participants. The results of this research study will be described in a report provided to NHTSA after the study is complete.

When teens come to the DMV to obtain their first license, DMV staff members will give them a paper invitation to participate in the study. The DMV will electronically transmit to TIRF, via encrypted means, the names and addresses of the teens to whom they gave invitation letters, ensuring that no unauthorized users can access PII. Invitation letters will contain the URL of the study website; teens must visit the site within two weeks of licensure to participate in the study. If an eligible teen has not visited the study link within 10 days of licensure, the research team will mail a follow-up invitation reminder. TIRF will store participants' names and addresses in encrypted form and in accordance with the company's security and confidentiality policy. (In brief, the contractor's technology environment is safeguarded by a firewall with advanced malware and intrusion prevention services, as well as anti-virus and spyware tools. Names and passwords are needed to access the secure network and computers; all the contractor's end user devices are monitored for malware and viruses.)

Eligible teens will visit the study website URL on their home computer or mobile phone. Once on the website, participants will complete an online consent form. Participants younger than 18 will be required to have a parent or guardian complete an online consent form, as well. After providing consent, participants will enter on the study website self-report information necessary to determine study eligibility, experimental group assignment, and to send compensation (see below).

The information participants will provide at this time is: name, mailing address, telephone number, driver's license number, date of birth, sex, and whether the teen has previously completed a driver training course. Participants' driver's license numbers will be used to obtain driving records from State DMVs later in the study, as described below.

Participants will be compensated with cash, both in-person ($2 cash will be included in each invitation letter) and by mail (between $5-$25 cash, depending on whether the participant takes part in the follow-up and driving log portions of the study in addition to the training protocol.) Therefore, participants will not need to provide SSN or bank account information to receive compensation.

All information participants submit via the study website will be protected by secure encryption. The TIRF research team will access this information using password protected administrative tools and encryption. All accesses of the data will be logged. Once downloaded by TIRF, all PII and other self-report data will be protected by the securities outlined in the company's security and confidentiality policy. Participants will also complete an online driver training protocol, and the website will log each participant's performance (i.e., accuracy) on tests of hazard recognition before and after training.

Six months after participants complete the training protocol, the research team will e-mail an invitation to participate in a follow-up session along with the URL of the study website. When participants visit this site, they will be asked to self-report the number and characteristics of crashes (severity, fault) and violations (moving violations, violations for crashes) in which they have been involved in the past 6 months. The study site will also log each participant's performance on a follow-up test of hazard recognition. All information submitted via the study website will follow the protocols outlined above. Additionally, during the six months following training, a subsample of participants will be sent an e-mail invitation and instructions to complete a one-week driving log. Participants will visit a URL included in the invitation and will enter information they have recorded during the week about their driving: name, driver's license number, and date/time/mileage information about trips taken on each day of the past week.

Finally, the TIRF research team will provide the two State DMVs with a list of driver's license numbers of consented study participants to obtain the driving record of each participant over the six months following training, including the date and characteristics of each crash and traffic violation. All exchanges of information will occur electronically via password protected and encrypted data transmission protocols. Throughout the study, a unique ID will be used to refer to each participant. PII (e.g., name, driver's license number) about each participant will be stored separately from study data (e.g., hazard recognition test performance, crash information) and linked via the unique ID. Once study participants have been mailed compensation or once the invitation to participate in the follow-up has expired, and once TIRF has received driver records for consented participants from the DMVs, PII for each participant will be (electronically) purged/deleted.

In-Vehicle Drowsiness Detection and Alerting Project

System Manager Contact Information: Jordan Blenner, jordan.blenner@dot.gov, 202-366-9982

Date of DOT Chief Privacy Officer Review of Privacy Threshold Assessment (PTA): 2/6/2019

System Overview: The National Highway Traffic Safety Administration (NHTSA) proposes to collect information from licensed drivers to determine (1) their eligibility to participate in a study evaluating procedures designed to detect and mitigate drowsy driving, (2) their driving performance during a simulated driving task to measure lane departure warning and drowsiness mitigation system effectiveness, and (3) their opinions about the safety systems and their perceptions of the benefits of the systems.

The objective of this study is to compare the impact of various in-vehicle drowsiness countermeasures on drivers while using in a driving simulator. This study will add to the state of knowledge by systematically comparing drowsy drivers' performance in a simulation that incorporates lane departure warnings and a drowsiness mitigation system to performance of participants without such systems.

NHTSA has a contract with Westat to conduct research, who will subcontract with the University of Iowa to conduct this study. The University of Iowa will recruit participants through the National Advanced Driving Simulator participant registry, an electronic database of individuals maintained by the University of Iowa who have participated in previous studies or expressed interest in participating in studies.

To determine eligibility for the study, the University of Iowa will conduct telephone interviews with individuals identified in the registry and administer a phone screening that provides a brief description of the study and ensures that respondents who move to the next step are interested in participating, available to take part in the study, and

meet inclusion criteria. The study will ask questions regarding sleep patterns, and about each participant's health. Health questions include whether the individual has a serious illness, infection, epilepsy, vertigo or anxiety to assist in the eligibility determination.

Each eligible participant must complete a screening session at the National Advanced Driving Simulator. During the screening session, a research team member will review the study procedures with each participant, obtain informed consent through an executed consent form approved by NHTSA and the University of Iowa Institutional Review Board, and answer any questions a participant may have about the study. Each participant will complete a short drive in the driving simulator for team members to evaluate whether the participant has any adverse reaction to the simulator and complete a wellness survey to evaluate any symptoms after experiencing the driving simulator. The survey requests that participants indicate any symptoms they experienced such as general discomfort, fatigue, headache, eye strain, vertigo, sweating, etc. on a scale that provides: none, slight, moderate or severe. A driver that exhibits an adverse reaction to the simulator will be excluded from further participation and compensated for their time.

The sample will consist of 75 male drivers between the ages of 21 and 30. The selected participants will complete the screening visit identified above that will last approximately one hour. The study visit will last approximately nine hours. Prior to the study visit, each participant will wear an activity monitor and complete a food and activity log to confirm that each participant is awake by 8 AM the day of the study visit, do not sleep during the day, or consume caffeine after 1 PM. Each participant will arrive at the lab by 11 PM, complete a sleep and food intake survey and remain awake until the study begins at 2 AM. During this time, at thirty-minute intervals, each participant will complete the Stanford Sleepiness Scale, a subjective questionnaire that permits the participant to rate sleepiness on a scale from one (1) to seven (7). This provides a measure of subjective sleepiness, which compliments the objective measures of drowsiness collected during each study drive. Each participant will drive the simulator from 2 AM to 6 AM, to assess the effectiveness of drowsiness countermeasures. During the drive, the participant will have the option to stop to rest. During each rest break, the participant will complete the Stanford Sleepiness Scale to evaluate drowsiness.

Following the simulated drive, each participant will complete a post drive survey that evaluates decision making throughout the study drive and the participants preferences regarding the drowsiness countermeasure to understand their acceptance, trust, and perceptions of the drowsiness countermeasure they experienced during study drive.

The University of Iowa researchers will use the information collected during the study to evaluate driver drowsiness countermeasures. In addition, the researchers will use certain information to determine whether the driver state detection algorithm functioned appropriately. The study data will support the evaluation of drowsy driving and sleep habits that will assist NHTSA to improve the agency's drowsiness detection algorithms and countermeasures.

Neither NHTSA, nor its contractors will publish individual results or personal information. Published documents will provide only summary statistics that are anonymized. Links between individual names and study numbers will be securely stored pursuant to Federal law, as required by NHTSA's contract, and the University of Iowa Institutional Review Board. Using a NHTSA and an IRB approved consent form, the University of Iowa will obtain consent from each participant to release video images and auditory data. The consent will inform the participants that their images or auditory data may be released to the publicly or used for scientific, regulatory, educational, outreach, legislative, or research purposes.

The University of Iowa will maintain the data collected about participants based upon the medium in which it was collected. The University of Iowa will maintain paper/hard copy documents (consent documents, hard copy surveys, questionnaires, and case report forms) in a locked cabinet within a secure building with access to only personnel with a marlock key. After completion of the study and analysis, the University of Iowa will scan the hard copies (becoming electronic records) and place them into the National Advanced Driving Simulator's (NADS) archival room that has limited access by designated archival personnel.

The sleep and food intake survey, drive break survey, post drive survey, and Stanford sleepiness scale data are collected via a web based application by Qualtrics that saves the data in a nonpublic, password protected account on its website. University of Iowa project staff download the data to the NADS server that is password protected. Only authorized University of Iowa may access the data. After a survey is closed, the University of Iowa staff will remove all information that identifies each subject prior to exporting the data. The exported survey data will be stored in a separate file than the subject key. Only the members of the research team will have access to the locally stored subject key, which will be saved in a password protected directory.

For electronic records (simulator data, other computer files, and electronic databases), the University of Iowa maintains the data on secure servers that will be password protected. Only the lead investigator, study personnel, or system administrator can access the electronic records. The data is behind a hardline firewall. Data backups are maintained as dual copies on physical hard drive devices. One drive is stored within a secured location on-site and the other is stored off-site under the auspices of the University of Iowa Information Technology Services. All backup drives are inventoried and access to study data requires a request for access and authorization from a designated authority.

The University of Iowa will maintain the list linking study ID number and participant name (subject key) separate from the information obtained from each participant and obtained during the participant's drive in the simulator in a secure location accessible only to the researchers at the University of Iowa.

At the conclusion of the study, the University of Iowa will transfer all the data collected during the study to a permanent data storage area where it will be available only to the principal investigator or authorized research team members. At the conclusion of the study, NHTSA will receive a report and a deidentified analysis data set.

Participants will be offered compensation for completing the study. In order to receive compensation, each participant will have to submit his social security number. The University of Iowa requires all participants to provide their social security number to receive compensation.