



**COOPERATIVE AGREEMENT FOR  
CRASH INJURY RESEARCH AND ENGINEERING NETWORK (CIREN)**

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation (DOT).

**ACTION:** Announcement of a Request for Applications (RFA) to support the research conducted under the Crash Injury Research and Engineering Network (CIREN) and to increase its benefits to the public.

**SUMMARY:** The National Highway Traffic Safety Administration (NHTSA) announces discretionary Cooperative Agreement opportunities to provide funding to Level One Trauma Centers and biomechanics research laboratories in support of the Crash Injury Research and Engineering Network. NHTSA anticipates funding these Cooperative Agreements in annual installments for one base year plus four one-year option years at NHTSA's option and subject to the availability of funds. Due to budgetary constraints and the levels of effort proposed, NHTSA is uncertain as to the number of Cooperative Agreements that will be funded. These Cooperative Agreements will support projects to improve the prevention, treatment, and rehabilitation of motor vehicle crash injuries to reduce deaths, disabilities and human economic costs. This Notice solicits applications from American College of Surgeons (ACS) or State equivalent Level One Trauma Centers and university-based biomechanics research laboratories. Interested applicants must follow the instructions in the application section of this Notice below.

**DATES:** Application(s) must be submitted to the National Highway Traffic Safety Administration, Office of Acquisition Management (NPO-320), ATTN: Brenda K. Brummer, 1200 New Jersey Avenue, S.E., W53-404, Washington, D.C. 20590. All application(s) submitted must include a reference to NHTSA Cooperative Agreement No. DTNH22-10-R-00315. Complete packages will be considered only if received on or before **3:00 P.M. Eastern Standard Time on Tuesday, February 23, 2010.**

**Applicant(s) shall provide a complete mailing address where Federal Express mail can be delivered.**

**FOR FURTHER INFORMATION, CONTACT:** General administrative and program questions may be directed to the Office of Acquisition Management to the attention of Brenda K Brummer, Contract Specialist (CTR), by e-mail at [Brenda.Brummer.CTR@dot.gov](mailto:Brenda.Brummer.CTR@dot.gov), or by phone at (202) 366-0031, or Chelly Johnson-Jones, Contracting Officer, by email at [Chelly.Johnson-Jones@dot.gov](mailto:Chelly.Johnson-Jones@dot.gov), or by phone at (202) 366-1943. To allow for sufficient time to address questions appropriately, all questions must be received **via e-mail** no later than **2:00 P.M. Eastern Standard Time, Tuesday, January 19, 2010.**

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UNITED STATES DEPARTMENT OF TRANSPORTATION (U.S. DOT)  
National Highway Traffic Safety Administration

DTNH22-10-R-00315

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**ARTICLE I. BACKGROUND AND PURPOSE**

**A. Background.**

1. Motor vehicles are the dominant means of travel in the United States for both personal and business trips and provide Americans with an extraordinary degree of mobility. Traffic fatalities account for more than 90 percent of all transportation-related fatalities. These injuries and fatalities are a major public health problem. About 40,000 people die each year as the result of injuries received in motor vehicle crashes and more than 2 million people are injured. Motor vehicle injuries comprise nearly half of all traumatic injury deaths.

2. The large number of motor vehicle injuries places a considerable burden on the nation's health care system. It is estimated that about 20 percent of all Emergency Medical Service (EMS) calls are motor vehicle related, and persons are treated in trauma centers largely as the result of motor vehicle crashes. This care results in a significant economic burden on society, estimated at more than \$17 billion a year. Because motor vehicle injuries often have long-term effects, they are a leading cause of long-term disability.

3. NHTSA is an agency of the U.S. Department of Transportation (DOT). NHTSA's mission 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. As part of its mandate, NHTSA supports research to improve motor vehicle and traffic safety, diagnose specific problems, implement standards and programs to address these problems and evaluate their impact. In addition to supporting internal NHTSA efforts, NHTSA-sponsored research provides high-quality publicly-accessible data that serves as the basis for countless other research endeavors.

4. The Crash Injury Research and Engineering Network (CIREN) is a sponsor-led multi-center research program involving a collaboration of clinicians and engineers in academia, industry, and government pursuing in-depth studies of crashes, and the resultant injuries and treatments, to improve processes and outcomes. Its mission is to improve the prevention, treatment, and rehabilitation of motor vehicle crash injuries to reduce deaths, disabilities, and human and economic costs. The CIREN process combines prospective data collection with professional multidisciplinary analysis of medical and engineering evidence to determine injury causation in every crash investigation conducted. CIREN is the only source of detailed, prospective crash-related injury data in the United States. The injury data collected under the CIREN program includes over 500 data elements such as radiological images, operative notes, and pre-existing conditions that may play a role in injury severity and long-term outcome. Injured occupants are tracked for one year to determine the societal cost of an injury, which can be just as significant as the initial treatment costs. This data is collected and reviewed by highly-regarded professionals from the medical and engineering fields, as well as academia. The biomechanical causation of all serious injuries is an attribute

exclusive to CIREN, and serves as a starting point for further injury and vehicle safety research.

5. Grantees in the CIREN program benefit from having direct and exclusive access to CIREN's network of medical and engineering experts for information exchange, collaborative research and problem solving. Collaboration between the medically- and engineering-oriented grantees in CIREN leads to a better understanding of the issues related to injury causation and treatment for the medical side, and enables the engineers to develop better designs for automobiles, restraint systems, and test devices and criteria. Grantees' access to and participation in CIREN provides a rich learning experience for all who are involved, and the real-world knowledge contributed from involved parties is not something that can be found in a textbook. Thanks to input from various professionals, including vehicle designers, social workers, and first responders, CIREN brings together many facets of the automobile crash and provides a more comprehensive overview of the effects of passenger vehicle trauma.

6. CIREN is also the name of a data collection system, developed, enhanced and maintained by the Volpe National Transportation Systems Center (Volpe) in Cambridge, Massachusetts to help researchers collect and review injury data. Variables for CIREN crash reconstruction data are an extension of the National Automotive Sampling System Crashworthiness Data System (NASS-CDS) Oracle data model. Variables for the medical injury data are based on a variety of sources including the National Trauma Registry, the Orthopedic Trauma Association, and the Uniform Pre-Hospital EMS Data Elements. CIREN grantees have direct access to this database and are encouraged to conduct research using the findings of the program to study different topics in occupant crash response.

7. NHTSA has funded hospital-based crash injury studies since the 1980s. Several Level One Trauma Centers were funded to collect detailed injury information on passenger vehicle occupants involved in crashes and to conduct research based on those findings. As more trauma centers became involved in this research, the need for a uniform method of data collection developed, and the result was the formation of the CIREN Network. The development of the CIREN data collection system provides benefit to grantees and other data users by providing accessible, detailed and consistently coded crash and injury data. Over the years, CIREN made significant contributions to the field of automobile safety research and has drawn financial support from industry and academia. Ford, Mercedes-Benz, Honda, Toyota, Froedtert Hospital and the Medical College of Wisconsin, and Inova Fairfax Hospital have all sponsored or supported CIREN operations since its inception.

#### **B. Purpose.**

This Agreement shall govern the relationship between the parties and add to the scope and expertise of the CIREN network. In addition, this Agreement will benefit the Grantees by enabling them to engage in unique state-of-the-art injury research related to automobile crashes. The research conducted by the grantees may be utilized to bolster grantees' academic endeavors and to enhance their research portfolios.

**ARTICLE II. SCOPE OF WORK**

For the period of performance stated in Article III of this Agreement, NHTSA and the Grantee shall furnish cooperatively the necessary personnel, equipment, and facilities, and otherwise perform all things necessary for, or incident to, the performance of work as set forth in this Agreement.

**A. NHTSA Involvement.**

NHTSA will be involved in all activities undertaken as part of this Agreement program and will:

1. Provide a Contracting Officer's Technical Representative (COTR) to participate in the planning and management of this Agreement and to coordinate activities between the Grantee and NHTSA;

2. Provide information and technical assistance from other government sources within available resources as determined appropriate by the COTR;

3. Maintain a Certificate of Confidentiality from the National Institutes of Health that covers the entire CIREN program;

4. Review and provide comments on oral and written presentations, research notes, white papers and other material submitted for publication to medical, technical or scientific journals;

5. Stimulate the exchange of information among Grantee and other CIREN Centers and encourage research projects;

6. Maintain on-going contact with the Grantee regarding progress of this Agreement;

7. Approve, in writing, through the Contracting Officer (CO), any deviations from the planned efforts before such deviation is implemented.

**B. Grantee's General Requirements.**

As performance under this Agreement, the Grantee shall:

1. Provide a Program Officer to perform the activities described in this Agreement;

2. Perform the activities as described in Article II, Section C, CIREN System Requirements, and do so in conjunction with NHTSA and other CIREN grantees;

3. Provide the necessary materials, information, personnel and technical assistance within the Grantee's resources for completion of the program;

4. Ensure ongoing disclosure of conflicts of interest as specified in Article IX, Section A, Conflict of Interest, of this Agreement;

5. Attend training sessions on CIREN System Coding, crash reconstruction or related topics deemed necessary by NHTSA COTR or CIREN Program Manager;

6. Attend a kick-off meeting upon award to review any contractual matters and discuss the nature and objectives of the award.

### **C. CIREN System Requirements.**

#### **1. General Requirements for All CIREN Centers.**

NHTSA's current CIREN model will be modified for the period of performance stated in Article III. The revised model will incorporate two different types of teams designed to work in conjunction with one another to deliver state-of-the-art passenger vehicle crash and injury causation data and research: Medical Centers and Engineering Centers. The two types of Centers will be funded in equal numbers. Medical Centers will be primarily responsible for prospective high-volume enrollment of CIREN participants (case occupants), conducting crash investigations and providing medical and research expertise to the entire network. Engineering Centers will also enroll CIREN participants and conduct crash investigations, though in fewer numbers. Engineering Centers will also assist the entire network in the analysis of crash data, engineering science and assignment of injury causation. Both types of Centers will conduct research and public safety awareness, as described in detail below. The intended outcome of this arrangement is a balanced multidisciplinary network dedicated to timely, high-quality data and initiation of relevant research. The new team structure within CIREN will be leveraged to generate robust research using the combined strengths available within the established network. The shared resources in CIREN will allow for improved efficiency and cross-pollination of knowledge.

##### **a. Patient Enrollment.**

The Grantee regularly shall enroll patients, enter, and complete medical/crash case information as reflected in the CIREN computer applications provided by Volpe. The Grantee shall collect detailed crash and injury information on a specified number of eligible passenger vehicle crashes involving vehicle occupants sustaining injury and treated at their participating trauma facility(s) (see Appendices A and B). The Grantee shall participate in a specified number of monthly electronic case reviews via internet video stream with NHTSA, the quality control contractor, and other CIREN Centers. The Grantee shall use its best, but at no time less than commercially reasonable, efforts to complete these cases as defined by the CIREN Coding Manual. The Grantee shall provide adequate, secure storage for the CIREN server and the associated hardware provided as part of the cost of this Agreement.

##### **b. Injury Coding.**

The Grantee shall review overall injury coding to ensure adherence to established procedures. All injuries shall be well-documented through the use of radiological reports, including but not limited to Computed Tomography (CT) scans, X-rays, and Magnetic Resonance Images (MRIs). Injuries shall be sourced to occupant contact points identified in the crash reconstruction process. Significant injuries shall be documented and coded with biomechanical mechanisms and contributing factors.

**c. Vehicle/Crash-Related Coding.**

The Grantee shall review overall coding related to the crash (including but not limited to vehicle measurements, scene diagram, contact points, and injury mechanisms) to ensure adherence to established procedures. All data shall be well-documented through the use of Easy Street Draw and photographs illustrating the scene and vehicle damage.

**d. Hiring Qualified Personnel.**

The Grantee shall hire qualified personnel in accordance with the staff member requirements as specified in Article II, Section 2.a.9 for a Medical Center or Section 2.b.10 for an Engineering Center, and shall not accept as a staff member anyone who intends to start or continue police, insurance or investigative activities, including expert witnessing, during his or her involvement with the CIREN program.

If evidence is detected that a CIREN Program personnel is participating in these activities after the award is made, Grantee shall provide written notification to the NHTSA COTR and CIREN Program Manager within one (1) business day that the aforementioned staff member is no longer working on the CIREN Program. NHTSA will immediately terminate his/her access to the CIREN Network. The Grantee shall ensure that staff members assigned to CIREN do not engage in such activities and will not be assigned to the duties that are part of this Agreement.

**e. Security Requirements.**

(1) The Grantee shall be required to sign a NHTSA Electronic Data System (EDS), Information Technology (IT) Systems Rules of Behavior Form before access to the Database is granted. This form will be provided by NHTSA's COTR within thirty (30) calendar days after award for each Center. All users shall agree not to discuss or divulge the source of any data to third parties (i.e., anyone outside the CIREN Network).

(2) CIREN deals with highly sensitive material that shall not be exposed to improper access within the Grantee across other CIREN Centers, or across the wide area network. Personal and location data identifiers shall not be accessible outside the Grantee originally acquiring the data.

(3) The Grantee shall follow established sanitization procedures for personally identifiable information as outlined in Article IX, Section F, CIREN Database, of this Agreement. Information released to the general public shall not include any "personal and/or location identifiers" or any "sensitive medical information" as defined in Article IX, Section F, CIREN Database, of this Agreement and shall not be traceable back to the CIREN Center that collected the data.

**f. Processing Requirements.**

(1) Certain processing requirements must be in place in order to expedite crash investigation procedures and crash documentation, as well as documentation of initial treatment. These include, but are not limited to, the establishment and maintenance of a good working relationship with law enforcement agencies, tow yards, EMS staff, and rehabilitation clinics.

(2) Procedures shall be established for monthly in-house medical/crash electronic case reviews which will be securely video-streamed to at least one other CIREN Center and NHTSA. These reviews shall include detailed discussion of the CIREN cases, including all medical and crash-related data. These reviews shall take place before cases are submitted to NHTSA's quality assurance contractor for quality control.

(3) The CIREN program will involve participation in the systematic collection and evaluation of new data concerning passenger vehicle crashes by a multi-center network. The outcomes/products of this program may include publication in a professional journal and/or presentations at professional meetings. Participation at CIREN meetings (annual research, team training, research reviews, electronic case reviews, etc.) is also required.

**g. Requirements for Program Material.**

The print materials must be provided to NHTSA in both printed format and appropriate media formats (DVD, CD-ROM).

**h. Program Materials.**

(1) Draft presentation materials for CIREN annual research meetings shall be submitted at least two (2) weeks prior to the meeting, and the final within two (2) weeks following the meeting. Presentation materials shall be submitted in the following formats for placement on CIREN's homepage on the Internet.

- Original application format, for example, \*.doc \*.ppt; etc.
- Section 508 compliancy checklist
- A PDF file for viewing with Adobe acrobat
- An HTML file

(2) Grantees preparing publications for NHTSA must submit them in a format ready for posting on the Web. All documents must be Section 508 compliant. All Web/HTML documents must comply with the accessibility standards of 36 CFR §1194.22 that implement Section 508 of the Rehabilitation Act of 1973. All submissions shall include a completed web-based Internet Information and Application Section 508 Checklist. These standards and guidelines are available for viewing in greater detail at the Access Board Web Site at: <http://www.access-board.gov/sec508/guide/1194.22.htm>.

**i. Computer and Network Requirements.**

(1) Network Requirements.

(a) Data storage and network requirements will carry the most significant impact to non-security aspects of the proposed CIREN site technical architecture. The ability to collect and store data files which range in size from 1MB to 2GB will be required of each CIREN site. Based on past CIREN data collection requirements and projected future requirements, the total data storage requirement for each CIREN site may be approximately 2TB.

(b) Each CIREN site must have the ability to enter, store, and replicate data from the site's location to Volpe. This data migration is typically facilitated through the use of telecommunications lines between the CIREN site and Volpe.

(c) All data collected during one business day must be replicated up to the central data repositories located at Volpe during the 12 hour (overnight) data replication window.

(d) Users located at the CIREN site will require the ability to update CIREN case data on-site and have no functional requirement to update data remotely or to take CIREN data off the CIREN network for analysis.

(e) CIREN users will require access to miscellaneous data sources such as DICOM imagery repositories that may be located on non-federal systems connected to local area networks not controlled by CIREN technical staff.

(f) Each CIREN site must have the ability to act independently in the event of a telecommunications line failure. Local hardware such as the CIREN server and workstations must continue to function regardless of the status of network connectivity between the site location and Volpe.

(g) Each CIREN user has a requirement to access resources which may be located on the Internet. Resources such as medical web sites, regional police jurisdictions and other resources that may be identified in the future as being required to facilitate CIREN case data collection.

## (2) Network Hardware Requirements.

(a) Each CIREN router will need to support a WAN port speed of no less than 3Mbps (6Mbps or greater preferred) in order to meet the migration requirements as outlined in this document while still providing support for the transmission of large DICOM imagery.

(b) Each CIREN router will require the ability to support one or more connections to local site resources via standard 100BASE-TX using standard Category 5 (Category 6 preferred) cabling.

(c) Each CIREN Ethernet switch will require a minimum of 24 ports, up to 1000BASE-T port speed on each port, support for VLANs and the ability to be managed remotely via SNMP V3 or equivalent.

## (3) Server Hardware Requirements.

HP Server:

Either Rack Mounted or Tower depending on the location

2-Quad Core Intel Processors 2.0GHZ or better

4GB of RAM 4x1GB

4-750GB HotPlug SATA Hard Drives

Windows Server 2008 with 5 CALS

Redundant Power Supply

DVD-ROM

Gigabit Network Adapter

Internal Tape Backup Drive  
5 year 4 Hour 24x7 Warranty  
15" LCD Monitor  
Keyboard/Mouse  
1-APC 1500VA Universal Power supply, tower or rack  
depending on location

(4) Network Security Requirements.

(a) All CIREN sites must agree to a memorandum of understanding which outlines the agreement between the Department of Transportation and the responsible parties at the site which will be hosting the CIREN system regarding the handling of Personally Identifiable Information (PII), system and network security. This Agreement must also identify critical contacts and a notification timeline for both parties in the event of a security incident or network breach.

(b) Each CIREN site will be required to provide documentation showing any network interconnects between the CIREN network and the host site's network. Documentation must clearly show both logical (VLAN, VPN, etc) and physical connections with detailed information on any network layer security precautions such as firewall rules, IPS/IDS, ACLs, for the purposes of troubleshooting network connectivity problems and ensuring that information security best practices are being followed whenever possible.

(c) All equipment provided by NHTSA/DOT or purchased with government funds consistent with this Agreement shall only be used on the CIREN network and will be managed by CIREN technical support staff. Access to external resources located on the host site's network will be provided as needed and will be required to pass through the CIREN network security boundary.

(d) Inbound connections to the CIREN network will not be allowed in order to comply with OMB Memorandum M-08-05 (Trusted Internet Connection) which governs the implementation of external connections into government networks. Internet access for CIREN client systems will also be provided through the CIREN network as no local (host provided) internet access for federal systems is allowed under the TIC.

(e) Each CIREN site will provide a complete list of all network resources external to the CIREN network for which access is required from within the CIREN network. This information will be used solely to configure the CIREN client systems and network security assets to allow access to those resources.

(5) Physical Security Requirements.

Each CIREN site will be required to provide a location for CIREN equipment that is both access and climate controlled. Additionally each CIREN site is responsible to ensuring only authorized CIREN or local site staff has access to CIREN equipment.

**j. Reporting.**

The Grantee shall provide the following reports as scheduled:

(1) Quarterly Progress Report – one page Excel spreadsheet recording the CIREN site's enrollment attempts and consents for the past three months. This report will be due by the 15<sup>th</sup> day after the end of the reporting quarter.

(2) Quarterly Financial Report/invoice – claim for reimbursement for activities related to this Agreement on a Standard Form 270. This report will be due by the 15<sup>th</sup> day after the end of the reporting quarter.

(3) Annual Productivity Report – detailed narrative report on the CIREN site's production and achievements during the annual period of performance. This report is due by the 30<sup>th</sup> day after the end of the annual period of performance.

## **2. Specific Requirements.**

There are two types of CIREN Center structures – Medical Centers and Engineering Centers. The structure of the CIREN system will require equal numbers of Medical Centers and Engineering Centers. Both Medical Centers and Engineering Centers will be required to collect cases, but the requirements differ for each Center type and are explained in detail below. One CIREN Center shall house and maintain the CIREN video streaming server. Details on this additional role are described below.

### **a. Medical Center.**

A Medical Center shall be based at a high-volume ACS-certified or State-equivalent Level One Trauma Center. The Medical Center's principal investigator shall be a clinically active trauma or emergency physician. These Centers may partner with another Level One or Level Two Trauma Center with whom they have a previously-established business or working relationship in order to achieve their annual case-count goal. The lead Center shall be denoted as the "Primary Enrollment Site" and the partnering Trauma Center shall be denoted as the "Secondary Enrollment Site." Partnerships must be designed to ensure efficiency in the data collection and research effort. Fully staffed teams at multiple locations would be cost prohibitive. Teams utilizing partnerships shall demonstrate their ability to maximize enrollment while minimizing costs. These Trauma Center relationships shall not change during the proposed five year period of performance of this Agreement. Changes or addition of staff members must be approved by the NHTSA COTR and CIREN Program Manager. Specific responsibilities for recommended Medical Center team members are covered in Article II, Section C.2.a.9.

(1) The Grantee shall prospectively review incoming admissions for eligible inclusion criteria as specified by NHTSA (see Case Inclusion Criteria in Appendix A and B).

(2) In accordance with Article II, Sections C.1.a, C.1.b, and C.1.c and Article V, Section A, Milestones/Deliverables Table, Items 2 and 3, a Medical Center shall collect and code detailed crash and injury information on at least 65 vehicle crash occupants sustaining applicable injury and treated at their facility (or at their partner Trauma Center) per year (see Appendix C, Center Structure and Case Enrollment Requirements). Medical Centers with Primary and Secondary Enrollment Sites must enroll at least 42 cases from the Primary Enrollment Site per year. All enrolled cases must meet NHTSA-specified case inclusion

criteria, which define the types of crashes, vehicles, occupants and injuries required for enrollment. Required elements of a case include–

(a) Complete vehicle and scene inspection in accordance with established NASS-CDS and CIREN coding methods and principles;

(b) Abbreviated Injury Scale (AIS) and International Classification of Diseases Ninth Revision (ICD-9) coding of all physical injuries sustained by the case occupant;

(c) Hospital course and initial outcome data as described in the CIREN Coding Manual V2.0;

(d) Radiologic images (digital format) utilized to document or diagnose case occupant injury;

(e) Complete injury radiology studies in DICOM format;

(f) Entry of all crash, vehicle and medical data elements into the CIREN data collection system in accordance with CIREN protocols.

(3) A Medical Center shall conduct five to six (5 to 6) monthly electronic case reviews with the full team present (see Appendix D, Video Stream/Case Review Assignment). The case reviews shall be broadcast via internet video stream to facilitate participation by an Engineering Center, NHTSA, and other applicable parties. An assigned Engineering Center will be required to participate in the Grantee's case reviews using the video streaming technology, and shall provide expertise related to biomechanics and vehicle safety systems to bolster the analysis of the case. The Grantee shall review case summaries and other narratives for information and remove any information that may suggest judgments of culpability. Culpability shall be determined by law enforcement and judicial proceedings and is not relevant to the research mission of NHTSA. Electronic case reviews shall be conducted in accordance with CIREN protocols with the final result being the coding of the biomechanical data elements for each coded injury's causation.

(4) The Grantee shall review all entered data for completeness and correctness according to NASS-CDS and CIREN protocols prior to submitting the case data to a third-party entity for quality assurance review. Data conflicts documented by the quality assurance review shall be addressed by the enrolling CIREN Center and documented in the CIREN data collection system.

(5) The Grantee shall conduct follow-up outcome data collection and entry at six (6) and twelve (12) months after the enrolled occupant's crash date.

(6) The Grantee shall assign personnel to participate in periodic telephone conference call committee meetings, provide peer review of papers written by other CIREN Centers, and attend annual research meetings and program briefings in Washington, DC. Training meetings may occur annually in Washington, DC, Cambridge, MA or Oklahoma City, OK.

(7) The Grantee shall be responsible for generating no less than one research project idea for each year (including option years if exercised) based on observations from the CIREN Program. Research projects approved by NHTSA will be completed annually and presented at the annual CIREN research meeting. Robust projects have the ability to act as a catalyst for additional long-term, focused research projects that are relevant to NHTSA. Such projects may qualify for additional research funding above and beyond the funding for the work described in this Agreement. Past examples include the knee-thigh-hip injury criteria developed by the University of Michigan (Rupp et al., 2009), research on long-term disability and cost associated with lower extremity injury conducted by the University of Maryland (DOT HS 809 871), and the narrow-offset frontal impact research and testing conducted by the Department of Neurosurgery at the Medical College of Wisconsin and VA Medical Center (Pintar et al., 2008). Research projects shall concentrate on utilizing injury causation data to advance NHTSA research priorities. Research projects will be presented at the annual CIREN research meeting to be held in Washington, DC. Some topics of interest include brain, thoracic and lower extremity trauma, pediatric occupant injury, elderly occupant impact tolerance and injury prediction. CIREN Centers will be encouraged to leverage the multidisciplinary resources available across the entire CIREN Network, and cooperative research between applicable Centers is expected.

(8) The Grantee shall be responsible for participating in at least five public outreach endeavors annually to promote passenger vehicle safety. Examples include, but are not limited to—

- EMS and law enforcement education
- Drinking and driving awareness
- Child safety seat education and inspection
- Teen driving education
- Community safety awareness

(9) The following core staff members are required for a Medical Center –

- Principal Investigator – The full-time Principal Investigator must be a clinically-active trauma surgeon or a clinically-active emergency medicine physician at the Primary Enrollment Site. Responsibilities of the Principal Investigator of a Medical Center include, but are not limited to, overall leadership of the team, interpretation of case occupant medical injury data and radiology, assessment of factors influencing injury causation and identification of medical evidence relevant to the injury causation to support injury biomechanics assessment during case review sessions.
- Crash Investigator – The full-time Crash Investigator shall demonstrate an established working relationship with local law enforcement, EMS, and salvage/tow yard facilities. Responsibilities of the Crash Investigator include, but are not limited to, conducting crash investigations (following NASS-CDS and CIREN protocol relevant to vehicle and scene), participating in case review sessions and identifying physical evidence relevant to injury causation to support injury biomechanics assessment.

- Study Coordinator – The full-time Study Coordinator shall be familiar with, and have a working knowledge of, medical terminology, basic human anatomy, and the various injury coding methodologies, including, but not limited to, International Classification of Diseases Ninth Edition (ICD-9), Abbreviated Injury Scale (AIS), and Current Procedural Terminology (CPT) codes. The Study Coordinator shall possess basic computer skills and a working knowledge of software packages for graphics, documents and presentations. The Study Coordinator should possess knowledge of digital radiology systems and have experience handling DICOM datasets in a clinical setting. The Study Coordinator shall serve as NHTSA’s conduit to the Grantee’s team.

Additional support team members are recommended to ensure adequate support of the Medical Center. Other team members may include, but are not limited to: SAS/SQL programmer, statistician, epidemiologist and research scientist(s).

**b. Engineering Center.**

An Engineering Center shall be based at a university-based biomechanics laboratory. The Engineering Center shall be led by a senior-level biomechanical engineer with technical expertise to direct research related to injury or impact biomechanics, anthropomorphic test devices or similar activities. Each Engineering Center shall partner with an ACS-certified or State-equivalent Level One Trauma Center with whom they have a previously-established business or working relationship in order to enroll cases (denoted as “Primary Enrollment Site”). An Engineering Center may partner with an additional Level One or Level Two Trauma Center, denoted as “Secondary Enrollment Site,” with whom they have a previously-established business or working relationship in order to achieve their case-count goal. Partnerships must be designed to ensure efficiency in the data collection and research effort. Fully staffed teams at multiple locations would be cost prohibitive. Teams utilizing partnerships shall demonstrate their ability to maximize enrollment while minimizing costs. These relationships shall not change during the proposed five year period of performance of this Agreement. Changes or addition of staff members within those facilities must be approved by the NHTSA COTR and CIREN Program Manager. Specific responsibilities for recommended Engineering Center team members are covered in Article II, Section C.2.b.10.

(1) The Grantee shall prospectively review incoming admissions for eligible inclusion criteria as specified by NHTSA (see Case Inclusion Criteria in Appendix A and B).

(2) In accordance with Article II, Sections C.1.a, C.1.b, and C.1.c and Article V, Section A, Milestones/Deliverables Table, Items 2 and 3, an Engineering Center shall collect and code detailed crash and injury information on at least 40 vehicle crash occupants sustaining applicable injury and treated at their partner Trauma Center(s) per year (see Appendix C, Center Structure and Case Enrollment Requirements). Engineering Centers with Primary and Secondary Enrollment Sites must enroll at least 26 cases from the Primary Enrollment Site per year. All enrolled cases must meet NHTSA-specified case inclusion

criteria, which define the types of crashes, vehicles, occupants and injuries required for enrollment. Required elements of a case include–

(a) Complete vehicle and scene inspection in accordance with established NASS-CDS and CIREN coding methods and principles;

(b) Abbreviated Injury Scale (AIS) and International Classification of Diseases Ninth Revision (ICD-9) coding of all physical injuries sustained by the case occupant;

(c) Hospital course and initial outcome data as described in the CIREN Coding Manual v2.0;

(d) Radiologic images (digital format) utilized to document or diagnose case occupant injury;

(e) Complete injury radiology studies in DICOM format;

(f) Entry of all crash, vehicle and medical data elements into the CIREN data collection system in accordance with CIREN protocols.

(3) An Engineering Center shall conduct three to four (3 to 4) local monthly electronic case reviews on the cases enrolled at their Center with the full team present (see Appendix D, Video Stream/Case Review Assignment). The local case reviews shall be broadcast via internet video stream to facilitate participation by another Engineering Center, NHTSA, and other applicable parties. Another assigned Engineering Center will be required to participate in each of the Grantee's case reviews using the video streaming technology. The Grantee shall incorporate, when possible, video and results from crash tests similar to the case crash, prior research findings, and crash expert analysis into its review of the cases enrolled at its trauma center. The Grantee shall review case summaries and other narratives for information and remove any information that may suggest judgments of culpability. Culpability shall be determined by law enforcement and judicial proceedings and is not relevant to the research mission of NHTSA. Electronic case reviews shall be conducted in accordance with CIREN protocols with the final result being the coding of the biomechanical data elements for each coded injury's causation.

(4) The Grantee shall review all entered data for completeness and correctness according to NASS-CDS and CIREN protocols prior to submitting the case data to a third-party entity for quality assurance review. Data conflicts documented by the quality assurance review shall be addressed by the enrolling CIREN Center and documented in the CIREN data collection system.

(5) The Grantee shall conduct follow-up outcome data collection and entry at six (6) and twelve (12) months after the enrolled occupant's crash date.

(6) An Engineering Center shall review eight to ten (8 to 10) assigned remote cases each month from both Medical and other Engineering Centers prior to the date of the enrolling Center's scheduled video stream case review (see Appendix D, Video Stream/Case Review Assignment). The objective of this preliminary review is to validate the scene, crash and occupant kinematics documented in the case. The Grantee's team shall work with the

enrolling Center's team to bolster critical aspects of the case prior to the scheduled video stream case review. The Grantee shall incorporate, when possible, video and results from crash tests similar to the case crash, prior research findings, and crash expert analysis into its review of the enrolling Center's case. The Grantee shall participate, via internet video stream, in the enrolling Center's case review for every case for which it plays a review role.

(7) The Grantee shall assign personnel to participate in periodic telephone conference call committee meetings, provide peer review of papers written by other CIREN Centers, and attend annual public research meetings and program briefings in Washington, DC. Periodic training meetings may occur annually in Washington, DC, Cambridge, MA, or Oklahoma City, OK.

(8) The Grantee shall be responsible for generating no less than one research project idea for each year (including option years if exercised) based on observations from the CIREN Program. Research projects approved by NHTSA will be completed annually and presented at the annual CIREN research meeting. Robust projects have the ability to act as a catalyst for additional long-term, focused research projects that are relevant to NHTSA. Such projects may qualify for additional research funding above and beyond the funding for the work described in this Agreement. Past examples include the knee-thigh-hip injury criteria developed by the University of Michigan (Rupp et al., 2009), research on long-term disability and cost associated with lower extremity injury conducted by the University of Maryland (DOT HS 809 871), and the narrow-offset frontal impact research and testing conducted by the Department of Neurosurgery at the Medical College of Wisconsin and VA Medical Center (Pintar et al., 2008). Research projects shall concentrate on utilizing injury causation data to advance NHTSA research priorities. Each research project will be presented at the annual CIREN research meeting to be held in Washington, DC. Some topics of interest include brain, thoracic and lower extremity trauma, pediatric occupant injury, elderly occupant impact tolerance and injury prediction. CIREN Centers will be encouraged to leverage the multidisciplinary resources available across the entire CIREN Network, and cooperative research between applicable Centers is expected.

(9) The Grantee shall be responsible for participating in at least five public outreach endeavors annually to promote passenger vehicle safety. Examples include, but are not limited to—

- EMS and law enforcement education
- Drinking and driving awareness
- Child safety seat education and inspection
- Teen driving education
- Community safety awareness

(10) The following core staff members are required for an Engineering Center –

- Principal Investigator – The full-time Principal Investigator must be a mechanical or biomechanical engineer serving in a research scientist or professor position at an engineering school. The Principal Investigator should possess experience with field crash research, laboratory-based

crash research, and be able to demonstrate evidence of prior work related to injury or impact biomechanics. The Principal Investigator shall have access to the resources necessary to conduct crash research using post-mortem human surrogates or anthropomorphic test devices. Responsibilities of the Principal Investigator of an Engineering Center include, but are not limited to, overall leadership of the Analytical Center team, providing expert input on injury mechanisms and causation during local or remote case reviews, interpretation of relevant crash/biomechanical test data, understanding of crash dynamics and occupant kinematics, familiarity with vehicle safety restraint systems, assessment of factors influencing injury causation and identification of engineering evidence relevant to the injury causation to support injury biomechanics assessment during case review sessions. The Principal Investigator shall also guide the CIREN research projects undertaken by the Engineering Center.

- Medical Investigator – The full-time Medical Investigator must be a clinically-active trauma surgeon or a clinically-active emergency medicine physician at the Primary Enrollment Site. Responsibilities of the Medical Investigator of an Engineering Center include, but are not limited to, interpretation of case occupant medical injury data and radiology, assessment of factors influencing injury causation and identification of medical evidence relevant to the injury causation to support injury assessment during case review sessions.
- Crash Investigator – The full-time Crash Investigator shall demonstrate an established working relationship with local law enforcement, EMS, and salvage/tow yard facilities. Responsibilities of the Crash Investigator include, but are not limited to, conducting crash investigations (following NASS-CDS and CIREN protocol relevant to vehicle and scene), participating in case review sessions and identifying physical evidence relevant to the injury causation to support injury biomechanics assessment.
- Study Coordinator – The full-time Study Coordinator shall be familiar with, and have a working knowledge of, medical terminology, basic human anatomy, and the various injury coding methodologies, including, but not limited to, International Classification of Diseases Ninth Edition (ICD-9), Abbreviated Injury Scale (AIS), and Current Procedural Terminology (CPT) codes. The Study Coordinator shall possess basic computer skills and a working knowledge of software packages for graphics, documents and presentations. The Study Coordinator should possess knowledge of digital radiology systems and have experience handling DICOM datasets in a clinical setting. The Study Coordinator shall serve as NHTSA's conduit to the Grantee's team.

Additional support team members are recommended to ensure adequate support of the Engineering Center. Other team members may include, but are

not limited to: SAS/SQL programmer, statistician, epidemiologist and research scientist(s).

**c. Streaming Server Host.**

One CIREN Center within the Network shall house and maintain the server to support CIREN's video streaming capability. Any Applicant submitting a proposal as either an Engineering or Medical Center also has the option of hosting the video streaming server at their site. The server hosting is an option and will have no bearing on the evaluation of the proposal to become a CIREN Center. Only one Center shall serve as the Streaming Server Host, and NHTSA shall provide equipment and additional funding for this responsibility. Current streaming software utilized by CIREN is Wirecast distributed by Telestream. Current technical requirements for Wirecast can be reviewed at – <http://www.telestream.net/wire-cast/tech-specs.htm>.

(1) The Grantee shall provide a secure physical location for the streaming server hardware with dedicated connectivity sustainable at 10+ mbps upload Internet bandwidth (fractional T3 line or faster preferred).

(2) The Grantee shall provide the necessary maintenance and infrastructure support to ensure proper streaming server operation at all required times.

(3) The Grantee shall maintain account access security in accordance with NHTSA/DOT guidelines.

(4) The Grantee shall install and use Wirecast, or similar video streaming software, to support CIREN's video streaming needs as chosen by NHTSA at the time of award.

**ARTICLE III. PERIOD OF PERFORMANCE**

**A. Base Year.**

The period of performance for this Agreement shall include one Base Year and four (4) 12-month Option Years (if exercised). The Base Year shall be from the date of award to twelve (12) months after award, i.e., the Option Years, if exercised, shall begin for a period of 12 months each. The total of the Base Year and Option Years (if exercised) shall not exceed 60 consecutive months.

**B. Exercise of Option Years.**

The Government at its sole discretion reserves the right to exercise up to four (4) 12-month Option Years. The Government may extend the term of this Agreement by written notice to the Grantee no later than 60 calendar days prior to expiration of the then-current Option Year. The exercise of an Option Year will be considered achieved upon the execution of a unilateral modification to this Agreement.

**ARTICLE IV. FINANCIAL ADMINISTRATION****A. Funding.**

1. Current CIREN Centers are funded between \$300,000 and \$500,000 per year. Applicants should consider these ranges when submitting their proposals. Applicants are encouraged to include non-Federal funding and/or in-kind contributions in their budget proposals. The Agency plans to make multiple awards from this announcement and expects to fund a minimum of four (4) Centers, subject to the availability of funds. Funding for each of the four (4) 12-month option years for each of the Grantees will be based on the availability of funds in future fiscal years. NHTSA will select from among the proposals received from the prospective CIREN Center(s) to obtain the best mix of price/performance for the program as a whole.

2. The current amount of Federal funds may be increased at any time by the NHTSA Contracting Officer, subject to available funds, without concurrence of the Grantee. The Grantee shall not incur costs to be charged to NHTSA, nor shall NHTSA be obligated to reimburse the Grantee in excess of the Federal funds available under this Agreement.

3. In the event that the Agreement is not funded up to the total not-to-exceed amount of Federal funding, as set forth above, the Grantee shall, after notification from the NHTSA Contracting Officer, deliver to the NHTSA COTR the data collected.

4. To ensure that reimbursement is commensurate with performance during the performance period, a Grantee shall not be reimbursed for more than the greater of the pro rata funding amount for medical/crash cases or 25% of its total funding per quarter.

**B. Reduced Funding.**

Notwithstanding any other provision in this announcement, to ensure that production levels are met, the Government will monitor performance at all times and reserves the right to adjust levels of reimbursement at any time if performance or progress is deemed inadequate. A reduction of funding shall occur if the Grantee is unable to meet its performance requirements outlined in Article II, Scope of Work. The following financial penalties shall apply if, at the end of each year of performance, the specified conditions are not met:

- Case Enrollment Count – If the Grantee is unable to meet their minimum case enrollment count in a given year, there will be a reduction in funding of \$3,600.00 per case short of the quota during that funding year.
- Research – If the Grantee fails to produce an approved research project related to passenger vehicle safety and the advancement of CIREN data and/or methodology on an annual basis, there will be a reduction in funding of \$10,000.00 during that funding year.
- Outreach – If the Grantee fails to conduct at least five public safety outreach endeavors, there will be a reduction in funding of \$3,000.00 during that funding year.

- Case Review – If an Engineering Center Grantee fails to review an assigned case, there will be a reduction in funding of \$900.00 for every case that it fails to review.

### **C. Option Year Funding.**

If the Grantee performance meets all production levels by the end of the performance period, the Grantee may be eligible for funding at the same level of performance in the subsequent Option Year, subject to the availability of funds (if the then current Option Year is exercised).

### **D. Program Budget.**

1. The Program Budget on SF 424 submitted by each successful Applicant shall be incorporated and made a part of this Agreement.

2. The application package must be submitted with the Office of Management and Budget (OMB) Standard Form 424 (Rev 4-88), Application for Federal Assistance, including 424A, Budget Information-Non-construction Program and 424B, Assurances-Non-construction Programs, with the required information provided and the certified assurances included. A Standard Form 424A & 424B must be submitted and packaged separately for each performance period. Forms are electronically available for downloading at: [www.whitehouse.gov/omb/grants/index.html](http://www.whitehouse.gov/omb/grants/index.html).

3. While the Form 424A deals with budget information, and Section B identifies Budget Categories, the available space does not permit a level of detail that is sufficient to provide for a meaningful evaluation of proposed costs. Therefore, supplemental information must be provided which presents a detailed breakout of the proposed costs (detailed labor, including labor category, level of effort and rate; direct materials, including itemized equipment, travel and transportation, including projected trips and number of people traveling; subcontracts/subgrants with similar detail if known; and overhead) as well as any non-Federal funding and/or in-kind contributions the Applicant proposes to contribute.

4. The Applicant also shall provide documentation supporting all costs for which Federal funding is being requested. The estimated costs must be separated and proposed by base year and by each of the four (4) one-year option years, such that the Applicant's budget will reflect the total possible performance of five (5) years.

### **E. Salary Limitations.**

1. Applicants shall provide budget estimates for all staff following the statutory provisions used by the National Institutes of Health (NIH) on their Agreements. These provisions restrict the amount of direct salary to Executive Level 1 of the Federal Executive Pay scale. Effective January 1, 2009, this amount is \$196,700. For the purposes of the salary limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are exclusive of fringe benefits and facilities and administrative (F&A) expenses, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities.

Base salary excludes any income that an individual may be permitted to earn outside of the duties to the applicant organization.

2. In preparing these budgets actual base salaries shall be reflected and any salary greater than the NIH limit previously mentioned should be noted. NHTSA shall use the information available in the existing application and make adjustments for the salary cap based on information available at the time of the award.

#### **F. Revisions to Budget and Program Plan.**

1. Any revisions to the budget or program plans shall be required and approved in accordance with 49 CFR Part 19 “Uniform Administrative requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations.”

2. Pursuant to 49 CFR Part 19, Section 19.25, Revision of budget and program plans, if NHTSA elects to exercise its option under Subsection f, NHTSA may, at its option, restrict the transfer of funds among direct cost categories or programs, functions and activities for awards in which the Federal share of the program exceeds \$100,000 and cumulative amount of such transfers exceeds or is expected to exceed 10% of the total budget as last approved by the NHTSA Contracting Officer. Any transferring of funds meeting the requirements of the above shall require the written approval of the NHTSA CO before any such transfers are implemented.

#### **G. Payments.**

1. **Minimum Requirements for Payment.** All costs claimed for reimbursement and payment, including the final payment, shall be submitted on a **Standard Form 270, Request for Advance or Reimbursement**, or any other format pre-approved by the NHTSA Contracting Officer (CO). The Grantee shall submit a claim for reimbursement on a **Quarterly basis**, accompanied by the Quarterly Progress Reports (See Article V, Section A, Items 5, 6, and 7). The information required for each reimbursement claim shall, at minimum, contain the following:

- Grantee’s Name
- Cooperative Agreement Number
- Task Order/Delivery Order Number (if applicable)
- Dollar amount claimed on the invoice
- Invoice Number
- Invoice Date
- Contract Specialist or Contracting Officer Name, Phone Number and E-mail Address
- Grantee’s TIN
- Grantee’s DUNS Number

2. **Where to send Reimbursement Claims.** The Grantee shall submit one (1) original Invoice and all supporting documents to:

DOT/NHTSA  
Mike Monroney Aeronautical Center  
Accounts Payable Branch, AMZ-150  
Post Office, Box 268911  
Oklahoma City, OK 73125

3. Payment Certification. The NHTSA COTR or alternate COTR (see Article VI, Sections A and B) shall review and certify the receipt of all goods and services rendered by the Grantee under this Agreement.

4. Payment Approval. The NHTSA Contracting Officer or designee (i.e., Contract Specialist) shall approve all payments made under this Agreement. Payments are subject to satisfactory progress and acceptance of the Quarterly Progress Reports and Annual Productivity Report by the NHTSA COTR.

## **ARTICLE V. PERFORMANCE MILESTONES AND DELIVERABLES**

### **A. Milestones/Deliverables Schedule.**

The Grantee must submit all milestones and deliverables on their respective due dates which are considered to be significant in the performance of this Agreement in accordance with the following:

<b>Item</b>	<b>Article and Section Reference</b>	<b>Milestone (M)/Deliverable (D)</b>	<b>Due Date After Award (Calendar)</b>	<b>No. of Copies</b>
1.	II.B.6	Kickoff Meeting	Within 1 month of award	N/A
2.	II.C.1.a II.C.1.b	Collect Occupant and Injury Data	Within 1 month of award	N/A
3.	II.C.1.c	Collect Crash Data	Within 1 month of award	N/A
4.	II.C.2.a.3 II.C.2.b.3	Monthly Case Reviews / Video Streaming	Monthly	N/A
5.	IV.G.1 IV.G.2	Quarterly Submission of Standard Form 270, Request for Advance or Reimbursement	15 <sup>th</sup> day after each reimbursement quarter	1
6.	IV.G.1 IV.G.2	Quarterly Progress Reports (M) (D)	15 <sup>th</sup> day after each reporting quarter	3
7.	IV.G.1 IV.G.2	Quarterly Financial Reports / Invoices (M) (D) *	15 <sup>th</sup> day after each reporting quarter	3
8.	IV.G.4	Annual Productivity Report (M) (D)	Within 30 days post completion of the annual performance period	3
9.	II.C.2.a.6 II.C.2.b.7	Annual Meeting Research Project Presentation (M) (D)	Yearly as scheduled	3
10.	II.C.2.a.8 II.C.2.b.9	Outreach Presentations / Projects (M)	5 per year	N/A

\*See Agreement Article IV, Financial Administration, Paragraph G, Payments

#### **B. Place of Delivery/Number of Copies.**

The above referenced deliverables shall be delivered electronically (one (1) copy each) to the locations and the persons as indicated below.

<u>Item</u>	<u>Address</u>
4	Department of Transportation National Highway Traffic Safety Administration Office of Vehicle Safety (NVS-323) Attention: 1200 New Jersey Avenue, S.E. W46-475 Washington, DC 20590 Telephone: E-mail:
5	
6	
7	
8	
4	DOT/NHTSA Mike Monroney Aeronautical Center Accounts Payable Branch, AMZ-150 P.O. Box 268911 Oklahoma City, OK 73125
5	Department of Transportation National Highway Traffic Safety Administration Attention: Office of Acquisitions Management (NPO-320) 1200 New Jersey Avenue, S.E. Washington, DC 20590 Telephone: E-mail:
7	
<i>All equipment reports shall be submitted to:</i>	Department of Transportation National Highway Traffic Safety Administration Office of Property Management Attention: 1200 New Jersey Avenue, S.E. Washington, DC 20590 Telephone: E-mail:

## ARTICLE VI. NHTSA'S PROGRAM OFFICERS

### A. Designation of NHTSA COTR.

The NHTSA COTR for this Agreement is [TBD]. While this list is not exhaustive, the major responsibilities of the NHTSA COTR are as follows:

1. To provide information and technical assistance from available Government resources as determined appropriate by the NHTSA COTR;
2. To provide liaison with other Government/private agencies as appropriate;
3. To stimulate the exchange of ideas and information among recipients of related projects through periodic meetings; and
4. To review and certify invoices.

The COTR's business information is provided below:

Department of Transportation  
National Highway Traffic Safety Administration  
Office of Vehicle Safety (NVS-330)  
Attention:  
1200 New Jersey Avenue, S.E., Room W46-312  
Washington, DC 20590  
Telephone:  
E-mail:

**B. Designation of “Alternate” COTR/Program Manager.**

In the event that the NHTSA COTR of record is unavailable for a period of time that would jeopardize the timely certification of incoming invoices, then the person indicated below has been designated by the NHTSA Contracting Officer to perform the functions associated with the certification of invoices ordinarily performed by the NHTSA COTR. The “Alternate” COTR shall have no other responsibility under this Agreement than to review and certify invoices in the absence of the NHTSA COTR.

Department of Transportation  
National Highway Traffic Safety Administration  
Office of Vehicle Safety (NVS-330)  
Attention:  
1200 New Jersey Avenue, S.E., Room W46-473  
Washington, DC 20590  
Telephone:  
E-mail:

**C. Designation of Task Manager.**

The individual name below, together with the CIREN COTR and the CIREN Program Manager shall provide overall guidance and assistance to the Grantee as needed.

Department of Transportation  
National Highway Traffic Safety Administration  
Office of Vehicle Safety (NVS-330)  
Attention:  
1200 New Jersey Avenue, S.E., Room W46-444  
Washington, DC 20590  
Telephone:  
E-mail:

**ARTICLE VII. GRANTEE’S PROGRAM OFFICER**

The Grantee shall designate a Program Officer for this Cooperative Agreement. The responsibility for the Grantee Program Officer is to oversee the activities as described in this Agreement and to do so in conjunction with the NHTSA COTR’s technical direction.

## **ARTICLE VIII. GENERAL PROVISIONS**

The NHTSA General Provisions for Assistance Agreements (dated 7/95), as provided in Appendix E, shall be applicable to this Agreement. (See Article XII, GOVERNMENT FURNISHED INFORMATION).

The Grantee shall comply with the NHTSA General Provisions for Assistance Agreements. (See Appendix E) The following exceptions to the NHTSA General Provisions for Assistance Agreements apply:

- Section 2 (Allowable Costs): Item (c) is not applicable to this requirement.
- Section 5 (Data Collection): This section is not applicable to this requirement.
- Section 7 (Rights in Data): This section is not applicable to this requirement. (See Article IX, SPECIAL PROVISIONS) for appropriate related material).

## **ARTICLE IX. SPECIAL PROVISIONS**

### **A. Conflict of Interest.**

It is U.S. DOT policy to award Cooperative Agreements only to those Applicants whose objectivity is not impaired because of any related past, present, or planned interest, financial or otherwise, in organizations regulated by U.S. DOT, or in organizations whose interests may be substantially affected by Departmental activities and which is related to work specified in this Cooperative Agreement Announcement. Based on this policy, if, after award, the Grantee discovers a conflict of interest with respect to the Cooperative Agreement that could reasonably have been known prior to the award, an immediate and full disclosure shall be made in writing to the Contracting Officer. The disclosure shall include a full description of the conflict along with a description of the action the recipient has taken, or proposes to take, to avoid or mitigate such conflict.

### **B. Disputes.**

1. The parties to this Agreement shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Disputes provision. Any dispute, which for the purposes of this provision includes any disagreement or claim, between NHTSA and the Grantee concerning questions of fact or law arising from or in connection with this Agreement and whether or not involving alleged breach of this agreement, may be raised only under this Disputes provision.

2. Whenever a dispute arises, the parties shall attempt to resolve the issues involved by discussion and mutual agreement as soon as practical. In no event shall a dispute that arose more than three months prior to the notification made under the following paragraph of this provision constitute the basis for relief under this article unless NHTSA waives this requirement.

3. Failing resolution by mutual agreement, the aggrieved party shall document the dispute by notifying the other party in writing of the relevant facts identify unresolved issues and specify the clarification or remedy sought. Within five working days after providing

written notice to the other party, the aggrieved party may, in writing, request a decision from the Contracting Officer. The other party shall submit a written position on the matters in dispute within thirty calendar days after being notified that a decision has been requested. The Contracting Officer shall conduct a review of the matters in dispute and may render a decision in writing within thirty calendar days of receipt of such written position. Any decision of the Contracting Officer is final and binding unless a party shall, within thirty calendar days, request further review as provided below.

4. The dispute shall be further reviewed, upon the Grantee's written request to NHTSA, Director, Office of Acquisition Management, or designee, made within thirty calendar days after the Contracting Officer's written decision or upon unavailability of a decision within the stated time frame under the preceding paragraph, the dispute shall be further reviewed. The NHTSA Director of the Office of Acquisition Management, or designee, shall conduct the review. Following the review, the NHTSA Director of the Office of Acquisition Management, or designee, will resolve the issues and notify the parties in writing. Such resolution is not subject to further administrative review and to the extent permitted by law, shall be final and binding. Nothing in this Agreement is intended to prevent the parties from pursuing disputes in a United States Federal Court of competent jurisdiction.

### **C. Termination.**

1. Notwithstanding any other provision of this Agreement, the Government may terminate this Agreement in whole or in part, upon providing written notification to the Grantee, if the prescribed funds are not available or if the Contracting Officer determines that a termination is in the Government's best interest or the Grantee defaults in performing the work and fails to cure the default within the time specified in writing by the Contracting Officer. The Grantee must deliver acceptable reports on work accomplished as part of any such termination.

2. The parties shall negotiate in good faith an equitable adjustment for work performed toward the accomplishment of this Agreement, at the time of termination. Failure of the parties to agree on an equitable adjustment will be resolved pursuant to the Disputes provision of this Agreement.

### **D. Seat Belt Use Policies and Programs.**

In accordance with Executive Order 13043, Increasing Seat Belt Use in the United States, dated April 16, 1997, the Grantee is encouraged to adopt and enforce on-the-job seat belt use policies and programs for its employees when operating company-owned, rented, or personally-owned vehicles. The National Highway Traffic Safety Administration (NHTSA) is responsible for providing leadership and guidance in support of this Presidential initiative. For information on how to implement such a program, or statistics on the potential benefits and cost-savings to your company or organization, please visit the *Buckle Up America* section on NHTSA's website at [www.nhtsa.dot.gov](http://www.nhtsa.dot.gov). Additional resources are available from the Network of Employers for Traffic Safety (NETS), a public-private partnership headquartered in the Washington, D.C. metropolitan area, and dedicated to improving the traffic safety practices of employers and employees. NETS is prepared to help with technical

assistance, a simple, user-friendly program kit, and an award for achieving the President's goal of 90 percent seat belt use. NETS can be contacted at 1 (888) 221-0045 or visit its website at [www.trafficsafety.org](http://www.trafficsafety.org).

#### **E. Protection of Human Subjects.**

1. The Grantee 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.

2. The Grantee shall obtain prior written authorization from NHTSA for all consent and release forms to be presented to human subjects participating in NHTSA conducted or funded research, including but not limited to informed consent and media releases.

#### **F. CIREN Database.**

1. CIREN Data Collection Requirements. The CIREN database, as configured at the time of this Agreement, consists of over 1,000 discrete fields of data concerning passenger vehicle crashes related to crash reconstruction and medical injury profiles as described in the CIREN Coding Manual, and provided to the Grantee **within ninety (90) calendar days after award**. The parties to this Agreement intend that the information collected for each case and about each case occupant under this Agreement be sufficient to ensure data input for each of these fields of data where applicable and available. The exact configuration of the CIREN database is subject to change during the period of performance of this Agreement as periodic upgrades are made to the system.

2. Protection of Individual Privacy. The Grantee shall follow established sanitization procedures for inclusion of information in the CIREN database as outlined below.

a. Personal and/or Location Identifiers. Personal and/or Location Identifiers, which may be discrete (e.g., database elements) or visual (e.g., photographs that include the face, without masking), shall not be included in the CIREN database. The following information is deemed to be "Personal and/or Location Identifiers":

Discrete Identifiers: Patient's name, address, telephone number  
 Social Security Number, patient ID number  
 Specific location identifiers (e.g., town, city, county, state, road name)  
 Employment information  
 Originating CIREN Center  
 Driver license number, license plate  
 Vehicle Identification Number\*  
 Date of birth\*\*  
 Date of accident\*\*\*  
 Time of accident\*\*\*\*

- \* Last six digits (sequential production portion) of VIN will not appear in the CIREN database.
- \*\* Age only will appear in the CIREN database.
- \*\*\* Month and year only will appear in the CIREN database.
- \*\*\*\* “Morning,” “Afternoon” or “Evening” only will appear in the public CIREN database.

Visual Identifiers: All photographs, drawings, etc., with recognizable identifiers to personal identity or to location of the crash. This includes unmasked photographs of faces, license plates, car vendor bumper plates, store signs, locality signs, and road signs.

b. Sensitive Medical Information. Sensitive Medical Information shall be included in the database only in specially designated fields, as directed by Volpe or NHTSA. The following information is deemed to be Sensitive Medical Information:

Patient photographs, X-rays, CT-Scans, MRIs, detailed medical information and/or history (e.g., surgical procedures and medical treatments, pre-existing medical conditions, laboratory results).

c. Sanitization and Data Segregability. The Grantee, NHTSA, NHTSA's quality assurance contractor, and Volpe shall work cooperatively to ensure that all data has been properly sanitized to remove all Personal and/or Location Identifiers, before the data are added to the CIREN database, and that all Sensitive Medical Information resides only in specially designated fields, so that such information is segregable from the remaining information in the database.

d. Consent and Dissemination. The Grantee shall be responsible for obtaining informed consent for each case occupant, to the extent required by its Institutional Review Board. The Grantee shall ensure that such informed consent is sufficient under its established policies and procedures and consistent with applicable laws and regulations, to enable the information is collected to be used and disseminated in full accord with the terms and restrictions of this Agreement.

### 3. Rights in Data and Use of Information.

a. General. Information released to the general public shall not include any “personal and/or location identifiers” or any “sensitive medical information” and shall not be traceable back to the CIREN collection site or Center. For the purposes of this section, CIREN Tier 1 Data means all sanitized data resident in the CIREN database, excluding Sensitive Medical Information, as described above but including injury coding information based on the Abbreviated Injury Scale used by NHTSA; and CIREN Tier 2 Data means all sanitized data resident in the CIREN database, without exclusions.

#### b. CIREN Tier 1 Data.

(1) CIREN Tier 1 Data shall be considered to be appropriate for public domain and available for access or release by or to any person. Following an established quality

control process, this data is published to the CIREN Internet: <http://www.nhtsa.dot.gov/portal/site/nhtsa/menuitem.1c5bf5af32c6dfd24ec86e10dba046a0/>

(2) The parties to this Agreement shall have unlimited rights to use, disclose, or reproduce such data and to prepare derivative works, distribute copies to the public, and display such data publicly, in any manner or for any purpose permitted by law.

c. CIREN Tier 2 Data.

(1) Except as provided in Section 2 below, access to CIREN Tier 2 Data shall be limited to CIREN Grantees (including their partners) and the research sponsors (if any) that are parties to their agreements, NHTSA and its agents and partners, and Volpe. Use of this data shall be strictly limited to the research purposes of this Agreement in furtherance of traffic safety, medical research to reduce passenger vehicle crash injuries, and improved vehicle design. Any other use is prohibited. Without limiting the generality of the foregoing, prohibited uses include but are not limited to any use in support of offensive or defensive litigation. NHTSA will protect all Sensitive Medical Information residing in the CIREN database from public dissemination to the full extent authorized by under Federal law.

(2) The parties understand that, from time to time, access to CIREN Tier 2 Data by others may properly be authorized, by NHTSA only, for limited research purposes in furtherance of vehicle or traffic safety, injury reduction, and improved vehicle design, and subject to strict limitations against further disclosure. NHTSA agrees that any such authorization shall be subject to all applicable laws, regulations, policies, and procedures.

4. Dissemination of Information By Educational Institutions.

a. Publications. The Department of Transportation ("DOT") desires widespread dissemination of the results of supported transportation research. Accordingly, the Grantee may publish documented research results in professional journals, books, trade publications, or other appropriate media. All costs of such academic publications shall be borne by the Grantee and shall not be charged to NHTSA and/or Volpe under this Agreement or any other Federal agreement.

b. Disclaimer. Any copy of material published must contain an acknowledgment of NHTSA's support of the research effort with this Agreement number and a disclaimer stating that the published material represents the position of the author(s) and not necessarily that of NHTSA. Articles for publication or papers to be presented to professional societies require authorization of NHTSA prior to release. The abstract must be submitted to NHTSA upon acceptance by the publishing organization. Two copies of each paper or article shall be transmitted to the NHTSA COTR and the CIREN program manager for Agency review at least two weeks prior to the date of final revision. A copy of the final paper once it is published or presented shall be submitted to the NHTSA COTR and the CIREN program manager.

c. Press Releases. Press releases concerning the results or conclusions from any research conducted under this Agreement shall not be made or otherwise distributed without the advance review and written consent of NHTSA.

d. No Waiver. Notwithstanding the foregoing, publication or other presentation of data obtained through this Agreement shall not release the Grantee or any of its employees from its obligation to prepare and submit other reports or case summaries containing the findings and results of research, as set forth in this Agreement.

e. Warranty. The parties make no express or implied warranty as to any matter whatsoever, specifically including hardware or software.

f. Governing Law. The laws of the United States shall govern the construction, validity, performance and effect of this Agreement for all purposes.

g. No Benefits. No member of, or delegate to, the United States Congress or resident commissioner, shall be admitted to any share or part of this Agreement, nor to any benefit that may arise there from, but this provision shall not be construed to extend to this Agreement if made with a corporation for its general benefit.

h. Independent Contractors. The relationship of the parties to this Agreement is that of independent contractors and not agents of one another or joint-ventures' or partners.

i. Use of Name or Endorsements. The Grantee shall not in any way state or imply that this Agreement is an endorsement by DOT, NHTSA or Volpe of it or any of the Grantee products or services.

j. Integration. All attachments, exhibits and schedules referenced in this Agreement are incorporated as if fully set forth herein. In the event of a conflict between any of these attachments, exhibits, or schedules, and this Agreement, the provisions of this Agreement shall be controlling.

k. Other Activities. The Grantee shall comply with the certification requirements of 49 CFR part 20, Department of Transportation New Restrictions on Lobbying, and 49 CFR part 29, Department of Transportation Government-wide Debarment and Suspension (Non-procurement) and Government-wide Requirement for Drug Free Work Place (Grants). Certification requirements are available electronically for download at [www.whitehouse.gov/omb/grants/index.html](http://www.whitehouse.gov/omb/grants/index.html).

## ARTICLE X. MODIFICATIONS

### A. Unilateral.

The NHTSA Contracting Officer (CO) has the right, under this Agreement, to execute unilateral modifications for the following purposes:

- Provide incremental federal funding;
- Change the NHTSA Program Officer/Contracting Officer's Technical Representative; and
- Make other administrative changes, which do not affect the legal obligations of the Grantee.

## **B. Bilateral.**

Bilateral modifications to this Agreement may be proposed by either party, at any time during the period of performance of this Agreement, and shall become effective upon written approval by both parties.

Note: When changes are made, the Government may supply the Grantee with replacement pages to the Agreement.

## **ARTICLE XI. ACRONYMS AND DEFINITIONS**

The acronyms listed below are used during the performance of this Agreement. If the Grantee is currently using, or has used any of the acronyms listed below differently, the Grantee shall use the acronyms listed below as defined under this Agreement *only*.

- Accreditation Board for Engineering and Technology (**ABET**)
- American College of Surgeons (**ACS**)
- Abbreviated Injury Scale (**AIS**)
- Abbreviated Injury Scale – 1990 Version (**AIS-90**)
- Anthropomorphic Test Device (**ATD**)
- Collision Deformation Classification (**CDC**)
- Crashworthiness Data System (**CDS**)
- Contracting Officer (**CO**)
- Crash Injury Research and Engineering Network (**CIREN**)
- Contracting Officer’s Technical Representative (**COTR**)
- Current Procedural Terminology (**CPT**)
- Contract Specialist (**CS**)
- Computed Tomography (**CT**)
- Curriculum Vitae (**CV**)
- Digital Imaging and Communications in Medicine (**DICOM**)
- Department of Transportation (**DOT**)
- “Electronic Case Reviews” are round table discussions with the CIREN Centers reviewing cases to determine the cause of the injuries.
- Emergency Medical Services (**EMS**)
- International Classification of Diseases – 9<sup>th</sup> Edition (**ICD-9**)
- International Classification of Diseases Modifications (**ICDM**)
- Institutional Review Board (**IRB**)
- Information Technology (**IT**)
- Magnetic Resonance Image (**MRI**)
- National Automotive Sampling System (**NASS**)

- National Highway Traffic Safety Administration (**NHTSA**)
- Office of Management and Budget (**OMB**)
- Orthopedic Trauma Assessment (**OTA**)
- Post-Mortem Human Surrogate (**PMHS**)
- Special Crash Investigations (**SCI**)
- Short Form 36 Health Survey (**SF36**)
- Type of Communication Circuit (**T1**)
- United States (**U.S.**)
- A software package used to create scene diagrams (**VISIO**)
- EDS and CIREN Database support (**VOLPE**)

## **ARTICLE XII. GOVERNMENT FURNISHED INFORMATION**

The Government Furnished Information listed below shall be provided to the Grantee at time of award.

1. 2010 CIREN Case Inclusion Criteria for Adults (13+)
2. 2010 CIREN Case Inclusion Criteria for Infants and Children (12 and under)
3. The NHTSA General Provisions for Assistance Agreements dated 7/95.
4. CIREN Digital Photography Guidelines
5. NHTSA Electronic Data System (EDS), Information Technology (IT) System Rules of Behavior
6. CIREN Coding Manual V2.0

Additional information maybe furnished during the period of performance if deemed appropriate.

## **ARTICLE XIII. GOVERNMENT FURNISHED PROPERTY/EQUIPMENT**

The Grantee shall maintain all Government-furnished equipment or Government acquired equipment in working order. The Grantee shall provide NHTSA with a yearly listing of all Government-furnished equipment or Government acquired equipment on the Contractor Inventory Schedule (NHTSA Form HS-324) when requested to do so by Contracting Officer Technical Representative (COTR). The Grantee shall keep in storage all boxes for the equipment in order to use them for returning the equipment to the Government at the end of this Agreement or to the Volpe for repair. The Grantee shall not dispose any equipment without the prior written approval of the COTR. Any equipment lost or stolen must be replaced at no cost to the Government.

1. Crash Data Recorder for use by Crash Investigator for Field Investigations
2. Dell Laptop for use by Crash Investigator
3. HP Desktop for use by Study Coordinator
4. HP Desktop for use by Medical or Engineering Investigator
5. HP Server for storing data
6. Digital Camera for taking medical photos
7. Digital Camera for taking crash photos

Additional equipment or property maybe furnished during the period of performance if deemed appropriate

#### **ARTICLE XIV. MINIMAL REQUIREMENTS**

Interested Applicants are advised that no fee or profit will be allowed under this Agreement program.

Eligible candidates must meet the basic requirements for the core staff members as described in Article II, Sections C.2.a.9 or C.2.b.10.

#### **ARTICLE XV. APPLICATION PROCEDURE**

Each Applicant shall submit one (1) original and five (5) copies of the application package via FedEx to: National Highway Traffic Safety Administration, Office of Acquisition Management (NPO-320), ATTN: Brenda K. Brummer, 1200 New Jersey Avenue, S.E., W53-404, Washington, D.C. 20590. Applications shall be typed on one side of the page only, must not exceed 60 typed pages with spacing of one and one half with no font size less than 10 point, with one inch (1") margins, page numbers at bottom center of each page and must include a reference to RFA No. DTNH22-10-R-00315 and the Catalogue of Federal Domestic Assistance (CFDA) number, 20-600. Appendices, which may be included, are not counted in the 60-page limit but should not contain information unrelated to the current scope of work. In addition, no single appendix should be more than 10 pages.

The curriculum vitae (CV) for each proposed team member should be included as an appendix and should be limited to the last 15 working years and should not exceed 10 pages. Publication references should be limited to those relating to passenger vehicle research or injury analysis. Do not submit copies of publications or case studies.

***Only complete packages received on or before 3:00 P.M. EST on February 23, 2010 will be considered.*** No facsimile transmissions will be accepted. Applications must contain a reference to NHTSA Request For Application (RFA) No. DTNH22-10-R-00315. Unnecessarily elaborate applications beyond what is sufficient to present a complete and effective response to this Grants.Gov Notice should not be submitted.

## ARTICLE XVI. APPLICATION CONTENTS

### A. Standard Forms and Supplemental Budget Information.

1. The application package must be submitted with the Office of Management and Budget (OMB) Standard Form 424 (Rev 4-88), Application for Federal Assistance, including 424A, Budget Information-Non-construction Program and 424B, Assurances-Non-construction Programs, with the required information provided and the certified assurances included. A Standard Form 424A & 424B must be submitted and packaged separately for each Center type (Medical or Engineering) effort for which the Applicant wishes to be considered. (See Article IV, Section D.)

2. Forms are electronically available for downloading at: [www.whitehouse.gov/omb/grants/index.html](http://www.whitehouse.gov/omb/grants/index.html).

3. While the Form 424A deals with budget information, and Section B identifies Budget Categories, the available space does not permit a level of detail that is sufficient to provide for a meaningful evaluation of proposed costs. Therefore, supplemental information must be provided which presents a detailed breakout of the proposed costs (detailed labor, including labor category, level of effort and rate; direct materials, including itemized equipment, travel and transportation, including projected trips and number of people traveling; subcontracts/subgrants with similar detail if known; and overhead) as well as any non-Federal funding and/or in-kind contributions the Applicant proposes to contribute.

4. The Applicant also shall provide documentation supporting all costs for which Federal funding is being requested. The estimated costs must be separated and proposed by base year and by each of the four (4) one-year option years, such that the Applicant's budget will reflect the total possible performance of five (5) years.

5. In addition, Applicants shall provide budget estimates for all staff following the statutory provisions used by the National Institutes of Health (NIH) on their Agreements. These provisions restrict the amount of direct salary to Executive Level 1 of the Federal Executive Pay scale. Effective January 1, 2009, this amount is \$196,700. For the purposes of the salary limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are exclusive of fringe benefits and facilities and administrative (F&A) expenses, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of the duties to the applicant organization.

6. In preparing these budgets, Applicants shall provide information on the actual base salaries of all staff paid by the individual's institution and indicate whether the actual base salary of any staff exceeds the NIH salary cap. NHTSA shall use the information available in the existing application and make adjustments for the salary cap based on information available at the time of the award.

7. Program Narrative Statement.

a. Medical Center Applicants shall fully describe how they will accomplish the work to be performed under this Agreement. Applications must include the following information in the program narrative statement:

(1) A table of contents including page number references.

(2) **Work Plan, Technical Approach, and Technical Capability and Understanding:** A complete listing of any and all partners including a description of the nature, length of relationship and scope of the existing relationship among and between the partners. A description of the goal(s) of the project/program and how the applicant plans to meet the goal(s), including specific methodologies for the completion of tasks associated with the initiating, tracking and submission of enrolled medical/crash cases. The Applicant shall include steps that will be used to enroll medical/crash cases (at all Enrollment Sites, if applicable) and perform in-house quality control of enrolled cases prior to submission to NHTSA's quality assurance contractor. The Applicant shall discuss technical problems, barriers and/or critical issues related to the successful completion of this Agreement effort. The Applicant shall describe steps and processes that will be used to screen and enroll prospective cases outside of the Monday through Friday workweek. In other words, describe how admissions occurring between Friday evening and Monday morning will be captured. To facilitate evaluation of the Applicant's Technical Capability and Understanding, the proposal must include information explaining how the Applicant meets the following:

- i. Understanding of the methodology used in an electronic data collection system for medical/crash case assignment, medical/crash case tracking, and consistency of data coding, quality control and timeliness of medical/crash case submissions.
- ii. Proof that an approved IRB document has been obtained from all partners consistent with data being collected as described in Article II, Scope of Work. Describe IRB submissions related to passenger vehicle crashes and documenting blunt trauma and data collection (resulting injuries). This proof shall describe the process through which all medical records, radiology and other related data will be obtained and coded into the CIREN database.
- iii. Understanding of trauma system injury coding [Abbreviated Injury Scale (AIS), International Classification of Diseases Modifications (ICDM), Orthopaedic Trauma Assessment (OTA), Current Procedural Terminology (CPT)]
- iv. Ability to communicate effectively the results of research efforts in publications and to conduct effectively outreach activities to the community at large
- v. Access to and "hands-on" working knowledge of all available electronic medical records at all Enrollment Sites.

(3) **Trauma Registry Data:** The trauma registry data of all Enrollment Sites (Applicant and Trauma Center partners) for the last three (3) years documenting the number of passenger vehicle crash occupants admitted to the trauma center(s). For each year, the

Applicant shall identify the maximum level of severity (AIS1-AIS6) using AIS 90/98 for the injuries incurred by each admitted occupant/patient. The following chart should be completed for each trauma center and any partners to indicate the raw count of occupants/patients in the trauma registry for the given year who was involved in a passenger vehicle crash and their resulting maximum AIS. Please supply the three most recent years of admission data available.

Year	AIS 1	AIS 2	AIS 3	AIS 4	AIS 5	AIS 6
2007						
2008						
2009						

(4) Radiology Systems: A description of current radiology systems utilized and methods (digital or film) used to obtain radiological images for presentation and research. Describe technology available [Computed Tomography (CT), Magnetic Resonance Image (MRI), High Speed CT etc.].

(5) Patient Data Systems: A description of patient data systems utilized at the Enrollment Sites (100% electronic medical records versus hard copy paper medical records or a hybrid system) and what access Applicant has to these records (real time versus post discharge; central access versus network access).

b. Engineering Center Applicants shall fully describe the work to be performed under this Agreement. Applications must include the following information in the program narrative statement:

(1) A table of contents including page number references.

(2) Work Plan, Technical Approach, and Technical Capability and Understanding: A complete listing of any and all partners including a description of the nature, length of relationship and scope of the existing relationship among and between the partners. A description of the goal(s) of the project/program and how the applicant plans to meet the goal(s), including specific methodologies for the completion of tasks associated with the initiating, tracking and submission of enrolled medical/crash cases. The Applicant shall include steps that will be used by its Enrollment Site(s) (Level One or Level Two Trauma Centers) to enroll medical/crash cases and perform in-house quality control of enrolled cases prior to submission to NHTSA's quality assurance contractor. The Applicant shall discuss technical problems, barriers and/or critical issues related to the successful completion of this Agreement effort. The Applicant shall describe steps and processes that will be used by the Trauma Center partner(s) to screen and enroll prospective cases outside of the Monday through Friday workweek. In other words, describe how admissions occurring between Friday evening and Monday morning will be captured. To facilitate evaluation of the Applicant's Technical Capability and Understanding, the proposal must include information explaining how the Applicant meets the following:

i. An overview of research experience in injury and impact biomechanics. A description of long-term, focused research projects that demonstrate technical expertise in managing such projects shall be included. The Principal

Investigator should be a senior biomechanical engineer who has directed or acted in a leadership role at a university-based crash injury research laboratory. This individual should have research experience related to PMHS impact testing, ATD testing/development and occupant injury research. Experience related to crash sled work and computer modeling is preferred.

- ii. A description of the nature and scope of projects in the areas of crash investigation and reconstruction, PMHS biomechanical testing, ATD research involving design and evaluation, structures and restraints.
- iii. Demonstrated experience with impact/injury biomechanics (i.e., investigation of injury causation in humans and animals due to mechanical loading or experimental work with biological tissues).
- iv. Description of sled and/or crash lab experience, including full-scale impact testing of ATD or PMHS for evaluation of injury causation, restraint/structure performance or consumer information.

(3) For all Engineering Center Enrollment Sites, the following shall be included as part of the work plan:

- i. Understanding of the methodology used in an electronic data collection system for medical/crash case assignment, medical/crash case tracking, and consistency of data coding, quality control and timeliness of medical/crash case submissions;
- ii. Proof that an approved IRB document has been obtained from all partners consistent with data being collected as described Article II, Scope of Work. Describe IRB submissions related to passenger vehicle crashes and documenting blunt trauma and data collection (resulting injuries). This proof shall describe process through which all medical records, radiology and other related data will be obtained and coded into the CIREN database.
- iii. Understanding of trauma system injury coding [Abbreviated Injury Scale (AIS), International Classification of Diseases Modifications (ICDM), Orthopedic Trauma Assessment (OTA), Current Procedural Terminology (CPT)];
- iv. Ability to communicate effectively the results of research efforts in publications and to conduct effectively outreach activities to the community at large;
- v. Access to and “hands-on” working knowledge of all available electronic medical records at all Enrollment Sites.

(4) Trauma Registry Data: The trauma registry data of all Enrollment Sites for the last three (3) years and the number of passenger vehicle crash occupants admitted to the trauma center. Applicants shall identify the maximum level of severity (AIS1-AIS6) using AIS 90/98 for the injuries incurred by each admitted occupant/patient. The following chart should be completed for each Trauma Center partner and should indicate the raw count of

occupants/patients in the trauma registry for the given year who was involved in a passenger vehicle crash and their resulting maximum AIS. Please supply the three most recent years of admission data available.

Year	AIS 1	AIS 2	AIS 3	AIS 4	AIS 5	AIS 6
2007						
2008						
2009						

(5) Radiology Systems: A description of current radiology systems utilized and methods (digital or film) used to obtain radiological images for presentation and research. Describe technology available [Computed Tomography (CT), Magnetic Resonance Image (MRI), High Speed CT, etc.].

(6) Patient Data Systems: A description of patient data systems utilized at all Enrollment Sites (100% electronic medical records versus hard copy paper medical records or a hybrid system) and what access Applicant has to these records (real time versus post discharge; central access versus network access).

c. All Applicants: Proposal shall include:

(1) Prior Work and Experience: A description of previous passenger vehicle safety research work associated with medical cases and/or biomechanics. The Applicant shall demonstrate its experience with on-site, real-time enrollment of patients and data collection activities. The Applicant also shall describe its experience in research relating to the documentation of passenger vehicle crash injuries and in relating these injuries with in-depth passenger vehicle crash investigations. The Applicant shall demonstrate experience in managing a multi-disciplinary research project and in operating a business enterprise as evidenced by the organization of the entity, previous experience collecting medical data and in conducting in-depth crash reconstruction and investigations, and in understanding of related highway safety programs. The Applicant shall describe its experience in obtaining IRB approval for research objectives.

(2) Personnel Plan: The Applicant shall have the infrastructure in place and demonstrate the personnel, expertise and technical proficiency to perform the duties described for each type of Center as described in Article II, Section C.2.a.9 or C.2.b.10. The Applicant shall provide a description of human resources to be used in this Agreement effort to perform the duties described, including the identification of the proposed principal investigator, crash investigator, medical investigator (Engineering Centers), study coordinator and other personnel considered critical to the successful accomplishment of the program. Staff shall be comprised of full- and part-time individuals and shall include a multi-disciplinary research team to support collaborative research efforts. Roles, responsibilities, and proposed levels of effort shall be provided for all proposed team members, along with an organizational chart depicting the personnel structure. The Applicant shall, for each proposed team member, include a CV and a brief description of their respective organizational responsibilities and their qualifications to meet the staff requirements and duties herein described.

(3) Past Performance and Financial Responsibility: The Applicant shall provide the following information:

- i. At least three (3) references who can attest to the past performance history and quality of work provided by the Applicant on previous assistance agreements and/or contracts. In doing so, the Applicant shall provide the following information for each reference:
  - Assistance Agreement/Contract Number;
  - Title and brief description of Assistance Agreement/Contract;
  - Name of organization, name of point of contact, telephone number, and e-mail address of point of contact at the organization with which the Applicant entered into an Assistance Agreement/Contract
  - Dollar value of Assistance Agreement/Contract
  - Any additional information to address the issue of past performance and financial responsibility
- ii. The Applicant shall indicate if it has ever appeared on the General Service Administration's (GSA) List of Parties Excluded from Federal Procurement and Non-procurement Programs or on GSA's "Excluded Parties List." If so, the Applicant shall discuss the circumstances leading up to its appearance on either of these lists and its current status to enter into Assistance Agreements (i.e., Cooperative Agreements and Grants) and/or Contracts.
- iii. The Applicant shall indicate if it has ever filed for bankruptcy or has had any financial problems that may affect its ability to perform under the Assistance Agreement.

(4) Streaming Server Hosting and Management Applicants: Applicants wishing to submit the optional, supplemental proposal for hosting the CIREN video streaming server shall demonstrate that they have the infrastructure in place and possess the personnel and technical proficiency to perform the streaming server hosting duties described in Article II, Section C.2.c, Streaming Server Host. The proposal shall describe the available Internet bandwidth at the proposed hosting location and the approach that would be used to ensure proper operation of the streaming server when required for electronic case reviews.

## **ARTICLE XVII. APPLICATION REVIEW PROCESS AND EVALUATION FACTORS**

### **A. CIREN Team Evaluation.**

Each application package will be reviewed initially to confirm that the Applicant is an eligible candidate (as described under Article XIV, Minimum Requirements) and has included all of the items specified in the Article XVI, Application Contents section of this Grants.gov Notice. The NHTSA Evaluation Committee will evaluate applications submitted by eligible candidates. NHTSA may request oral presentations of technical proposals from Applicants remaining in the competitive range during the evaluation process. Awards may

be made to multiple Applicants, and will include equal numbers of Medical Centers and Engineering Centers. It is anticipated that awards will be made in April 2010 with work commencing within ninety (90) days of award. NHTSA will select from among the proposals received from the prospective CIREN Center(s) to obtain the best mix of price/performance for the program as a whole.

1. Technical Evaluation Factors: The applications will be evaluated using the following criteria:

<b>Factor</b>	<b>Overall Weight</b>
Operational Plan	40%
<ul style="list-style-type: none"> <li>(1) Demonstrated proof (submission of 3 years of trauma registry data) that Applicant's medical institution receives a sufficient number of passenger vehicle crash victims from which cases can be selected for the CIREN program and plan to maximize participation.</li> <li>(2) The adequacy of Applicant's plan to complete tasks associated with the initiating, tracking, and submission of enrolled cases, conduct vehicle and scene inspections, perform in-house quality control, and coordinate staff.</li> <li>(3) The Applicant's available Trauma Center diagnostic equipment and availability of medical talent and expertise.</li> <li>(4) The Applicant's degree of understanding of trauma system injury coding and the methodologies used in an electronic data collection system.</li> <li>(5) The Applicant's degree of understanding of passenger vehicle crash injury causation.</li> <li>(6) The Applicant's ability to effectively communicate results of research efforts in publications.</li> <li>(7) The Engineering Center Applicant's available biomechanical test facilities.</li> </ul>	
Personnel Plan	30%
<ul style="list-style-type: none"> <li>(1) The proposed team's experience in the management of, collection, coding, and validation of medical data.</li> <li>(2) The proposed team members' experience in verifying crash-related physical evidence with the reported injury, injury mechanism, occupant kinematics, damage severity, and restraint usage.</li> <li>(3) The proposed team members' experience in applying scientific theories and in analyzing physical evidence, substantiating injury mechanisms, and reconstructing crash events and speeds.</li> </ul>	

<b>Factor</b>	<b>Overall Weight</b>
<p>(4) The experience of the proposed Study Coordinator in managing the prospective research program.</p> <p>(5) The overall composition of the proposed team, its readiness to begin work at project kickoff, and the proposed plan to handle staffing contingencies.</p>	
<b>Corporate and Academic Experience</b>	<b>15%</b>
<p>(1) The Applicant's demonstrated experience in managing a multidisciplinary research program and in operating a business enterprise as evidenced by the organization of the entity; previous experience collecting medical data and conducting in-depth crash reconstruction and investigations; experience in obtaining IRB approval for research objectives; and understanding of related highway safety programs.</p> <p>(2) The Applicant's level of experience with on-site, real-time capture of patients and data.</p> <p>(3) The Applicant's level of experience with delivery of products in the form of research papers, technical presentations, etc. to diverse audiences.</p> <p>(4) The Engineering Center Applicant's level of experience in injury and impact biomechanics research related to human injury tolerance and causation in passenger vehicle crashes.</p>	
<b>Past Performance and Financial Responsibility</b>	<b>15%</b>
<p>(1) The Applicant's record of complying with the terms and conditions applicable to previous Assistance Agreements and/or Contracts, including the quality of services or deliverables provided and the adherence to milestones and performance and delivery schedules.</p> <p>(2) The degree to which the Applicant efficiently achieved the purposes of previous Assistance Agreements and/or Contracts within the approved budget.</p> <p>(3) The degree to which the proposed Grantee complied with applicable Office of Management and Budget (OMB) Circulars and/or the Federal Acquisition Regulation on previous Assistance Agreements and/or Contracts.</p> <p>(4) The level of financial stability possessed by the proposed Grantee.</p> <p>(5) The Applicant's record of retaining critical personnel throughout the duration of multi-year programs and demonstration of a low personnel turnover rate for non-critical positions.</p>	

## 2. Cost Evaluation:

Based on the Applicant's prepared budget, the total financial value of the project (as determined by adding the requested Federal funding to the non-Federal funding and/or in-kind contributions being proposed by the Applicant) will be reviewed. Cost proposals will not be provided any specific numerical rating. However, NHTSA may give preference to applications that identify additional funding sources or in-kind contributions. If there are no significant technical proposal differences, costs may be used as a determining factor for making awards.

### **B. CIREN Streaming Server Hosting Evaluation.**

Each application package will be reviewed initially to confirm that the Applicant is an eligible candidate (as described under Article II, Scope of Work, Sections C.1, C.2.a and C.2.b) and has included all of the items specified in the Article XVI, Application Contents section of this Grants.gov Notice. Any Applicant for the streaming server hosting must also be an Applicant for a CIREN Center Team. Independent CIREN streaming hosting will only be considered if a suitable candidate is not available as an additional function of an awarded Center.

#### 1. Technical Evaluation Factors:

<b>Factor</b>	<b>Overall Weight</b>
1. Infrastructure	55%
a. Bandwidth	
(1) Description of dedicated internet bandwidth availability and access (2) Description of circuit type and average upload speeds	
b. Security	
(1) Description of physical security for the streaming server	
2. Maintenance Experience	45%
a. Personnel Plan	
(1) Technical experience of personnel responsible for the video streaming server (2) Real-time availability	
b. Security	
(1) Description of security procedures related to server maintenance	

## 2. Cost Evaluation.

Based on the Applicant's prepared budget, the total financial value of the project (as determined by adding the requested Federal funding to the non-Federal funding and/or in-kind contributions being proposed by the Applicant) will be reviewed. Cost proposals will not be provided any specific numerical rating. However, NHTSA may give preference to applications that identify additional funding sources or in-kind contributions. If there are no significant technical proposal differences, costs may be used as a determining factor for making awards.

### **C. Proposal Questions.**

NHTSA reserves the right to ask one or all of the proposed contractors clarifying questions concerning their respective proposals. NHTSA will ask specific questions relating to the proposal and expect clear answers in an expedited manner.

### **D. Negotiations.**

NHTSA reserves the right to make an award without discussion, that is, an award of a cooperative agreement without conducting any negotiations or discussions with any applicant. As an alternative to making an award without discussion, NHTSA is also reserving the right to negotiate with competing applicants, prior to making any award. Negotiations may be conducted if NHTSA concludes that, after studying the initial applications, negotiations are in fact necessary or are in the Government's best interests.

## **ARTICLE XVIII. TERMS AND CONDITIONS**

Prior to award, each applicant shall comply with the certification requirements of 49 CFR Part 20, U.S. DOT New Restrictions on Lobbying, and 49 CFR Part 29, U.S. DOT Government-wide Debarment and Suspension (Non-procurement) and Government-wide Requirement for Drug Free Work Place (Grants). Certification requirements are electronically available for download at <http://www.whitehouse.gov/omb/grants/index.html>.

In addition, prior to award each applicant shall comply with the NHTSA General Provisions for Assistance Agreements, dated July 1995 (see Appendix E).

## **ARTICLE XIX. REFERENCES**

- Dischinger, P.C., Read, K.M, Kufera, J.A., Kerns, T.J., Burch, C.A., Jawed, N., Ho, S.M. and Burgess, A.R. (2005) "CIREN Report: Consequences and Costs of Lower Extremity Injuries." U.S. Department of Transportation, National Highway Traffic Safety Administration, DOT HS 809 871.
- Pintar, F.A., Yoganandan, N. and Maiman, D.J. (2008) "Injury Mechanisms and Severity in Narrow Offset Frontal Impacts." Proceedings of the Association for the Advancement of Automotive Medicine, vol. 52, pp. 185-189.
- Rupp, J.D., Reed, M.P., Miller, C.S., Madura, N.H., Klinich, K.D., Kuppa, S.M. and Schneider, L.W. (2009) "Development of New Criteria for Assessing the Risk of Knee-Thigh-Hip Injury in Frontal Impacts Using Hybrid III Femur Force Measurements." 21<sup>st</sup> International Technical Conference on the Enhanced Safety of Vehicles, paper 09-0306.

## APPENDIX A

## 2010 CIREN CASE INCLUSION CRITERIA FOR ADULTS (13 years and older)

Crash Type	Crash Direction	Vehicle Criteria	Restraint Criteria	Occupant Positions	Injury Thresholds	Exclusion / Inclusion Issues
Frontal	10 to 2 o'clock Full frontal Offset frontal	CY-6 yrs* (Priority on newest vehicles)	-Deployed air bag and 3-point belt (must constitute 80% or more of adult frontals) -Deployed air bag only (cannot exceed 20% of adult frontal cases)	Row 1	AIS $\geq$ 3 or **	<ul style="list-style-type: none"> <li>Case vehicles experiencing two severe impacts are excluded. Severe impacts classified as: <ul style="list-style-type: none"> <li>Rollover top plane crush &gt; CDC extent zone 4 at case occupant position</li> <li>Side plane w/ &gt;25 cm of compartment intrusion</li> <li>Swiping impact w/ &gt; 25 cm of compartment intrusion</li> <li>Override/Underride where hood/trunk and top of fenders involved and &gt;25 cm of compartment intrusion</li> <li>Undercarriage = Significant crush or bending of the main chassis</li> <li>Overlapping = single impact measure/estimate &gt; 35 cm of crush</li> </ul> </li> <li>Case vehicles experiencing vertical change of &gt; 8 feet (2.44m) are excluded</li> <li>Case vehicles experiencing a gradient change &gt; 30 degrees are excluded</li> <li>Case vehicles experiencing catastrophic impacts are excluded</li> <li>Fatal case occupants without a complete CT/MRI injury record or complete internal autopsy are excluded</li> <li>Case vehicles experiencing fire damage to a significant portion of the occupant position are excluded</li> </ul>
			-Must be in 3-point belt with no evidence of gross misuse	Rows 2+		
Side	8 to 10 o'clock 2 to 4 o'clock	CY-6 yrs* (Priority on newest vehicles)	-Any and all, including unrestrained on struck side and far side	Any	AIS $\geq$ 3 or **	
Rollover	All	CY-6 yrs* (Priority on newest vehicles)	-Any and all, including unrestrained (fully-ejected occupants cannot be enrolled)	Any	AIS $\geq$ 3 or **	
Success Case***	Any	CY-6 yrs*	-Properly restrained (3-point belt and/or air bag)	Any	Any	<ul style="list-style-type: none"> <li>High energy crashes with little or no injury to the case occupant (ISS 0-7) can be considered.</li> <li>Fatalities or seriously injured occupant in the same vehicle w/comparable restraint/scenario can be considered.</li> <li>NHTSA approval required prior to enrollment***</li> </ul>

\* Cases where the vehicle is >6 yrs old may be considered for enrollment under sisters and clones protocol if there are no significant chassis and safety technology changes – NHTSA approval required

\*\* AIS of 2 in 2 or more body regions with medical significance (avoid concussive type injury for inclusion) or AIS of 2 in the lower extremity with significant articular injury (pilon/talus/calcaneus/Lisfranc/Choparts)

\*\*\* Cases must be extraordinary for consideration – NHTSA approval required

## APPENDIX B

## 2010 CIREN CASE INCLUSION CRITERIA FOR INFANTS AND CHILDREN (12 years and younger)

Crash Type	Crash Direction	Vehicle Criteria	Restraint Criteria	Occupant Positions	Injury Thresholds	Case Priorities / Issues
Frontal	10 to 2 o'clock Full frontal Offset frontal	CY-8 yrs (Priority on newest vehicles)	-CRS used by case occupant	Any	AIS $\geq$ 2	<ul style="list-style-type: none"> <li>Air bag deployment at occupant position*</li> <li>Advanced air bag systems</li> <li>Curtain type air bags</li> <li>Capture of CRS is a priority</li> <li>Fatality (worthy of review if: useful crash scenario, complete autopsy (scan/capture))</li> <li>CRS installed with LATCH</li> <li>Non-catastrophic cases only</li> </ul>
			-3 point manual belt with no evidence of gross misuse -Deployed air bag with or without belt -Unrestrained okay, but low priority	Any	AIS $\geq$ 2	
Side	8 to 10 o'clock 2 to 4 o'clock	CY-8 yrs (Priority on newest vehicles)	-CRS used by case occupant -3 point manual belt with no evidence of gross misuse -Side air bag with or without belt -Unrestrained okay, but low priority	Any	AIS $\geq$ 2	<ul style="list-style-type: none"> <li>Side air bag deployments (thorax, combo, or curtain)</li> <li>CRS misuse/LATCH</li> <li>Integrated 3 pt belts in position 22,32...</li> <li>Fatality (worthy of review: useful crash scenario, complete autopsy (scan/capture))</li> <li>Non-catastrophic cases only</li> <li>Capture of CRS is a priority</li> </ul>
Rear	5 to 7 o'clock	CY-8 yrs (Priority on newest vehicles)	-CRS used by case occupant	Rows 2+	AIS $\geq$ 2	<ul style="list-style-type: none"> <li>CRS misuse</li> <li>Fatality (worthy of review: useful crash scenario, complete autopsy (scan/capture))</li> <li>Capture of CRS is a priority</li> </ul>
Rollover	All	CY-8 yrs (Priority on newest vehicles)	-CRS used by case occupant -3 point manual belt with no evidence of gross misuse -Air bag with or without belt -Unrestrained okay, but low priority (fully ejected occupants cannot be enrolled)	Any	AIS $\geq$ 2	<ul style="list-style-type: none"> <li>Side air bag systems and rollover curtains</li> <li>Safety belt pretensioners</li> <li>Fatality (worthy of review if: useful crash scenario, complete autopsy (scan/capture))</li> <li>Non-catastrophic cases only (avoid more than 6-8 quarter turns)</li> <li>CRS misuse/LATCH</li> <li>Capture of CRS is a priority</li> </ul>
Success Case **	Any	Any	-Properly restrained in age-appropriate restraint	Any	AIS $\leq$ 1	<ul style="list-style-type: none"> <li>High-energy crashes with little or no injury to the child/infant occupant</li> <li>Fatalities in the same vehicle</li> <li>NHTSA approval required prior to enrollment**</li> </ul>

\* Case with air bag might be of interest to SCI – CIREN cases should involve AIS 2+ injury

\*\* Cases must be extraordinary for consideration – NHTSA approval required

### Appendix C

#### Center Structure and Case Enrollment Requirements

Center Type	Total Annual Enrollment	Number of Enrollment Sites	Primary Enrollment Site	Primary Enrollment Site Case Minimum	Secondary Enrollment Site	Secondary Enrollment Site Case Maximum
<b>Medical</b> Led by L1TC	65 cases	1	L1TC	65	n/a	n/a
		2 (optional)	L1TC	42	L1TC <b>or</b> L2TC	23
<b>Engineering</b> Led by university-based biomechanics laboratory partnered with L1TC	40 cases	1	L1TC	40	n/a	n/a
		2 (optional)	L1TC	26	L1TC <b>or</b> L2TC	14

L1TC = ACS or state-designated Level One Trauma Center

L2TC = ACS or state-designated Level Two Trauma Center

**Appendix D****Video Stream / Case Review Assignment**

<b>Center Type</b>	<b>Enrolled Cases Presented per Month via Video Stream</b>	<b>Cases Reviewed per Month via Video Stream</b>	<b>Video Stream Sessions per Month</b>	<b>Field Work and Data Collection Days*</b>
<b>Medical</b>	5-6	n/a	1	19
<b>Engineering</b>	3-4	8-10	3	17

\*Day counts based on a 20 work day month

## **NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION**

### **GENERAL PROVISIONS FOR ASSISTANCE AGREEMENTS**

This assistance agreement shall be subject, as applicable, to the administrative requirements contained in the following documents or regulations which are hereby incorporated by reference, with the same force and effect as if they were given in full text:

49 CFR Part 18 - Department of Transportation Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments.

49 CFR Part 19 - Department of Transportation Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations, and, for purposes of this agreement, with commercial organizations, except as otherwise provided elsewhere in these terms and conditions.

49 CFR Part 20 - Department of Transportation New Restrictions on Lobbying.

49 CFR Part 29 - Department of Transportation Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants).

In addition, the following provisions are applicable to this agreement which provides Federal financial assistance authorized by statute.

1. Definitions
2. Allowable Costs
3. Audit Requirements
4. Standard Patent Rights
5. Data Collection
6. Protection of Individual Privacy
7. Rights in Data
8. Restrictions on Printing
9. Other Administrative Provisions and Assurances
10. Order of Precedence

DATE: 7/95

1. **DEFINITIONS.** Throughout this assistance agreement, the following terms shall have the meanings set forth below:

- a. The term "Secretary" means the Secretary of the Department of Transportation or his duly authorized designee.
- b. The term "Department" means the Department of Transportation (DOT).
- c. The term "Agency" means the National Highway Traffic Safety Administration (NHTSA).
- d. The term "Contracting Officer" or "CO" means any person authorized to execute the agreement on behalf of the NHTSA.
- e. The term "Contracting Officer's Technical Representative" or "COTR" means the CO's authorized representative responsible for the programmatic/technical administration of the agreement, the evaluation of performance under the agreement, the acceptance of technical reports, and for other specific responsibilities as may be stipulated in various provisions of the agreement.
- f. The term "Grantee" means the recipient of the award of the assistance agreement, whether a grant or cooperative agreement, and includes the following:
  - (1) States, local governments or Federally-recognized Indian tribal governments as defined in 49 CFR Part 18.
  - (2) Nonprofit organizations including public and private institutions of higher education, public and private hospitals, and other quasi-public and private nonprofit organizations as further described in 49 CFR Part 19.
  - (3) Commercial organizations including small and large businesses organized for profit; organizations which are not otherwise included among those specified in 49 CFR Part 18 or 49 CFR Part 19; or international organizations.
- g. The term "Third-Party Contract" means any legal instrument entered into between the grantee and a third party, or any lower tier, for the performance of a portion of the effort provided for under this assistance agreement and includes contracts, grants, and cooperative agreements.
- h. The term "Third-Party Contractor" means the recipient of a "Third-Party Contract."
- i. The acronym "OMB" means the Office of Management and Budget.
- j. The acronym "FAR" means Federal Acquisition Regulation.

2. **ALLOWABLE COSTS.**

- a. Payments up to the amount specified in the assistance agreement shall be made only for costs determined by the CO to be allowable, allocable and reasonable in performing the effort under the agreement in accordance with its terms and with the following cost principles:
  - (1) OMB Circular A-21 (applicable to educational institutions).
  - (2) OMB Circular A-87 (applicable to State and local governments and Federally-recognized Indian tribal governments).
  - (3) OMB Circular A-122 (applicable to non-profit organizations).
  - (4) FAR 31.2 (applicable to all other organizations).
- b. During performance of this assistance agreement, certain direct cost expenditures, not itemized in the approved budget, may become necessary. In order to avoid subsequent disallowances, or dispute based on unreasonableness or unallocability, written agreement in advance of the incurrence of such costs is appropriate. In addition, selected cost principles contain a number of items of cost for which prior approval is required. Direct cost expenditures requiring such written notification from the CO include, but are not limited to, the following:
  - (1) Purchase or rental of any item of general purpose equipment having a useful life of more than two years and an acquisition cost of \$500 or more; and all items of office and automatic data processing equipment, regardless of cost, if not itemized in the approved budget.

- (2) Purchase or rental of any item of special purpose equipment having a unit cost of \$1,000 or more if not itemized in the approved budget.
  - (3) Personnel movement of a special or mass nature not itemized in the approved budget.
  - (4) Foreign travel (each separate trip) not itemized in the approved budget.
  - (5) Domestic travel when not included in the approved budget or when the cumulative travel expenditures will exceed the approved travel budget by \$500 or 25%, whichever is greater.
  - (6) Consultant and professional services not itemized in the approved budget.
  - (7) Subcontracts not identified in the approved budget, except those for incidental supplies, materials, and general support services.
  - (8) Purchase or lease of any interest in real property, or improvements in real property not itemized in the approved budget.
- c. NHTSA may provide in advance for costs to be incurred or reimburse costs accrued by the grantee up to the maximum amount of the federal assistance payable for the period of performance. However, payment of such costs, whether in advance or by reimbursement, shall not constitute a final determination by NHTSA of the allowability of such costs and shall not constitute a waiver of any violation of the terms of the assistance agreement committed by the grantee. NHTSA shall make a final determination as to the allowability only after the final audit is completed, if required, or at the time of final payment.
- d. NHTSA shall not be obligated to reimburse the grantee for outlays (costs) in excess of the Federally-funded amount of the assistance agreement unless and until the CO executes a modification which increases the Federally-funded amount. The Federally-funded amount is the amount actually obligated under the agreement which may be less than or equal to the budgeted Federal share of the agreement.

### 3. AUDIT REQUIREMENTS.

- a. If this assistance agreement is with an institution of higher education, hospital or other nonprofit organization, the grantee shall conduct audits in accordance with the provisions of OMB Circular A-133, "Audits of Institutions of Higher Education and Other Nonprofit Organizations."
- b. If this assistance agreement is with a State or local government or Federally-recognized Indian tribal government, the grantee shall obtain audits in accordance with the Single Audit Act of 1984 (31 U.S.C. 7501-7), as provided in 49 CFR Part 18.26.
- c. If this assistance agreement is with a commercial organization, the following conditions shall be applicable:
  - (1) Examination of costs - The grantee shall maintain--and the CO or representatives of the CO shall have the right to examine and audit--books, records, documents, and other evidence and accounting procedures and practices, regardless of form (e.g., machine readable media such as disk, tape, etc.) or type (e.g., data bases, applications software, data base management software, utilities, etc.), sufficient to reflect properly all costs claimed to have been incurred or anticipated to be incurred in performing this agreement. This right of examination shall include inspection at all reasonable times of the grantee's facilities, or parts of them, engaged in performing the agreement.
  - (2) Reports - If the grantee is required to furnish cost, funding, or performance reports, the CO or representatives of the CO shall have the right to examine and audit books, records or other documents, and supporting materials, for the purpose of evaluating (a) the effectiveness of the grantee's policies and procedures to produce data compatible with the objectives of these reports and (b) the data reported.
  - (3) Availability - The grantee shall make available at its office at all reasonable times the materials described in paragraph (1) above, for examination, audit or reproduction, until the later of 3 years after final payment or any resulting final settlement of a termination, appeal, litigation or claim, or for any shorter period specified in FAR Subpart 4.7, Records Retention, or for any longer period required by statute.

- (4) Except as otherwise provided in FAR Subpart 4.7, Records Retention, the grantee may transfer computer data in machine readable form from one reliable computer medium to another. The grantee's computer data retention and transfer procedures shall maintain the integrity, reliability, and security of the original data. The grantee's choice of form or type of materials described in paragraphs (1) and (2) of this clause affects neither the grantee's obligations nor the Government's rights under this clause.
- (5) The grantee shall insert a clause containing all the terms of this paragraph c in all third-party contracts over \$10,000 with commercial organizations under this agreement, altering the clause only as necessary to identify properly the parties and the CO under the NHTSA prime agreement.

4. **STANDARD PATENT RIGHTS.** [The clause at 37 CFR Part 401.14(a), as modified below (or as further modified in accordance with the provisions of 37 CFR Part 401), shall be applicable to all assistance agreements involving the performance of research and development efforts by small business firms, non-profit organizations, State, local, and Federally-recognized Indian tribal governments, and, unless otherwise provided, by other commercial organizations.]

The following modifications to the clause at 37 CFR Part 401.14(a) apply:

- a. The parenthetical information shall be removed from the title of the clause;
- b. The terms "contract" and "contractor" shall be replaced by the terms "assistance agreement" and "grantee," respectively, as defined in these General Provisions (except that the grantee may modify these terms pursuant to paragraph (g)(1) of the clause for use in third-party contracts);
- c. The terms "agency," "Federal agency," and "funding Federal agency" shall be replaced by the term "NHTSA" (except that the grantee may modify these terms pursuant to paragraph (g)(1) of the clause for use in third-party contracts);
- d. The terms "subcontract(s)" and "subcontractor" shall be replaced by the terms "third-party contract(s) and "third-party contractor," respectively, as defined in these General Provisions;
- e. The terms "to be performed by a small business firm or domestic non-profit organization" shall be deleted from paragraph (g)(1) of the clause;
- f. The following subparagraph shall be added at the end of paragraph (f) of the clause:
  - (5) The grantee agrees to provide, upon request by the CO, periodic (but no more frequently than annual) listings of all subject inventions which were disclosed to NHTSA pursuant to paragraph (c)(1) and/or a report (DD Form 882) prior to the close-out of the assistance agreement listing all subject inventions or stating that there were none.
- g. Paragraphs (g)(2) and (g)(3) of the clause shall be deleted; and
- h. Paragraph (l) of the clause, entitled "Communications," shall read as follows:
  - (l) Communications. All notifications required by this clause shall be submitted to the NHTSA CO.

5. **DATA COLLECTION.** (Paperwork Reduction Act of 1980) [This clause shall be applicable to all assistance agreements involving the collection of information as defined in 5 CFR 1320.7.]

- a. OMB requires review and approval of plans and reports used to collect identical information from 10 or more persons (other than Federal employees) under assistance agreements sponsored by NHTSA. A collection of information undertaken by a grantee is considered to be "sponsored" by NHTSA only if:
  - (1) The grantee is collecting information at the specific request of NHTSA; or
  - (2) The terms and conditions of the agreement require specific approval by NHTSA of the collection of information or the collection procedures.
- b. Unless otherwise specified, data collection conducted under the assistance agreement is the responsibility of the grantee, and NHTSA support of the effort does not constitute NHTSA approval of the survey design,

questionnaire content, or data collection procedures. The grantee shall not represent to respondents that such data is being collected for, or in association with, NHTSA or any Federal agency without the specific written approval of such data collection plan or device by NHTSA. However, this requirement is not intended to preclude mention of NHTSA support of the effort in response to any inquiry or acknowledgment of such support in any publication of this data.

6. **PROTECTION OF INDIVIDUAL PRIVACY.** [This clause shall be applicable to all assistance agreements under which the grantee, or its employees, or its third-party contractors, administer any system of records on individuals on behalf of the Federal Government.]
- a. **Privacy Act Notification.** The design, development, or operation of any system of records on individuals to accomplish a Government function is subject to the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 U.S.C. 552a) and applicable regulations. Violation of the Act may involve the imposition of criminal penalties.
- b. The grantee agrees to:
- (1) Comply with the Privacy Act of 1974 (the Act), and rules and regulations issued pursuant to the Act when performance under this agreement involves the design, development, or operation of any system of records on individuals to be operated by the grantee, its employees, or its third-party contractors to accomplish a Government function.
  - (2) Notify the NHTSA CO when the grantee anticipates operating a system of records on individuals on behalf of the Government in order to accomplish the requirements of this agreement, if such system contains information about individuals which will be retrieved by the individual's name or other particular identifier assigned to the individual. A system of records on individuals subject to the Act may not be employed in the performance of this agreement until the necessary approval and publication requirements applicable to the system have been carried out. The grantee agrees to collect, maintain, disseminate, and use such records in accordance with the requirements of the Act, and comply with all applicable requirements of the Act;
  - (3) Include the Privacy Act Notification contained in this agreement in every solicitation and in every resulting third-party contract and in every third-party contract awarded without a solicitation, when the performance of work under the third-party contract requires the design, development, or operation of a system of records on individuals that is subject to the Act;
  - (4) Include this clause b, including this paragraph, in all third-party contracts under this agreement which require the design, development, or operation of such a system of records on behalf of the Government.
- c. For purposes of the Privacy Act, when the agreement involves the design, development, or operation of a system of records on individuals to accomplish a Government function, the grantee, its employees, and its third-party contractors are considered to be employees of the Government with respect to the Government function, and the requirements of the Act, including civil and criminal penalties for violation of the Act, are applicable. In addition, failure to comply with the provisions of the Act or of this clause will make this agreement subject to termination.
- d. The terms used in this clause have the following meanings:
- (1) "Operation of a system of records" means performance of any of the activities associated with maintaining the system of records on behalf of the Government, including the collection, use, and dissemination of records.
  - (2) "Record" means any item, collection, or grouping of information about an individual that is maintained by the grantee on behalf of the Government including, but not limited to, education, financial transactions, medical history, and criminal or employment history and that contains the person's name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a fingerprint or voiceprint or photograph.
  - (3) "System of records on individuals" means a group of any records under the control of the grantee on behalf of the Government from which information is retrieved by the name of the individual or by some identifying number, symbol, or other particular assigned to that individual.

7. **RIGHTS IN DATA.** [This clause is applicable in its entirety to all assistance agreements and third-party contracts, except those involving State, local, and Federally-recognized Indian tribal governments, for which this clause applies only where not inconsistent with 49 CFR 18.34, and Nonprofit Organizations, for which this clause applies only where not inconsistent with 49 CFR 19.36.]

a. Definitions.

- (1) "Computer software," as used in this clause, means computer programs, computer data bases, and documentation thereof.
- (2) "Data" as used in this clause, means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to agreement administration, such as financial, administrative, cost or pricing, or management information.
- (3) "Form, fit, and function data," as used in this clause, means data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, as well as data identifying source, size, configuration, mating, and attachment characteristics, functional characteristics, and performance requirements; except that for computer software it means data identifying source, functional characteristics, and performance specifications, but specifically excludes the source code, algorithm, process, formulae, and flowcharts of the software.
- (4) "Limited Rights," as used in this clause, means the rights of the Government in limited rights data as set forth in the Limited Rights Notice of subparagraph g(2).
- (5) "Limited rights data," as used in this clause, means data (other than computer software) that embody trade secrets or are commercial or financial and confidential or privileged, but only to the extent that the data pertains to items, components, or processes developed at private expense, including minor modifications thereof.
- (6) "Restricted computer software," as used in this clause, means computer software developed at private expense and that is a trade secret; is commercial or financial and is confidential or privileged; or is published copyrighted computer software; including minor modifications of such computer software.
- (7) "Restricted rights," as used in this clause, means the rights of the Government in restricted computer software, as set forth in a Restricted Rights Notice of subparagraph g(3), or as otherwise may be provided in a collateral agreement incorporated in and made part of this agreement, including minor modifications of such computer software.
- (8) "Technical data," as used in this clause, means data (other than computer software) which are of a scientific or technical nature.
- (9) "Unlimited rights," as used in this clause, means the right of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

b. Allocation of rights.

- (1) Except as provided in paragraph c of this clause regarding copyright, the Government shall have unlimited rights in--
  - (i) Data first produced in the performance of this agreement;
  - (ii) Form, fit, and function data delivered under this agreement;
  - (iii) Data delivered under this agreement (except for restricted computer software) that constitutes manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or otherwise furnished for use under this agreement; and
  - (iv) All other data delivered under this agreement unless provided otherwise for limited rights data or restricted computer software in accordance with paragraph g of this clause.
- (2) The grantee shall have the right to--
  - (i) Use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the grantee in the performance of this agreement unless provided otherwise in paragraph d of this clause;

- (ii) Protect from unauthorized disclosure and use those data which are limited rights data or restricted computer software to the extent provided in paragraph g of this clause;
- (iii) Substantiate use of, add or correct limited rights, restricted rights or copyright notices and to take other appropriate action, in accordance with paragraphs e and f of this clause; and
- (iv) Establish claim to copyright subsisting in data first produced in the performance of this contract to the extent provided in subparagraph c(1) of this clause.

c. Copyright.

- (1) Data first produced in the performance of this agreement. Unless provided otherwise in paragraph d of this clause, the grantee may establish, without prior approval of the CO, claim to copyright subsisting in scientific and technical articles based upon or containing any data first produced in the performance of this agreement and published in academic, technical or professional journals, symposia proceedings or similar works. The prior, express written permission of the CO is required to establish claim to copyright subsisting in all other data first produced in the performance of this agreement. When claim to copyright is made, the grantee shall affix the applicable copyright notices of 17 U.S.C. 401 or 402 and acknowledgment of Government sponsorship (including agreement number) to the data when such data are delivered to the Government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office.

For data other than computer software the grantee grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable worldwide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. For computer software, the grantee grants to the Government and others acting in its behalf, a paid-up, nonexclusive, irrevocable worldwide license in such copyrighted computer software to reproduce, prepare derivative works, and perform publicly and display publicly, by or on behalf of the Government.

- (2) Data not first produced in the performance of this agreement. The grantee shall not, without prior written permission of the CO, incorporate in data delivered under this agreement any data not first produced in the performance of this agreement and which contains the copyright notice of 17 U.S.C. 401 or 402, unless the grantee identifies such data and grants to the Government, or acquires on its behalf, a license of the same scope as set forth in subparagraph c(1) of this clause; provided, however, that if such data are computer software Government shall acquire a copyright license as set forth in subparagraph g(3) of this clause or as otherwise may be provided in a collateral agreement incorporated in or made part of this agreement.
- (3) Removal of copyright notices. The Government agrees not to remove any copyright notices placed on data pursuant to this paragraph c, and to include such notices on all reproductions of the data.

d. Release, publication and use of data.

- (1) The grantee shall have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the grantee in the performance of this agreement, except to the extent that such data may be subject to the Federal export control or national security laws or regulations, or unless otherwise provided in this paragraph of this clause or expressly set forth in this agreement.
- (2) The grantee agrees that to the extent it receives or is given access to data necessary for the performance of this agreement which contains restrictive markings, the grantee shall treat the data in accordance with such markings unless otherwise specifically authorized in writing by the CO.

e. Unauthorized marking of data.

- (1) Notwithstanding any other provisions of this agreement concerning inspection or acceptance, if any data delivered under this agreement are marked with the notices specified in subparagraphs g(2) or g(3) of this clause and use of such is not authorized by this clause, or if such data bears any other restrictive or limiting markings not authorized by this agreement, the CO may at any time either return the data to the grantee, or cancel or ignore the markings. However, the following procedures shall apply prior to cancelling or ignoring the markings:
- (i) The CO shall make written inquiry to the grantee affording the grantee 30 days from receipt of the inquiry to provide written justification to substantiate the propriety of the markings;

- (ii) The grantee fails to respond or fails to provide written justification to substantiate the propriety markings within the 30-day period (or a longer time not exceeding 90 days approved in writing by the CO for good cause shown), the Government shall have the right to cancel or ignore the markings at any time after said period and the data will no longer be made subject to any disclosure prohibitions.
- (iii) If the grantee provides written justification to substantiate the propriety of the markings within the period set in subdivision e(1)(i) of this clause, the CO shall consider such written justification and determine whether or not the markings are to be cancelled or ignored. If the CO determines that the markings are authorized, the grantee shall be so notified in writing. If the CO determines, with concurrence of the head of the contracting activity, that the markings are not authorized, the CO shall furnish the grantee a written determination, which determination shall become the final agency decision regarding the appropriateness of the markings unless the grantee files suit in a court of competent jurisdiction within 90 days of receipt of the CO's decision. The Government shall continue to abide by the markings under this subdivision e(1)(iii) until final resolution of the matter either by the CO's determination becoming final (in which instance the Government shall thereafter have the right to cancel or ignore the markings at any time and the data will no longer be made subject to any disclosure prohibitions) or by final disposition of the matter by court decision if suit is filed.

- (2) The time limits in the procedures set forth in subparagraph e(1) of this clause may be modified in accordance with regulations implementing the Freedom of Information Act (5 U.S.C. 552) if necessary to respond to a request thereunder.

f. Omitted or incorrect markings.

- (1) Data delivered to the Government without either the limited rights or restricted rights notice as authorized by paragraph g of this clause, or the copyright notice required by paragraph c of this clause, shall be deemed to have been furnished with unlimited rights, and the Government assumes no liability for the disclosure, use, or reproduction of such data. However, to the extent the data has not been disclosed without restriction outside the Government, the grantee may request, within 6 months (or a longer time approved by the CO for good cause shown) after delivery of such data, permission to have notices placed on qualifying data at the grantee's expense, and the CO may agree to do so if the grantee--
  - (i) Identifies the data to which the omitted notice is to be applied;
  - (ii) Demonstrates that the omission of the notice was inadvertent;
  - (iii) Establishes that the use of the proposed notice is authorized; and
  - (iv) Acknowledges that the Government has no liability with respect to the disclosure or use of any such data made prior to the addition of the notice or resulting from the omission of the notice.
- (2) The CO may also (i) permit correction at the grantee's expense, of incorrect notices if the grantee identifies the data on which correction of the notice is to be made, and demonstrates that the correct notice is authorized, or (ii) correct any incorrect notices.

g. Protection of limited rights data and restricted computer software.

- (1) When data other than that listed in subdivisions b(1)(i), (ii), and (iii) of this clause are specified to be delivered under this agreement and qualify as either limited rights data or restricted computer software, if the grantee desires to continue protection of such data, the grantee shall withhold such data and not furnish them to the Government under this agreement. As a condition to this withholding, the grantee shall identify the data being withheld and furnish form, fit, and function data in lieu thereof. Limited rights data that is formatted as a computer data base for delivery to the Government are to be treated as limited rights data and not restricted computer software.
- (2) Notwithstanding subparagraph g(1) of this clause, the agreement may identify and specify the delivery of limited rights data, or the CO may require by written request the delivery of limited rights data that has been withheld or would otherwise be withholdable. If delivery of such data is so required, the grantee may affix the following "Limited Rights Notice" to the data and the Government will thereafter treat the data, subject to the provisions of paragraphs e and f of this clause, in accordance with such Notice:

**LIMITED RIGHTS NOTICE**

- (a) These data are submitted with limited rights under NHTSA Agreement No. \_\_\_\_\_  
These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the grantee, be used for purposes of manufacture or disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any, provided that the Government makes such disclosure subject to prohibition against further use and disclosure:
- (i) Use (except for manufacture) by support service contractors.
  - (ii) Evaluation by nongovernment evaluators.
  - (iii) Use (except for manufacture) by other grantees or contractors participating in the Government's program of which the agreement is a part, for information and use in connection with the effort or work performed under each agreement or contract.
  - (iv) Release to a foreign government, or instrumentality thereof, as the interests of the United States may require, for information or evaluation by such government.
- (b) This Notice shall be marked on any reproduction of these data, in whole or in part.

(End of notice)

- (3)(i) Notwithstanding subparagraph g(1) of this clause, the agreement may identify and specify the delivery of restricted computer software, or the CO may require by written request the delivery of restricted computer software that has been withheld or would otherwise be withholdable. If delivery of such computer software is so required, the grantee may affix the following "Restricted Rights Notice" to the computer software and the Government will thereafter treat the computer software, subject to paragraphs e and f of this clause, in accordance with the Notice:

**RESTRICTED RIGHTS NOTICE**

- (a) This computer software is submitted with restricted rights under NHTSA Agreement No. \_\_\_\_\_  
It may not be used, reproduced or disclosed by the Government except as provided in paragraph (b) of this Notice or as otherwise expressly stated in the agreement.
- (b) This computer software may be--
- (1) Used or copied for use in or with the computer for which it was acquired, including use at any Government installation to which such computer or computers may be transferred;
  - (2) Used or copied for use in a backup computer if any computer for which it was acquired is non-operative;
  - (3) Reproduced for safekeeping (archives) or backup purposes;
  - (4) Modified, adapted, or combined with other computer software, provided that the modified, combined, or adapted portions of the derivative software incorporating restricted computer software are made subject to the same restricted rights; and
  - (5) Disclosed to and reproduced for use by support service contractors in accordance with subparagraphs (b)(1) through (4) of this clause, provided the Government makes such disclosure or reproduction subject to these restricted rights; and
  - (6) Used or copied for use in or transferred to a replacement computer.
- (c) Notwithstanding the foregoing, if this computer software is published copyrighted computer software, it is licensed to the Government, without disclosure prohibitions, with the minimum rights set forth in paragraph (b) of this clause.
- (d) Any other rights or limitations regarding the use, duplication, or disclosure of this computer software are to be expressly stated in, or incorporated in the agreement.

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(e) This Notice shall be marked on any reproduction of this computer software, in whole or in part.

(End of notice)

(3)(ii) Where it is impractical to include the Restricted Rights Notice on restricted computer software, the following short-form Notice may be used in lieu thereof:

**RESTRICTED RIGHTS NOTICE – SHORT FORM**

Use, reproduction, or disclosure is subject to restrictions set forth in NHTSA Agreement No. \_\_\_\_\_ with (name of Grantee).

(End of notice)

(3)(iii) If restricted computer software is delivered with the copyright notice of 17 U.S.C. 401, it will be presumed to be published copyrighted computer software licensed to the Government without disclosure prohibitions, with the minimum rights set forth in paragraph b of this clause, unless the grantee includes the following statement with such copyright notice: "Unpublished—rights reserved under the Copyright Laws of the United States."

h. Third Party Contracts. The grantee has the responsibility to obtain from its third-party contractors all data and rights therein necessary to fulfill the grantee's obligations to the Government under this agreement. If a third-party contractor refuses to accept terms affording the Government such rights, the grantee shall promptly bring such refusal to the attention of the CO and not proceed with the third-party contract award without further authorization.

i. Relationship to patents. Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government.

**8. RESTRICTIONS ON PRINTING.**

a. Government Printing and Binding Regulations are published by the Joint Committee on Printing, Congress of the United States. These regulations are applicable to NHTSA when NHTSA bears the entire cost of printing of materials exclusively for its own use.

b. This assistance agreement is not made primarily or substantially for the purpose of typesetting or having material printed for NHTSA use.

c. The grantee may reproduce reports, data, or other written material required under the terms of the agreement for the use of NHTSA, provided that the material duplicated does not exceed 5,000 units of only one page, or that items consisting of multiple pages do not exceed 25,000 units in the aggregate. Grantees must advise the CO if the estimated quantities will exceed these ceilings so that Departmental/Committee approval can be obtained.

d. These restrictions do not preclude the writing, editing, preparation of manuscript copy and related illustrative material, or the publication of findings by grantees; or the administrative printing requirements of the grantee required for its own use to respond to the terms of the agreement.

**9. OTHER ADMINISTRATIVE PROVISIONS AND ASSURANCES.**

a. No Government Obligations to Third Parties. Absent its specific consent, the NHTSA shall not be subject to any obligations or liabilities with respect to any person or entity not a party to this agreement in connection with performance under the agreement, notwithstanding its concurrence in or approval of the solicitation or award of any third-party contract.

b. Severability. If any provision of this agreement is held invalid, the remainder of this agreement shall not be affected thereby if such remainder would then continue to conform to the terms and requirements of applicable law.

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- c. The grantee assures and certifies that no member of or delegate to Congress, or resident Commissioner, will be admitted to any share or part of this assistance agreement, or to any benefit arising from it. And further, it shall comply with the provisions of 18 U.S.C. 1913 which prohibits the direct or indirect use of any funds appropriated by Congress to pay for any personal service, advertisement, telegram, telephone, letter, printed or written matter, or any other device intended or designed to influence a member of Congress, to favor or oppose, any legislation or appropriation, whether before or after the introduction of any bill or resolution proposing such legislation or appropriation.
- d. The grantee warrants that it has not paid and agrees not to pay any bonus, commission or fee for the purpose of obtaining approval of its application for the financial assistance agreement.
- e. The grantee assures that it shall comply with all applicable provisions of Federal, State and local law. Nothing in this agreement shall require the grantee to observe or enforce compliance with any provision hereof, perform any other act or do any other thing in contravention of applicable State or territorial law, provided that if any of the provisions of the agreement violates any applicable State or territorial law, or if compliance with any of the provisions of the agreement would require the grantee to violate any applicable State or territorial law, the grantee will at once notify the CO in writing in order that appropriate modifications may be made to the agreement to remedy the violation.

All limits and standards set forth in this agreement are minimum requirements, and shall not affect the application of more stringent State or local standards; provided, however, that in its procurement actions under this agreement, the grantee shall not give any preference to or discriminate against goods and services produced or manufactured in any country, State, or other geographical area, except as provided in paragraph f below.

- f. The grantee assures and certifies that all manufactured products, steel, and cement used in carrying out this agreement are produced in the United States, in accordance with Section 165 of the Surface Transportation Assistance Act of 1982 (Pub. L. 97-424; 96 Stat. 2097), unless the Secretary of DOT has determined under Section 165 that it is appropriate to waive this requirement.

#### 10. ORDER OF PRECEDENCE.

In the event of any inconsistency between any provisions of this agreement, the following order of precedence shall apply:

- a. Statement of Purpose (excluding the grantee's proposal, if incorporated).
- b. Special provisions contained in the assistance agreement.
- c. General Provisions, whether referenced or stated in full text, contained herein.
- d. The grantee's proposal (if incorporated).