**Centers for Disease Control and Prevention**

**Supporting Statement A**

**Evaluation of the Effectiveness of the Training and Education Modules in the North American Fatigue Management Program**

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Acronyms

|  |  |
| --- | --- |
| CDL | Commercial Driver’s License |
| CMV | Commercial Motor Vehicle |
| ELD | Electronic Logging Device |
| FMCSA | Federal Motor Carrier Safety Administration |
| FMP | Fatigue Management Program |
| KSS | Karolinska Sleepiness Scale |
| LHTD | Long-Haul Truck Driver |
| NAFMP | North American Fatigue Management Program |
| NIOSH | National Institute for Occupational Safety and Health |
| NORA | National Occupational Research Agenda |
| NTSB | National Transportation Safety Board |
| PVT | Psychomotor Vigilance Test |
| SF-36v2 | Quality of Life Short Form 36 version-2 questionnaire |
| UTC | Universal Coordinated Time |
| VT | Virginia Polytechnic Institute and State University |
| VTTI | Virginia Tech Transportation Institute |

* The goal of the proposed study will be to evaluate the effectiveness and cost benefit of the NAFMP in increasing opportunities for sleep, proactive sleep-related work/personal behaviors, objective measures of sleep, positive familial interactions, and reduced missed work days, drowsiness while driving, and safety-critical events.
* We will use the results, if beneficial, to promote use of the NAFMP in commercial motor vehicle operations and related operational environments. The results will inform which part(s) of the NAFMP led to the greatest impact on reducing driver fatigue. We will also use the results to revise and improve the NAFMP, as needed.
* The proposed study will use a prospective, observational before-and-after study design. Data will include quantitative and qualitative dependent variables, including crashes, real-time fatigue detection, objective measures of sleep quantity and quality, objective measures of fitness for duty, records of duty status, exercise and eating habits, family relationships, medical history, opinions and perceptions of the NAFMP, job satisfaction, quality of life, employment history, demographic characteristics, and anthropometric measurements.
* We will observe a convenience sample of 180 (90 regional and 90 long-haul) truck drivers for 8 months (three months before and five months after the implementation of the NAFMP at the participating carriers).
* We will use generalized linear models for statistical inference as well as Poisson/negative binomial regression, and general linear models (dependent on the type of dependent variable analyzed).

## CIRCUMSTANCES THAT MAKE COLLECTION OF INFORMATION NECESSARY

This is a new information collection request (ICR) from the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). The request is for two years to complete data collection. This data collection is authorized by the Occupational Safety and Health Act of 1970 (Attachment A).

NIOSH is seeking OMB approval to collect information needed to evaluate the North American Fatigue Management Program (NAFMP). NAFMP is a voluntary, fully interactive, web-based educational and training program. The program was developed by the Federal Motor Carrier Safety Administration (FMCSA), Transport Canada, and other entities to address commercial motor vehicle (CMV) driver fatigue through a comprehensive approach that delivers prevention information to carriers, dispatchers, drivers, and family members. The NAFMP was designed to enhance carriers’ and drivers’ ability to effectively deal with the challenges of fatigue in a highly competitive and rapidly changing industry. The NAFMP is comprised of 10 complementary instructional modules. Each module provides specialized content applicable to one or more of the target audiences.

Table A-1. Instructional Modules in the NAFMP

|  |  |
| --- | --- |
| **Module** | **Target Audience** |
| Module 1: FMP Introduction and Overview | Carrier Executives and Other Managers |
| Module 2: Safety Culture and Management Practices | Carrier Executives and Other Managers |
| Module 3: Driver Education | Drivers |
| Module 4: Driver Family Education | Drivers’ Spouses and Family |
| Module 5: Train-the-Trainer for Driver Education and Family Forum | Trainers and Managers |
| Module 6: Shippers and Receivers | Shippers and Receivers |
| Module 7: Motor Carrier Sleep Disorders Management | Carrier Executives and Other Managers |
| Module 8: Driver Sleep Disorders Management | Drivers |
| Module 9: Driver Scheduling and Tools | Dispatchers and Managers\* |
| Module 10: Fatigue Monitoring and Management Technologies | Carrier Executives and Other Managers |

The specific questions for this evaluation include:

1. Is the NAFMP effective in: (1) improving driver sleep quantity and quality, psychomotor performance, eating habits and exercise habits; (2) improving carrier best practices in scheduling and safety climate; and (3) reducing near-crashes or crashes, missed workdays, and health care claims?
2. Can any positive changes seen immediately after implementation be maintained throughout the observation period?
3. Does the NAFMP provide a positive return on investment?
4. Does the impact of the NAFMP differ between long-haul and regional truck drivers?
5. Is the NAFMP acceptable to truck drivers? What are the barriers and incentives for completing the training? What are the drivers’ opinions about the NAFMP web site and how can it be improved? Has the program changed drivers’ and carriers’ perception of the risk of fatigued driving?

Driving while fatigued has long been recognized as a major cause of large truck crashes. The National Transportation Safety Board (NTSB) identified reducing fatigue-related crashes as one of the top 10 changes needed for 2019-2020 to decrease transportation crashes and thus save lives.[[1]](#endnote-2) One of NIOSH’s priority goals is:

*“Employers, vehicle manufacturers, government, and standards organizations will incorporate evidence-based interventions and technologies into policies, standards, and regulations to reduce work-related motor vehicle crashes for transportation, warehousing and utilities workers. Of highest priority are interventions and guidance addressing crash contributors such as fatigue, work organization factors, aging-related factors, distraction, and psychological stressors; and the potential safety consequences of active safety systems and connected-vehicle technology in fleet vehicles and specialized work vehicles.”*

The proposed study addresses this goal.[[2]](#endnote-3) and will provide FMCSA and carriers with evidence-based data on the effectiveness and cost-benefits of the NAFMP and help them make informed decisions on future comprehensive safety initiatives and programs to reduce truck driver fatigue.

The NTSB found fatigue to be the most frequently cited probable cause (31%) in fatal-to-the-truck-driver crashes.[[3]](#endnote-4) A large retrospective study by the FMCSA estimated that fatigue was a factor in 15% of all fatal large-truck-related crashes. The agency estimated that fatigue was directly involved in 4.5% of these crashes, while mental lapses and inattention associated with fatigue were directly involved in 10.5% of fatal large-truck-related crashes (FMCSA, 2006).[[4]](#endnote-5) These are among the reasons why the NTSB identified reducing fatigue-related crashes as one of the most critical changes needed to reduce transportation crashes and save lives for 2019-2020.

Drowsy driving is common among truck drivers. The NIOSH National Survey of U.S. Long-Haul Truck Driver (LHTD) Injury and Health (OMB No. 0920-0865, exp. 9/30/2011) revealed that: LHTDs work an average of 60 hours a week (Sieber et al., 2014) compared to the average of 42 hours per week for full-time workers in the U.S.; 74% of LHTDs (18% often and 56% sometimes) perceived their delivery schedules as unrealistically tight; 65% reported driving while drowsy at least once a month; 8% reported drowsy driving almost every day; 36% reported having fallen asleep or nodded off while driving their truck; and 3% reported falling asleep at the wheel at least once per week in the previous three months.[[5]](#endnote-6) Unfortunately, due to their size and weight, large truck crashes are more likely to result in an injury or fatality. And, the driver and/or occupant of the other vehicle, rather than the truck driver, is killed in ~75% of fatal truck crashes. Thus, increasing the safety of truck drivers will benefit all road users who share the roads with these vehicles. Fatal crashes involving large trucks and buses cost the U.S. economy an estimated $41 billion in 2014, and the economic impact escalates to $112 billion when crashes with injuries or property damage are included.[[6]](#endnote-7)

Main causes of drowsiness for workers behind the wheel include: the time of day of operating a vehicle (e.g., such as circadian lows in the early morning and mid-afternoon), a long duration of wakefulness without rest, inadequate sleep, and prolonged work hours.[[7]](#endnote-8),[[8]](#endnote-9) Another leading cause of drowsiness is sleepiness due to sleep-related disorders (such as obstructive sleep apnea).[[9]](#endnote-10) Although CMV drivers may routinely feel sleepy during the day, they may not realize they have an underlying sleep disorder. CMV drivers may be at a higher risk for having sleep apnea due to the following risk factors for this condition: approximately 95% of CMV drivers are males, tend to have a sedentary lifestyle and have a high obesity rate (measured as body-mass index).[[10]](#endnote-11),[[11]](#endnote-12),[[12]](#endnote-13) In a 2015 survey of top trucking industry concerns, Hours of Service (HOS) and Driver Health and Wellness were ranked #1 and #7, and have been included as top concerns for the industry by the American Transportation Research Institute for the past 3 years.[[13]](#endnote-14) HOS regulations were issued by the Federal Motor Carrier Safety Administration (FMCSA). The regulations limit the number of daily and weekly hours a commercial vehicle driver can drive, and work and regulate the minimum amount of time a commercial vehicle driver must spend resting between driving shifts in the United States.

There are three major areas in which a fatigue management program (FMP) can be beneficial to an organization. These include safety benefits, improved driver health and well-being, and economic benefits. (1) Safety benefits include reduced fatigue-related risks, reduced crashes and near-crashes, and improved alertness. Successful countermeasures to manage fatigue will reduce these risks while also decreasing the number of crashes and near-crashes associated with fatigue. (2) Health and wellness benefits of an FMP include increased job and life satisfaction, fewer health complications, and weight loss. Fatigue may contribute to drivers experiencing less satisfaction with their jobs and lives. Therefore, an FMP may promote increased job and life satisfaction by helping drivers attain adequate sleep. (3) Lastly, an FMP may include financial benefits such as reduced legal burden and costs of crashes, lower healthcare and workers’ compensation costs, and lower costs associated with missed workdays, turnover, and delivery errors. An FMP can help carriers proactively prevent fatigue-related crashes.

The proposed project will be a collaborative effort among NIOSH, FMCSA, and VTTI. NIOSH has contracted with the Virginia Tech Transportation Institute (VTTI) at the Virginia Polytechnic Institute and State University (VT) to assist in administering this study and analyzing results. Part of the NAFMP was pilot tested by NIOSH during the development stage and although the pilot test suggested positive trends in sleep duration, sleep efficiency, and reduced critical events after the implementation of the driver module; the observation period in the pilot test was too short (9 days before and 9 days after) to adequately evaluate if the NAFMP was effective in reducing fatigue (Smiley et al., 2006).[[14]](#endnote-15) The NAFMP has not been fully evaluated since the NAFMP web site ([www.nafmp.com](http://www.nafmp.com)) was launched on July 10, 2013. In 2015, the National Academy of Sciences published the report “Commercial Motor Vehicle Driver Fatigue, Long-Term Health, and Highway Safety Research Needs” that identified the need to fully evaluate the NAFMP so that recommendations for implementation of the NAFMP are supported by scientific evidence.[[15]](#endnote-16) The collaborative effort between NIOSH and FMCSA can ensure the success of the proposed study as we are stakeholders in truck safety (FMCSA) and worker health/fatigue (NIOSH).

The evaluation is based on a prospective, observational before-and-after study design. Carrier management, CMV drivers, and other personnel will complete their respective training modules. Primary study outcomes focus on drivers’ sleep and driving performance. Information relevant to these outcomes will be collected during a 3-month baseline observation period followed by drivers’ completion of NAFMP Modules 3 and 8, and additional data collection during a 5-month post-training observation period. Drivers will self-report information about their satisfaction with the training, sleep patterns, and behaviors and attitudes that correlate with fatigue. Each driver will report information to the study team primarily using a dedicated Smartphone with pre-installed apps (study-specific questionnaires). The study team will also collect objective information about drivers’ anthropometric measurements, as well as real-time data about sleep patterns, hours on duty, and driving performance. The majority of objective data will be sourced from an actigraph (a device worn by the driver); from specialized equipment installed on the driver’s vehicle (a standard electronic log device, plus study-specific equipment); and from safety, crash, and administrative data reports obtained from the carrier. Finally, the study team will collect information from carriers about management practices relevant to fatigue reduction, and the costs of implementing the NAFMP.

## 2. PURPOSE AND USE OF INFORMATION COLLECTION

Data will be collected from CMV drivers (hereafter referred to as “drivers”) during their application to participate in the study, briefing session, study participation (NAFMP modules), and debriefing session (see below for summary of each), and an example of phone debriefing is in Attachment V. Data collection will primarily focus on driving performance, sleep, and sleepiness. These outcomes will be compared between when drivers operated before their participation in the study and after the NAFMP (i.e., in which drivers and carrier management will operate with increased knowledge, strategies, and techniques to reduce their fatigue via completion of the NAFMP modules).

NIOSH will recruit two medium/large carriers that provide regional and long-haul services. From those carriers we will then recruit a convenience sample of 180 CMV drivers (90 regional, 90 long-haul). An overview of the study plan is provided in Table A-2, and an expanded study plan in Attachment T.

**Table A-2. Study Plan At-a-Glance**

|  |  |
| --- | --- |
| **Respondents, Information Collection Components, and Information Collection Schedule** | DATA COLLECTION PERIODS |
| START-UP | BASELINE (month) | POST-INTERVENTION (month) | CLOSE-OUT |
|  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |  |
| Carrier Enrollment | Recruitment, Participation agreement |  |  |  |  |  |  |  |  |  |  |
| NAFMP training Modules 1, 2, 5, 7, 9, and 10 for executives/mgmt/dispatchers/  |  |  |  |  |  |  |  |  |  |  |
| Manager data collection | Management Practices (time period 1) |  |  |  |  |  |  |  |  |  |  |
| Management Practices (time period 2) |  |  |  |  |  |  |  |  |  |  |
| Reports: ELD file, Admin/cost file; Crash/safety/violation events |  |  |  |  |  |  |  |  |  |  |
| Driver Enrollment and Close-out Procedures | Driver application and background materials, Briefing, Consent, Receive Smartphone and actigraph |  |  |  |  |  |  |  |  |  |  |
| Debriefing and equipment return;  |  |  |  |  |  |  |  |  |  |  |
| Driver Training and QA | Smartphone and actigraph training |  |  |  |  |  |  |  |  |  |  |
| NAFMP Modules 3, 8 |  |  |  |  |  |  |  |  |  |  |
| Monthly phone briefing |  |  |  |  |  |  |  |  |  |  |
| Driver family members  | NAFMP training module 4.  |  |  |  |  |  |  |  |  |  |  |
| Driver Data Collection | Background Questionnaire |  |  |  |  |  |  |  |  |  |  |
| Post-Study Questionnaire  |  |  |  |  |  |  |  |  |  |  |
| Smartphone questionnaires (daily3x/day) including: (1) Karolinska Sleepiness Scale, (2) Fatigue scale report, (3) Stress scale, and (4) Psychomotor vigilance test. |  |  |  |  |  |  |  |  |  |  |
| Smartphone sleep log (before and after sleep |  |  |  |  |  |  |  |  |  |  |
| Periodic questionnaires including: (1) Family Interactions Questionnaire, (2) Job Descriptive Index, (3) Quality of Life, Exercise and Food Consumption Questionnaire, (4) Safety Climate, and (5) Short Form-36 Version 2. |  |  |  |  |  |  |  |  |  |  |
| Actigraph data collection (passive and continuously) |  | *Continuous* | *Continuous* |  |
| Vehicle Data Collection | Electronic logging device (ELD) (standard on commercial vehicles) |  | *Continuous* | *Continuous* |  |
| Install/remove study instrumentation |  |  |  |  |
| Study Instrumentation: Vehicle performance data system (PDS) with accelerometers, video cameras, and integrated real-time fatigue monitoring system (FMS) |  | *Continuous with event-driven data capture* | *Continuous with event-driven data capture (vehicle and video)* |  |

CDC and partners will use findings to promote increased use of the NAFTP within the CMV industry; recommend updates to the NAFTP, if indicated; and inform the development of future comprehensive safety initiatives and programs to reduce CMV driver fatigue. More specifically, there are three major areas in which the NAFMP can be beneficial to an organization: safety benefits, improved driver health and well-being, and economic benefits. Findings from this study will provide CDC and motor carriers with scientific data on the effectiveness and cost-benefit of the NAFMP to help them make informed decisions on future comprehensive safety initiatives, rulemaking, and programs to reduce truck driver fatigue, which will ultimately aid in reducing CMV driver deaths and injuries. The study results will also benefit workers in other CDC sectors where CMVs are used to transport products and have possible global safety benefits for CMV drivers in North America and beyond. Findings will be disseminated to other stakeholders and may stimulate further research on translational activities on this topic. Research on alternative approaches to managing fatigue supports CDC efforts to supplement regulation with evidence-based management controls and technology-based interventions truck driver fatigue.

## 3. USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION

The application and driver information form includes check boxes, multiple choice, and fill-in-the-blank responses. During the field study, the real-time fatigue detection system and ELD data collection will be automated and require no action by the drivers following equipment installation at the briefing session. Similarly, the wrist actigraph will provide continuous recording and will require drivers to charge the device weekly (which can be completed during any waking period, including while driving) and sync it with a smartphone app daily (<5 min). The PVT and other short questionnaires will be completed via smartphone apps to reduce paper supplies or other equipment. The larger questionnaires will be completed on the web and/or smartphone, with the data automatically downloaded to a secure server. The debriefing questionnaire will be administered orally (over the phone) or completed on the web. The study is designed to collect the necessary information with minimal time demand from drivers. Thus, 99% of the responses will be collected electronically.

## 4. EFFORTS TO IDENTIFY DUPLICATIONS AND USE OF SIMILAR INFORMATION

The driver training module of the NAFMP was pilot tested during the development of NAFMP.[[16]](#endnote-17) This pilot test suggested positive trends in sleep duration, sleep efficiency, and reduced safety critical events after the implementation of the driver module, however, the observation period in the pilot test was too short (9 days before and 9 days after) to adequately evaluate if the NAFMP was effective in reducing fatigue. The NAFMP has not been fully evaluated since the NAFMP web site ([www.nafmp.com](http://www.nafmp.com)) was launched on July 10, 2013.[[17]](#endnote-18)

## 5. IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES

Given the required sample size and project resources minimizing travel, the research team is targeting medium to large carriers. To reduce work-related time conflicts, drivers may not complete the smartphone apps while driving. The real-time fatigue detection system and ELD data are continuously collected, with no extra demand on the driver. In addition, we will compensate drivers for their time. Participation in the study is voluntary, so no small business will have a burden imposed on them that they are not willing to bear.

## 6. CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY

NIOSH and the research team believe that, to meet its research objectives, data must be collected from drivers at several time points across their waking period across several months. Data collection has been designed to use the fewest possible measurements while still capturing the variation in fatigue and performance that naturally occurs during the day and night. In order to capture these daily fluctuations, the PVT, KSS, fatigue, and stress scales will be taken at the start of the waking period (prior to beginning a duty period during duty cycles), midway through the waking period (during a break) or after waking from a nap (when applicable), and towards the end of the waking period (after concluding a duty period during duty cycles). The sleep log will be completed immediately prior to and following sleep periods for accurate representation of when the driver is attempting to sleep and how they feel at the time. Other apps will be used as needed when drivers complete their duty period. Monitoring of wrist actigraphy will be continuous as drivers potentially sleep at any hour of the day or night. The real-time fatigue detection systems will continuously monitor driver’s driving performance, as fatigue and safety events can occur at any time while on duty.

Other information collection measures, including the application, driver information form, repeated questionnaires, and debriefing questionnaire, are each collected once to four times per driver at a time that meets their schedule. The briefing phone call will be initiated by the research team at a time that is convenient to drivers and when they are not on duty. This contact is critical to study design for maintaining study protocol adherence, providing an opportunity for the research team to rectify any data anomalies, and allowing the driver to ask questions throughout the study period.

We will ask drivers to participate in the field study for up to 8 months. The observation period will include 3-months before and 5-months after implementation of the NAFMP.

Accurate representation of driver sleep and performance during duty periods in which drivers operate will allow NIOSH and FMCSA to determine the safety and operational impacts of the NAFMP implementation. NIOSH and FMCSA’s safety goals are shared by motor carriers, researchers, public safety advocacy groups, trade associations and other organizations. An accurate data collection will benefit all those interested in truck safety and facilitate better informed discussions among these parties.

## 7. SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5

There are no special circumstances related to this information collection.

## 8. COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE THE AGENCY

8a. Federal Register Notice

A 60-day Federal Register Notice was published in the Federal Register November 4, 2019, Vol. 84, No. 213, pp. 59383-59384 (see Attachment B). NIOSH received one comment which was a letter of support from the National Transportation Safety Board (Attachment C).

8b. Consultations

Contractor Contractor

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Consulted on data collection design Consulted on data collection design

## 9. EXPLANATION OF ANY PAYMENT OR GIFTS TO RESPONDENTS

Incentives will be offered to recognize the time and effort involved in study participation, and to encourage continued participation throughout the data collection period. Drivers could receive up to $968 if they participate for the entire 8 months of the proposed study (~$121/month). Participants will receive monthly checks/debit cards over the course of their participation. If a participant elects to withdraw from the study or if their employment ends, the amount will be prorated based on their time in the study up to that point. Checks/debit cards will be issued by the research team. Incentivizing participation is considered essential for the reasons listed below:

*Availability and time burden*: CMV drivers are difficult to reach for research studies due to irregular schedules and long working hours. Drivers who choose to participate in the study will need to complete their daily data collection and have intermittent phone calls with researchers outside of their duty hours. The briefing/debriefing sessions will last approximately one hour each. Daily data collection is estimated at approximately 10 minutes per day. Telephone briefings are estimated at approximately 10 minutes per month. Incentives acknowledge the contribution of time for these contacts and encourage continued, consistent participation. Incentives may also influence respondents’ initial resistance to providing such information, which is essential for the study to be successful.

*Data quality*: Incentives will significantly increase response rates and decrease missing data for the information collection, thus improving the validity and reliability of findings. Incentives are awarded throughout the data collection period to encourage continued participation.

*Complex study design*: The proposed research requires ongoing participation for up to 8 consecutive months in order to achieve an accurate representation of drivers’ schedules which can vary significantly by day and season. Incentives may substantially reduce attrition and increase response rates on the questionnaires.

*Past experience*: Members of the research team have extensive experience conducting research with CMV drivers.[[18]](#endnote-19),[[19]](#endnote-20) Past experience indicates that it is difficult to obtain enough participants for studies of this size without providing adequate incentives, but that drivers will participate if they feel they are being provided with incentives that are sufficient to be considered respectful of their time. The incentive amounts proposed for daily participation in this study are appropriate based on the highest minimum wage in the nation.

## 10. PROTECTION OF THE PRIVACY AND CONFIDENTIALITY OF INFORMATION PROVIDED BY RESPONDENTS

NIOSH’s Information Systems Security Officer reviewed this submission and determined that the Privacy Act does not apply. Smartphone app data collected in the field will be transmitted to a secure server daily for data quality control purposes. If no mobile phone connection can be made by the app (e.g., because the driver is out of range of mobile phone signals), then the data will remain stored on the smartphone until the next available opportunity to transmit the data to the server. Smartphone app data will be reviewed daily by the research team. All data will be expressed in the driver’s home terminal time and coded with a driver ID number and no personally identifying information.

The method by which ELD data will be transmitted and reduced will depend on the decisions made by the participating carrier. The ELD data will be collected electronically from the participating carrier.

Drivers will be asked to sync the actigraph with a smartphone app daily. The wrist actigraphy data will then be transmitted via the smartphone to a secure, password-protected server for the research team to check. Actigraphy data will be stored using only the driver ID number (no identifying information).

Once real-time fatigue detection system data reduction has been completed, the data set (including video and kinematic data) will be sent to the research team for analysis. This data set will be sent in an Excel or SQL file via a secure file transfer portal. The data set will be stored on a secure, password-protected server at VTTI. Included in the data set will be the categorical reduction for each event, including unique time and date; GPS location of the event, which will be converted into a time zone; carrier ID number; unique driver ID number; unique event ID number; trigger type; severity (crash, near-crash, or other); categorical reduction of what took place during the event; maximum kinematic values; UTC; and offset of UTC to home terminal. A separate data key will be sent that provides coded information on the identity of the driver and carrier and definitions of the variables included in the data set.

A unique participant number will be generated for all drivers linking their responses to the field study data collected (smartphone apps, moving violations, real-time fatigue detection system, and ELD), briefings, repeated questionnaires, and debriefing questionnaire. After the project has been completed, any driver PII will be deleted from the file.

## 11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

NIOSH will not have any access to personal identifiable information, NIOSH will rely on Virginia Tech’s Institutional Review Board for review and approval of study procedures since VTTI staff are interacting with participants. Staff members of motor carriers who assist with participant recruitment will receive VT IRB ethics training to ensure that the rights of the research subjects are protected. The VT Institutional Review Board approved the methods outlined in this application (VT IRB-17-1087; see Attachment D).

Sensitive Questions

This study will include collection of information regarding each participant’s driving through ELD and real-time fatigue detection system data, which one may consider sensitive information. This is a critical component of data collection. If a fatigue or safety-related event occurs (e.g., hard braking, swerving), the event may be due to a sleepy driver (yawning, eyes closed) or due to a pedestrian or animal entering the roadway. The ELD system will use existing systems already installed in the participating driver’s truck prior to the beginning of data collection. The fatigue detection system will be installed by the research team prior to the start of data collection.

## 12. ESTIMATES OF ANNUALIZED BURDEN HOURS AND COSTS

It is estimated the driver sample will be drawn from about two carriers, each responsible for an average of 90 enrolled drivers. Thus, a convenience sample of 180 eligible drivers over a two-year period will be recruited to participate in the study. The study sample will include approximately 90 regional and 90 long-haul drivers.

Reviewing the study materials and granting permission for drivers to participate is estimated to take one hour per carrier (Attachment E). Carriers will also be asked to track and deliver records of participating drivers’ moving violations/crashes, ELD, and administrative cost data each month (Attachment F-1). The violations/crash and ELD data will be collected once a month for an 8-month period. As the carrier is already collecting these data, it is estimated it will take carrier personnel 1.5 hours to prepare and submit each report to the research team. The administrative cost data (Attachment F-2) will be collected twice a month over an 8-month period. As the carrier is already collecting these data, it is estimated it will take carrier personnel 2 hours to deliver each report to the researchers. Five carrier personnel from each participating carrier will be asked to complete the Management Practices questionnaire (Attachments G-1 and G-2) at two different time periods during the proposed study (5 carrier personnel x 2 time periods = 10 respondents). The Management Practices questionnaire has 39 items, each taking about 45 minutes to complete.

The application will be available to all drivers who are interested in participating in the study and are employed as drivers at the participating carriers (Attachment I). In order to recruit 90 eligible drivers who will be enrolled in the study, an estimated 150 drivers will complete the application. Because drivers will be provided with information about the study through email (via their carrier’s listserv), it is unlikely that many drivers will complete the driver information form at the briefing session and then choose not to be enrolled in the study. Of the 150 drivers estimated to complete the application, approximately 60% (90) will complete the driver information form and be enrolled in the study and begin daily data collection.

Participating driver burden is associated with completing the online application, driver information form, daily data collection during the field study period, and debriefing questionnaire. The driver application, which has 5 items, is estimated to take 5 minutes to complete. All 90 participating drivers will complete the Background Questionnaire (Attachment J), which has 41 items and takes 45 minutes to complete. The drivers will also be trained on how to wear, and recharge the Actigraph device (i.e., Actigraph Training, see Attachment K). The daily smartphone questionnaire (Attachment L), which is completed 3 times per day, has 6 questions and takes 1 minute to complete (3 times per day x 7 days per week x 34.2 weeks (i.e., 240 days x 3 responses/day = 720 responses. The PVT will be completed by all 90 participating drivers 3 times each day (3 times per day x 7 days per week x 240 data collection days = 720 responses). It takes 3 minutes to complete the PVT (Attachment M). Several questionnaires will be completed at four different times across data collection. These include the Exercise and Food Consumption Questionnaire (4 items, Attachment N), the SF-36v2 (11 items, Attachment O), Family Interactions Questionnaire (4 items, Attachment P), Job Descriptive Index (89 items, Attachment Q), and Safety Climate Questionnaire (Attachment R). The Post-Study Questionnaire (60 items, Attachment S) will be completed by all drivers at the end of the study. Lastly, monthly phone briefings are estimated to take 10 minutes each). The estimates of burden hours for the participating driver tasks are presented in table below.

**Table A-4, Estimated Burden by Task**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **No. of Respondents** | **No. of Responses per Respondent** | **Average Burden per Response (hours)** | **Total Burden Hours** |
| Carrier Management | Participation Agreement | 1 | 1 | 1 | 1 |
| Retrieval of Company Monthly Roadside Violations/Crash Reports | 1 | 8 | 1.5 | 12 |
| Retrieval of Company Administrative Costs | 1 | 16 | 2 | 32 |
| Management Practice questionnaire (Time 1) | 5 | 1 | 45/60 | 4 |
| Management Practice questionnaire (Time 2) | 5 | 1 | 45/60 | 4 |
| Drivers | Application to Participate | 150 | 1 | 12/60 | 30 |
| Actigraph Training | 90 | 1 | 10/60 | 15 |
| Background Questionnaire | 90 | 1 | 45/60 | 68 |
| Daily Smartphone Questions | 90 | 720 | 1/60 | 1,080 |
| PVT | 90 | 720 | 3/60 | 3,240 |
| Exercise and Food Consumption Questionnaire | 90 | 4 | 20/60 | 120 |
| SF-36v2 | 90 | 4 | 30/60 | 180 |
| Family Interactions Questionnaire | 90 | 4 | 15/60 | 90 |
| Safety Climate Questionnaire | 90 | 4 | 10/60 | 60 |
| Job Descriptive Index | 90 | 4 | 30/60 | 180 |
| Post-Study Questionnaire | 90 | 1 | 1 | 90 |
| Phone Briefings | 90 | 8 | 6/60 | 72 |
| **Total** |  |  |  |  | **5,278** |

Table A-5 shows the total respondent cost by task. The median hourly compensation for heavy and tractor-trailer truck drivers and their supervisors is $21.50 and $28.26, respectively, as reported by Bureau of Labor Statistics (2018).[[20]](#endnote-21)

**Table A-5, Estimated Cost by Task**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Respondent** | **Form Name** | **Total Burden Hours** | **Hourly Wage** | **Total Burden Cost** |
| Carrier Management | Participation Agreement | 1 | $28.26  | $28 |
| Retrieval of Company Monthly Roadside Violations/Crash Reports | 12 | $28.26 | 339 |
| Retrieval of Company Administrative Costs | 32 | $28.26 | $904 |
| Management Practices Questionnaire (Time 1) | 4 | $28.26  | $113 |
| Management Practices Questionnaire (Time 2) | 4 | $28.26  | $113 |
| Drivers | Application to Participate | 30 | $21.50  | $645 |
| Actigraph Training | 15 | $21.50  | $323 |
| Background Questionnaire | 68 | $21.50  | $1,462 |
| Daily Smartphone Questions | 1,080 | $21.50  | $23,220 |
| PVT | 3,240 | $21.50  | $69,660 |
| Exercise and Food Consumption Questionnaire | 120 | $21.50  | $2,580 |
| SF-36v2 | 180 | $21.50  | $3,870 |
| Family Interactions Questionnaire | 90 | $21.50  | $1,935 |
| Safety Climate Questionnaire | 60 |  | $1,290 |
| Job Descriptive Index | 180 | $21.50  | $3,870 |
| Post-Study Questionnaire | 90 | $21.50  | $1,935 |
| Phone Briefings | 72 | $21.50  | $1,548 |
| **Total** |  |  |  | **$113,835** |

## 13. ESTIMATES OF OTHER TOTAL ANNUAL COSTS BURDEN TO RESPONDENTS OR RECORD KEEPERS

There are no additional costs to respondents beyond those associated with the hourly burden presented above, which are not to be included in this section.

## 14. ANNUALIZED COST TO THE FEDERAL GOVERNMENT

The research design, protocol development, and implementation of the research methods will be completed between FY 2018 and FY 2021. For this study and the total cost for the contract is $873,362.

## 15. EXPLANATION OF PROGRAM CHANGES OR ADJUSTMENTS

This is a new data/information collection.

## 16. PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE

The results will be disseminated via the Internet, conference presentations, peer-reviewed journal articles, trade journal articles, blogs, topic pages, and NIOSH publications. Table A-6 shows the project time schedule for activities after OMB approval.

**Table A-6. Project Time Schedule**

|  |  |
| --- | --- |
| **Activity** | **Time Schedule** |
| Complete Driver Recruitment | 4 months after OMB approval  |
| End Data Collection | 14 months after OMB approval |
| Data Management and Reduction | 20 months after OMB approval |
| Data Analyses | 24 months after OMB approval |
| Final Report and Publications | 30 months after OMB approval |

## 17. REASON(S) DISPLAY OF OMB EXPIRTION DATE IS INAPPROPRIATE

None. The display of the OMB expiration date is appropriate.

## 18. EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS

There are no exceptions to the certification.

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