

Federal Motor Carrier Safety Administration Commercial Motor Vehicle Driver Restart Study Plan

Submitted to the U.S. Department of Transportation Office of Inspector General in accordance with Sec. 133 (d) of the Consolidated and Further Continuing Appropriations Act of 2015.

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1. INTRODUCTION

The Federal Motor Carrier Safety Administration (FMCSA) hours-of-service (HOS) regulations effective July 1, 2013, for property-carrying commercial motor vehicle (CMV) drivers prescribe that drivers: (i) may drive 11 hours in a 14-hour window after coming on duty following 10 consecutive hours off duty, (ii) may not drive after 60/70 hours on duty in 7/8 consecutive days, and (iii) may restart a 7/8 consecutive day period after taking 34 or more consecutive hours off duty (the 34-hour restart rule). The regulation requires the 34-hour restart to include two nighttime periods from 1 a.m. to 5 a.m.

Under the Moving Ahead for Progress in the 21st Century Act, PL-112-114 (2012), Congress directed FMCSA to conduct a field study on the efficacy of the restart rule published on December 27, 2011, applicable to operators of CMVs subject to the maximum driving time requirements. FMCSA completed this study and published the findings in January 2014, which indicated that drivers using a 1-night restart exhibited a higher level of fatigue than those drivers who had 2 nights of rest between 1 a.m. and 5 a.m. during the restart break.⁽¹⁾

The Consolidated and Further Continuing Appropriations Act, 2015 (The Act) directed FMCSA to conduct a CMV Driver Restart Study. This study plan outlines the scope and methodology as required by Sec. 133 (d) of The Act. Congress directed that within 90 days of enactment of the Act, “the Secretary shall initiate a naturalistic study of the operational, safety, health, and fatigue impacts of the restart provisions in Sections 395.3(c) and 395.3(d) of Title 49, Code of Federal Regulations, on commercial motor vehicle drivers.” The FMCSA study required under the Act should compare these impacts on CMV drivers working under provisions in effect between July 1, 2013, and the day before the date of enactment of the Act (i.e., 2-night rest period), compared to the impacts on drivers working under the provisions in effect on June 30, 2013, (i.e., 1-night restart period) in a sample of drivers large enough to produce statistically significant results. The required research design will compare the effects of different recovery times to be both an “in-subject and between-subject research design.” It is expected that the two groups of drivers operating under the two restart conditions will overlap, and consequently a paired study design will be used given its statistical power. The study will also analyze the safety and fatigue effect on those drivers who have less than 168 hours between their restart period and those drivers who have at least 168 hours between their restart periods.

1.1 PROJECT SUMMARY

This study will compare, at a minimum, 5-month driver work schedules and will assess safety-critical events (SCEs, or crashes, near-crashes, and crash-relevant conflicts) and operator fatigue among CMV drivers operating under a rest period with at least 2 nights versus drivers operating under a 1-night restart period, based on a sample size large enough to detect meaningful effects of work schedule on the outcomes. The study will include fleets of all sizes (i.e., small, medium, and large) and operations (including long-haul, regional, and short-haul) in various sectors of the industry (including flat-bed, refrigerated, tank, and dry-van) to the extent practicable, in order to facilitate an assessment of generalizability of the study results. The study will assess drivers’ SCEs, fatigue, and levels of alertness, and driver health outcomes by using electronic and captured records of duty status, including:

- Psychomotor Vigilance Tests (PVTs).
- Electronic logging devices (ELDs).
- Actigraph watches.
- Camera-based onboard monitoring systems (OBMSs).

This study will be a field operational test of the 34-hour restart provision requiring 2 nights of sleep between work weeks. Drivers will be studied for up to 5 months, permitting up to 22 observational periods. This field evaluation will oversample CMV drivers who are relatively more likely to have at least one type of each restart condition among their up to 22 opportunities. The sample will include CMV drivers who routinely drive and work approximately 70 hours per week. The naturalistic driving study will collect fatigue, safety performance, and other related data from the drivers during their duty cycles (including restart breaks), over the 5-month work period. The minimum 34-hour restart, 2-night provision generally pertains to CMV drivers who drive predominately during the nighttime hours. The 34-hour restart period is typically long enough for daytime drivers to have the opportunity for two nighttime sleeping periods. The sample selected in this study will be of sufficient size to ensure that there is enough power to detect a significant difference, and representative, to the extent practicable, of the diverse segments of the motor carrier industry.

1.2 RESEARCH OBJECTIVES AND PERFORMANCE MEASURES

The outcome variables derived from the required technologies to measure the operational, safety, performance, fatigue, and health impacts of the two restart provisions are described below. These include measures that will be generated to evaluate the study outcomes.

1.2.1 Operational Impacts

The measurement of operational impacts consists of acquiring electronic information on the effects of restart schedule on two major sources of driver fatigue: work and sleep.^(2,3) The first domain, work-related outcomes, involves electronic information on the impact of the restart schedule on the demands of driving, relative to four outcomes:

1. Duration of the drive.
2. Time of day of the drive.
3. Perceived difficulty of the drive.
4. Perceived degree of drive hazards.

Work-related outcomes 1 and 2 will be achieved using ELD data, and work-related outcomes 3 and 4 will be achieved using drivers' visual analog ratings from a smartphone application (app). Sleep-related outcomes will be measured using data collected via actigraph watches and the smartphone app. These tools will acquire data on the impact of restart schedule on (recovery) sleep relative to four outcomes:

- 24-hour cumulative total sleep time.

- Time of day sleep was obtained.
- Time from last sleep to the end of a drive.
- Sleep on duty days and non-duty days.

1.2.2 Safety Impacts

The primary safety outcome will be the number of SCEs captured via the OBMSs. These include electronically-recorded hard brakes, hard accelerations, swerves, contact with other objects, and driving in excess of posted speed limits. SCEs have been found to increase as a function of time of driving in interaction with time-on-duty of drive.⁽⁴⁾ Fatigue-related events (coded by video scorers trained to perform enhanced analysis of fatigue and drowsiness at the time of the SCE, spurious baseline, or random baseline) will also be analyzed to identify effects of the restart rule on fatigue-related events.

1.2.3 Fatigue Impacts

Driver fatigue will be objectively assessed by measuring driver performance on daily iterations of an electronic 3-minute Brief PVT (PVT-B), which is validated to be sensitive to fatigue from inadequate sleep (Basner et al., 2007),⁽⁵⁾ and subjectively via driver ratings on the Karolinska Sleepiness Scale (KSS), which is validated to be sensitive to sleep loss and sleepiness while driving.⁽⁶⁾ PVT-B performance and KSS ratings yielded statistically reliable differences between restart conditions in the original FMCSA HOS Restart Study.⁽⁷⁾ To capture any combined effects of work and sleep on drivers' self-perceptions, a visual-analog fatigue scale (FS) will also be completed on a smartphone app, as well as a stress scale (SS), described below.

1.2.4 Health Impacts

Driver health outcomes will be assessed in two primary ways: (1) evaluating the effects of certain preexisting common health conditions in interaction with restart schedules, and (2) determining the effects of restart schedules on health mediators (i.e., sleep duration and perceived stress) that could pose increased risks to health.

1.2.4.1 Impact of Preexisting Conditions that May Interact with Driver Fatigue and Safety Relative to Restart Schedule

Driver risk factors for fatigue will be assessed via a background survey (Appendix E) at study entry. These will include questions about:

1. Height and weight to calculate body mass index (BMI)—obesity has been associated with driver fatigue and SCEs.^(8,9)
2. The presence of common obesity-related and fatigue-related health conditions (e.g., sleep apnea, hypertension, diabetes, and insomnia), as well as interventions for these conditions (such as continuous positive airway pressure [CPAP] and/or medications).
3. Frequency that pain is experienced in a work shift.
4. Caffeine intake frequency.

Data from answers to these questions will be used as covariates in the analyses to determine if they interact with the restart rule, and if so, to measure the nature and magnitude of the interaction.

1.2.4.2 Impact of Restart Schedules on Physical Health Mediators Associated with Increasing Health Risks

Although the role of restricted sleep time in the restart provision for HOS has been assumed to be limited to driver alertness/safety, there is mounting evidence for the adverse effects of chronic sleep restriction on health outcomes. Actigraphy evidence has shown that CMV drivers sleep an average of 6.1 hours per 24 hours,⁽¹⁰⁾ and the initial HOS Restart Study confirmed that average daily sleep per 24 hours was 6.0 ± 0.2 hours per 24 hours when there was one nighttime sleep before restart, versus an average of 6.2 ± 0.1 hours per 24 hours when there were at least two nighttime sleeps before restart.⁽¹¹⁾ There are now dozens of published biomedical studies from around the world indicating the restriction of daily sleep time to less than 6 hours per day results in an increased prevalence and/or risk of the following adverse health outcomes: obesity, diabetes, hypertension, cardiovascular disease, inflammation, pain, and all-cause mortality (see references 12, 13, 14, 15, 16, and 17). It appears that CMV drivers are on the cusp of the threshold for elevated health risks relative to 24 hours sleep time, and that a substantial portion of them are frequently obtaining less than 6 hours of sleep per 24 hours.^(18,19) Moreover, the restart rule differences appear to result in more daytime sleep for the 1-night restart rule (see Figure 7 in Van Dongen & Mollicone).⁽²⁰⁾ This frequent circadian displacement of sleep time also poses additional risks to health.⁽²¹⁾ Actigraphic sleep monitoring of drivers for up to 5 months will provide an estimate of the extent to which neither, either, or both restart provisions place drivers in a chronic sleep-duration category associated with elevated risks for obesity, diabetes, hypertension, cardiovascular disease, inflammation, pain, and all-cause mortality.

1.2.4.3 Impact of Restart Schedules on Driver Perception of Stress as a Behavioral Health Mediator

Behavioral health refers to maintaining normal emotional and behavioral reactions. Stress, especially chronic stress, erodes behavioral and physical health. Stress leading to burnout in transportation workers has been found to result from reduced and irregular sleep times, resulting in poorer behavioral health and lower job satisfaction.^(22,23) The study will evaluate the perceived stress levels of study participants under each of the restart provisions using a visual-analog SS. This will provide information on the extent to which the restart provisions differ in driver perceptions of stress.

1.2.5 Actigraph Watches that Measure Physiological Metrics

The above approach (subsection 1.2.4.3) is more meaningful and practical for evaluating restart provisions on health outcomes than the use of actigraph watches that measure physiological metrics. An initial search of actigraph devices that claim to measure physiological metrics revealed no published scientific evidence of their measurement reliability and validity for medical interpretation. However, the study will conduct a scan of the publicly available technologies to determine how many of them meet the following criteria:

1. Are capable of reliably and validly providing physiological health metrics in the trucking environment.

2. Result in minimal time and intrusiveness (burden) for drivers, to ensure the device does not decrease driver recruitment and adherence to the protocol.
3. Are cost-effective relative to the device, device implementation, data extraction, and interpretation of data.
4. For those devices that meet criteria 1–3, an expert medical panel will be engaged to assess whether the physiological outcomes being measured have any valid health-relevant interpretations when acquired in an (uncontrolled) field study context.

Table 1 summarizes the operational, safety, performance, fatigue, and health variables indicated above, as well as how these variables will be collected in the study.

Table 1. List of operational, safety, fatigue, and health performance measures to evaluate study outcomes.

Tool	Operational	Safety	Fatigue	Health	Assessments
Electronic Logging Device (ELD)	Continuous when driving: <ul style="list-style-type: none"> Restart hours.¹ Duration of drive.¹ Time of day of drive.² Work hours.² Break hours.² Off-duty time.² 	N/A	N/A	N/A	The goal is to collect ELD data as frequently as possible in a manner that has the smallest impact for carriers. ELD data will be collected and variables related to driver status will be used to provide the primary independent study measure in the aggregate analysis.
Onboard Monitoring System (OBMS)	N/A	Safety Critical Events (SCEs)¹ <ul style="list-style-type: none"> Hard brakes. Swerves. Accelerations. Contact with other objects. Speeding. 	Fatigue-related SCE Events:² <ul style="list-style-type: none"> As scored by trained observer using video. 	N/A	SCEs are triggered by accelerometers in the vehicle event recorder (VER) with trigger thresholds of $ 0.3 g $ in any of the x, y, z axes. When triggered, VER saves 8 sec. prior to, and 4 sec. after trigger. Saved epochs are later coded for presence of fatigue via video analyses.
Smartphone Apps	Once daily driver ratings: <ul style="list-style-type: none"> Difficulty of drive.² Degree of drive hazard.² Weekly data acquisition calls: <ul style="list-style-type: none"> Restart at end of duty period (1 versus 2 nights).³ Reason for selection.³ 	N/A	3x Daily <ul style="list-style-type: none"> PVT-B Performance.¹ Fatigue Scale.² Karolinska Sleepiness Scale.² 	3x Daily <ul style="list-style-type: none"> Driver ratings of perceived stress.¹ Once Daily <ul style="list-style-type: none"> Sleep duration.² Sleep quality.² Caffeine intake.² 	Data are collected and transmitted in real-time via a secure mobile data link to a server. Weekly data quality reports are generated to support weekly participant telephone debriefings and for review by FMSCA and the peer review panel (PRP).
Wrist Actigraphy	N/A	N/A	<ul style="list-style-type: none"> 24-hour sleep time during 1-night versus 2-night restart periods.² Time of day sleep taken.² Time from last sleep to end of drive.² Sleep on duty days & non-duty days.² 	<ul style="list-style-type: none"> 24h sleep time on work days after 1-night restarts vs. after 2-night restart¹ Sleep quality ratings during 1-night vs. 2-night restarts² 	Data will be transmitted in real-time via secure mobile data link to the investigators' server. Weekly data quality reports will be generated to support weekly participant telephone debriefings & for review by FMSCA & the PRP.
Background Survey	<ul style="list-style-type: none"> Involvement in Fatigue Management Program (FMP).³ 	N/A	N/A	<ul style="list-style-type: none"> BMI, neck circumference, age, sex, marital status.³ Sleep apnea, insomnia, hypertension, diabetes.³ Pain (frequency).³ Caffeine intake.³ Tobacco use.³ 	Data will be collected once at study entry and transmitted in real-time via a secure mobile data link to a server.

KEY: 1 = Primary outcome; 2 = Secondary outcome; 3 = Covariate

1.3 RESEARCH HYPOTHESES

The design involves within-subject and between-subject comparisons of different work schedules with respect to the restart provision, and assessment of the operational, safety, fatigue, and health impacts for CMV drivers when operating under a 1-night rest period compared to when operating with a 2 (or more) nights rest period. The study null hypothesis is that these outcome variables are the same when CMV drivers operate under the 1-night recovery provision (older HOS rule) as when they operate under the more-than-1-night recovery provision (newer HOS rule). The alternative hypothesis is that these outcome variables are not the same for CMV drivers operating under the 1-night versus 2-night restart rule. The study will also analyze the safety and fatigue effects on those drivers who have less than 168 hours between their restart periods and those drivers who have at least 168 hours between their restart periods.

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2. ASSESSMENT TECHNOLOGIES

Below are descriptions of the technologies and questionnaires to be used in this study.

2.1 ONBOARD MONITORING SYSTEMS (OBMS)

The OBMS is designed to collect the total number of SCEs as well as fatigue-related events. The latter can only be evaluated using a video-based OBMS, as a kinematic-only OBMS does not allow the evaluation of fatigue-related events (which can only be accomplished by reviewing the video). Lytx, which offers the DriveCam Program, is the OBMS vendor in the study.

2.1.1 Overview of DriveCam Program

The video event recorder (VER) has two camera views: a driver face view and a forward-facing view. Figure 1 and Figure 2 show the VER and the two camera views captured by the event recorder, respectively. The VER has three accelerometers (y-, x-, and z-axes) that trigger an event to be recorded. If a certain criterion is met or surpassed (e.g., greater than or equal to $|0.5 g|$) the VER saves 12 seconds of video (i.e., 8 seconds prior to the criterion being met or surpassed and 4 seconds after). Triggers include hard brakes, hard accelerations, swerves, and contact with other objects. This specific threshold criterion was established by the technology vendor based on its prior experience with more than 60,000 installed VERs.

However, for the purposes of this study, a lower threshold will be used so that no SCEs are missed (e.g., greater than or equal to $|0.3 g|$). The operational definition of a SCE will not change; however, the lower threshold will minimize the number of potential missed SCEs and maximize the number of spurious baselines. Spurious baselines (similar to control events) have no relationship to safety, but include instances where the trigger threshold was exceeded (e.g., the vehicle traveled across train tracks or a pothole and exceeded the kinematic threshold; the driver braked in response to no apparent traffic safety situation, etc.). A study by Hickman et al.⁽²⁴⁾ using an OBMS found spurious baselines to be relatively similar to random baselines. Preliminary data from Lytx reveals that 250 tractor-trailers using the standard threshold (described above) triggered an average of 3.8 spurious baselines per truck per month, 0.4 SCEs per truck per month, and 5.3 speeding events per truck per month. Thus, with the lower threshold, one can expect to find greater rates.

Also available is a speed trigger that will record video if the difference between the posted speed and the vehicle speed exceeds a certain criterion (e.g., 5 miles per hour above the posted speed limit). Typically, a light on the VER informs drivers about their driving performance. However, this will be deactivated in the study, as the study team does not want to alter drivers' behavior. In addition, the reduced SCEs are typically uploaded to a secure server where safety managers can access the data and coach drivers (where warranted). This option will also not be available in the study, as the study team does not want to alter drivers' behavior. Moreover, though the DriveCam program normally involves coaching of drivers by fleet managers using individualized review of video and other OBMS collected data, there will be no data review or coaching by fleet managers in this study. As noted previously, the study will not alter the drivers' behavior but rather collect and analyze data to assess the rate of SCEs and compare these when

operating under either a 1-night restart or a more-than-1-night restart.



Figure 1. Image. VER and typical installation of VER.



Figure 2. Image. Front camera view (left) and driver's face view (right).

2.2 ELECTRONIC LOGGING DEVICES (ELDS)

HOS data will provide the primary independent variable (1 night versus at least 2 nights restart condition). From the HOS data, the study team will extract variables related to driver duty status (timing and duration of driving, work, break, off-duty, and restart). HOS data will be collected via ELDs. Most large carriers use enterprise-grade ELD solutions, such as Omnicam or Peoplenet. In cases where the carrier has already employed an ELD solution, the study will leverage the ELD solution already employed by the carrier and coordinate with carrier

operational personnel to receive data exports of participant ELD data throughout the study. In cases where a carrier has not yet adopted an ELD solution, a device will be provided for use during the study. This device will comply with current standards (see Federal Register 49 CFR 395.15) and will be delivered on the same smartphone that participants will be using to complete daily PVTs and questionnaires. See Section 2.4.3 for more details about the ELD apps that may be used during the study.

2.3 ACTIGRAPHY

Each participant will wear an actigraph watch on his/her wrist during the study to measure sleep timing and quantity. Actigraphy is a minimally obtrusive validated approach to assess sleep/wake patterns. Actigraphy features and measures that will be considered when selecting a device include:

1. Total sleep time and sleep efficiency.
2. Off-wrist detection.
3. Ambient light levels.
4. Long battery life.
5. Memory capacity.
6. Automatic data upload capability.

The wActiSleep-BT and Actigraph Link watches, produced by ActiGraph Company, are two candidate watches that are being evaluated relative to the study objectives (see Table 2).

Table 2. Actigraph devices that may be used in the study.

Product	Brief Description	Rechargeable Battery	Data Storage	Data Upload
wActiSleep-BT (www.actigraphcorp.com)	Provides objective 24-hour sleep/wake measurements including total sleep time (TST), sleep efficiency, and ambient light.	14 days with automatic data enabled	4 months (2 GB)	Automatic wireless (Bluetooth)
Actigraph Link (www.actigraphcorp.com)	Provides objective 24-hour sleep/wake measurements including TST, sleep efficiency (no ambient light).	7 days with automatic data enabled	8 months (4 GB)	Automatic wireless (Bluetooth)

2.4 SMARTPHONE APPS

At the participant briefing session, each participant will be assigned an Android smartphone that will be used for data collection for the duration of the study. This smartphone will be enabled with a mobile data plan only (no phone call capability). There will be three apps delivered on the smartphones to support data collection:

1. Pulsar custom SleepFit data collection app.
2. Background survey app.
3. ELD app.

2.4.1 Pulsar custom SleepFit data collection app

The Pulsar custom SleepFit data collection app was specifically developed to support transportation field studies. This app was used successfully in the previous field study evaluating the restart provision. Participants will use the app every duty day for up to 22 duty cycles (5 months) to complete PVTs, keep a sleep diary, record caffeine consumption, and submit subjective ratings related to perceived stress, fatigue, difficulty of drive, and degree of drive hazards (see Figure 3).

2.4.1.1 PVT-B

The PVT was invented by Dr. David F. Dinges, through support from the U.S. Office of Naval Research. It has been validated to detect slowing of psychomotor speed and lapses of attention,⁽²⁵⁾ as well as vigilance decrements and instability in behavioral alertness,⁽²⁶⁾ which are common adverse effects of fatigue on performance due to inadequate sleep, wakefulness at night, and prolonged time-on-task. Neuroimaging studies have established that deficits in PVT performance due to fatigue from inadequate sleep⁽²⁷⁾ and fatigue from increasing time-on-task⁽²⁸⁾ are reflected in brain changes. The original 10-minute PVT has been validated to be sensitive to fatigue^(29,30) in more than 100 published scientific studies that include a range of experimental, simulated, and some occupational (real-world) evaluations (e.g., transportation operators, health care professionals, first responders). U.S. Department of Transportation (USDOT) sponsored studies have included the use of the 10-minute PVT to identify and validate the most sensitive and reliable sensor technologies for monitoring truck driver fatigue. Scientific studies sponsored by other Federal agencies (e.g., the National Institutes of Health [NIH], Department of Defense, Department of Homeland Security, and National Aeronautics and Space Administration [NASA]) have established the sensitivity of the 10-minute PVT to the following conditions:

1. One or more nights of total sleep deprivation.⁽³¹⁾
2. Multiple nights of sleep restricted to less than 7 hours per day.^(32,33,34)
3. Chronic split-sleep schedules.⁽³⁵⁾
4. Nights of inadequate recovery sleep duration following sleep restriction.⁽³⁶⁾
5. Untreated disorders of excessive sleepiness (e.g., sleep apnea,⁽³⁷⁾ shift work disorder⁽³⁸⁾).
6. Wake-promoting substances (e.g., caffeine⁽³⁹⁾ and modafinil⁽⁴⁰⁾).

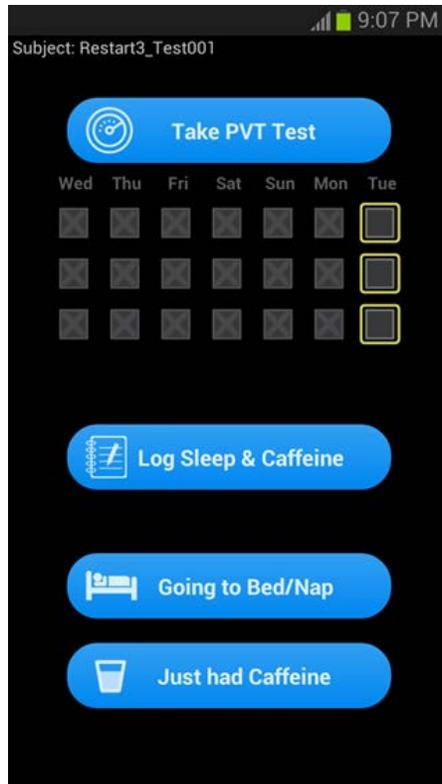


Figure 3. Image. Pulsar custom SleepFit data collection app.

The PVT also outperformed other brief widely-used performance measures of fatigue. In a comparison of various cognitive performance tests known to be sensitive to fatigue induced by sleep loss, investigators at the Walter Reed Army Institute of Research concluded that “the Psychomotor Vigilance Test was among the most sensitive to sleep restriction, was among the most reliable with no evidence of learning over repeated administrations, and possesses characteristics that make it among the most practical for use in the operational environment.”⁽⁴¹⁾

Through research supported by the National Space Biomedical Research Institute (NSBRI) via a NASA cooperative agreement, Dr. Dinges and colleagues empirically developed an algorithm for PVT stimulus delivery rate and response quantification that resulted in the briefer 3-minute PVT-B. Using experiments supported by NIH, NSBRI/NASA, and the Department of Homeland Security (DHS) on the performance effects in healthy adults of total and chronic partial sleep loss, they demonstrated that performance on the 3-minute PVT-B tracked performance on the 10-minute PVT throughout total and partial sleep loss.⁽⁴²⁾ Thus, the PVT-B resulted in a 70 percent decrease in task duration with only a 22 percent decrease in effect size (sensitivity), indicating the PVT-B would be useful for assessing behavioral alertness in operational settings. In the DHS-sponsored laboratory experiment, PVT-B performance was found to predict performance on a simulated threat detection task (i.e., identifying knives and guns hidden in simulated x-ray images of packed luggage) during night work and sleep loss.⁽⁴³⁾ Studies supported by the Veterans Administration have also found the PVT-B to be sensitive to a protected nocturnal nap sleep during a prolonged work period.^(44,45)

In the past 5 years, the NSBRI and NASA have supported the use of the PVT-B to track the behavioral alertness of 6 participants in a 520-day, high-fidelity simulated mission to Mars,⁽⁴⁶⁾ and of 24 astronauts before, during, and after 6-month missions on the International Space Station (data not yet published). Combined, these 2 studies have resulted in more than 3,700 PVT-B tests, indicating the feasibility of the PVT-B even in high-tempo work environments. This is consistent with the high rate of PVT-B completion in the first FMCSA-sponsored field study of the restart provision for HOS.⁽⁴⁷⁾ For the above reasons, the PVT-B will be used to provide data on drivers' behavioral alertness on and off duty during the study (see Figure 4).

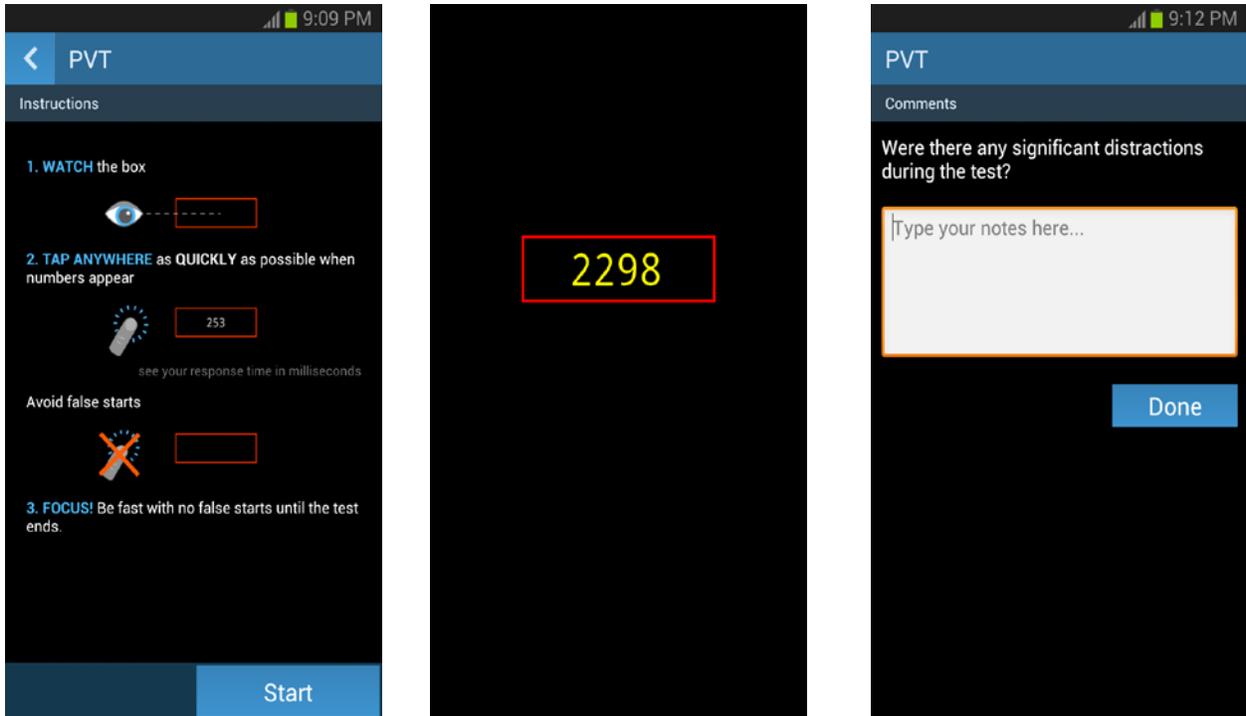


Figure 4. Screenshots. PVT performed on the Pulsar custom SleepFit data collection app.

2.4.1.2 Sleep and Caffeine Logs

In addition to wearing an actigraph device, subjects will complete a daily sleep diary providing inputs related to sleep timing and self-reported sleep quality (including naps) and caffeine use. The sleep log aids in interpreting the actigraph data and provides an opportunity to collect data related to participants' perceptions about their sleep quality and their caffeine consumption (see Figure 5).

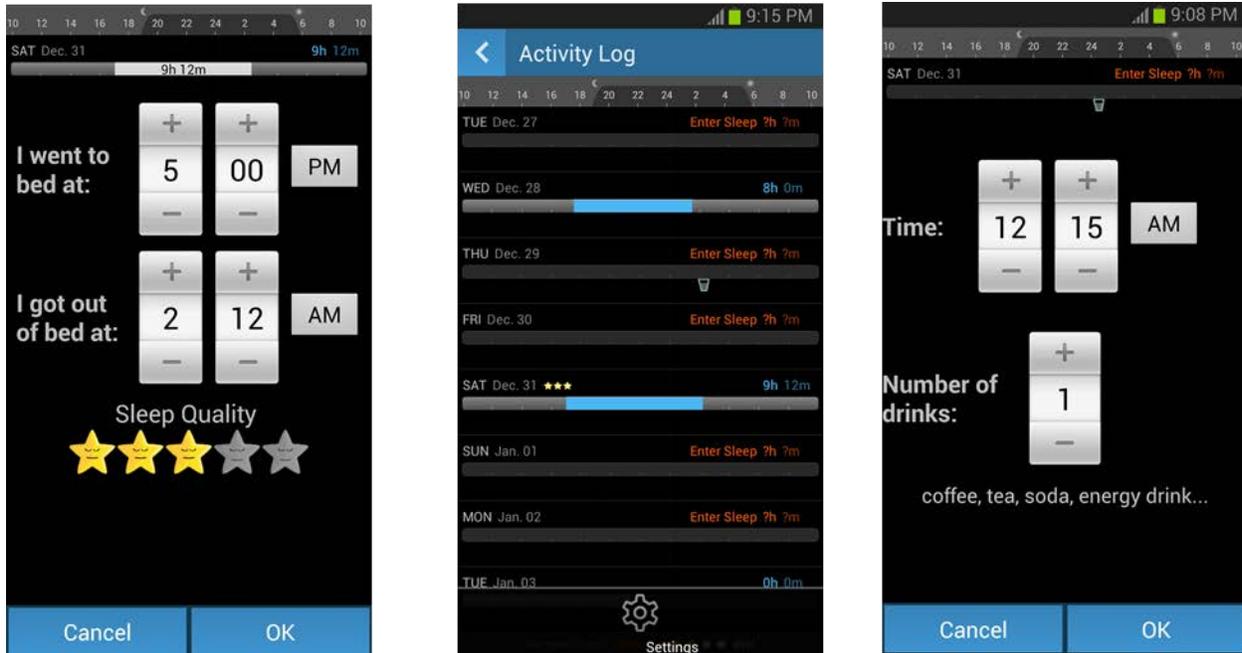


Figure 5. Screenshots. Sleep diary and caffeine log performed on the Pulsar custom SleepFit data collection app.

2.4.1.3 *Karolinska Sleepiness Scale (KSS) and self-reports related to perceived stress, fatigue, difficulty of drive, and degree of drive hazards*

After completing each PVT, participants will complete the KSS and provide ratings of their perceptions related to their stress, fatigue, difficulty of drive, and safety hazards during their drive. Both questionnaires were used in the previous field study on the restart provision. The KSS has been widely used in the literature as a subjective assessment of alertness (see Figure 6).

2.4.2 **Preexisting Health/Medical Conditions**

The Background Survey (Appendix E) questionnaire administered to drivers at study enrollment will be used to collect anthropometric measures (height, weight, age, and neck circumference) and data related to existing health conditions that will be carried in the analysis as covariates.

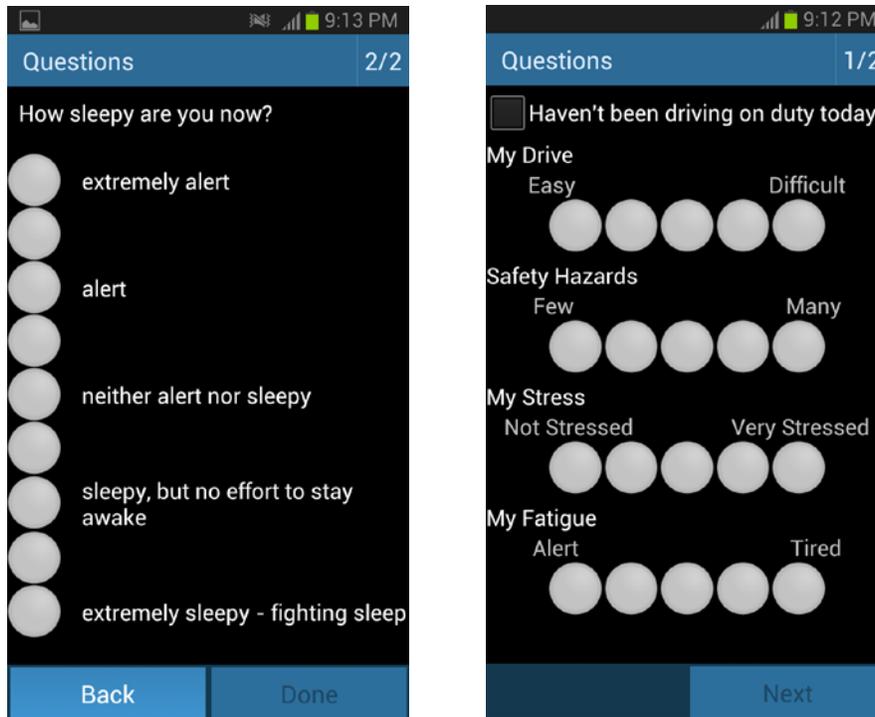


Figure 6. Screenshots. KSS and self-reports related to perceived stress, fatigue, difficulty of drive, and degree of drive hazards, performed on the Pulsar custom SleepFit data collection app.

2.4.3 Electronic Logging Device (ELD) Apps

For participants who work for carriers that do not employ an ELD solution, the study team will provide one. BigRoad and KeepTruckin are two candidate products that deliver ELD solutions as a smartphone app. During the study set-up period, the project team will evaluate the technical feasibility of these and other ELD solutions to employ during the study. BigRoad (www.bigroad.com) allows drivers to input time, location, and remarks through the app. BigRoad also offers a hardware product that couples with the smartphone to provide an ELD solution that complies with current standards (395.15). The driver can export daily logs to a portable document format (PDF) and transfer these to the study team via email (see Figure 7). KeepTruckin (www.keeptruckin.com) allows drivers to input time, location, and remarks through the app. Limited automatic logging mode is available based on phone global positioning system (GPS). The driver can export daily logs to PDF and transfer them to the study team via email. Driver data can also be retrieved via an administrative support website (see Figure 8). The project team will work with each carrier partner to establish the most efficient and reliable means of transferring ELD data.

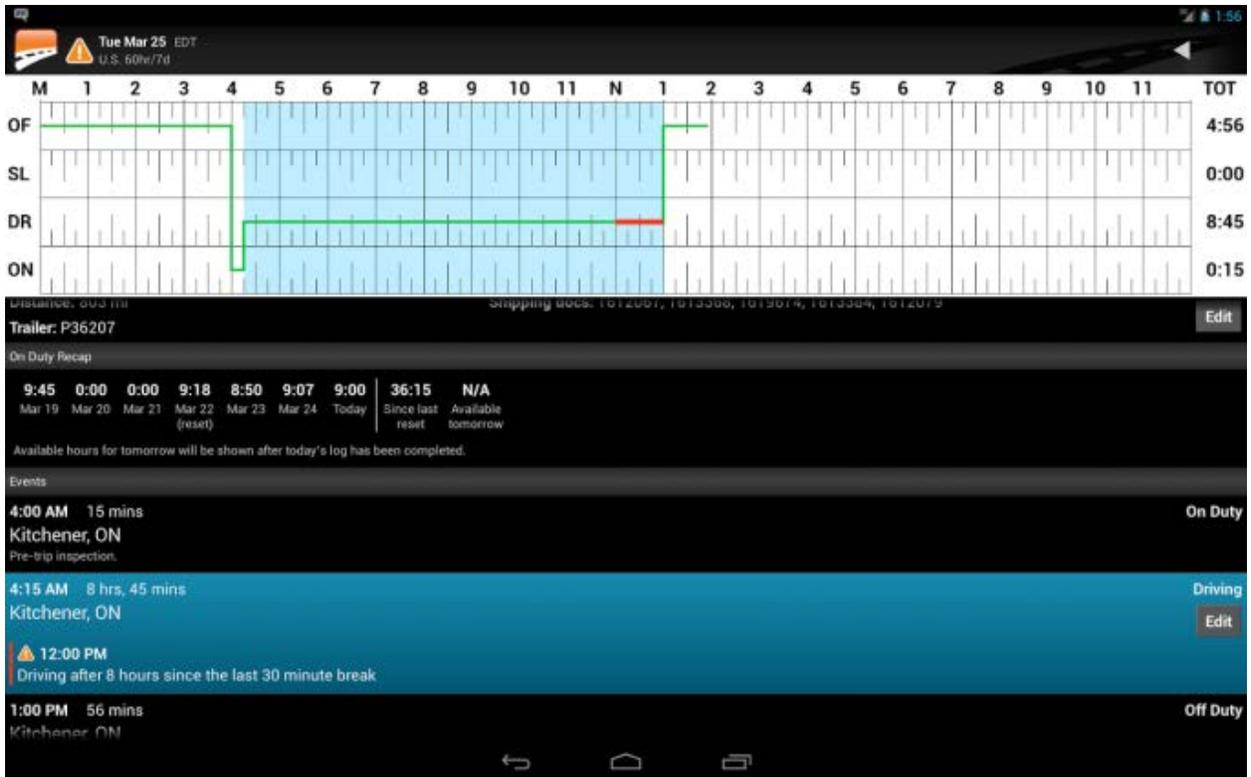


Figure 7. Screenshot. BigRoad app.

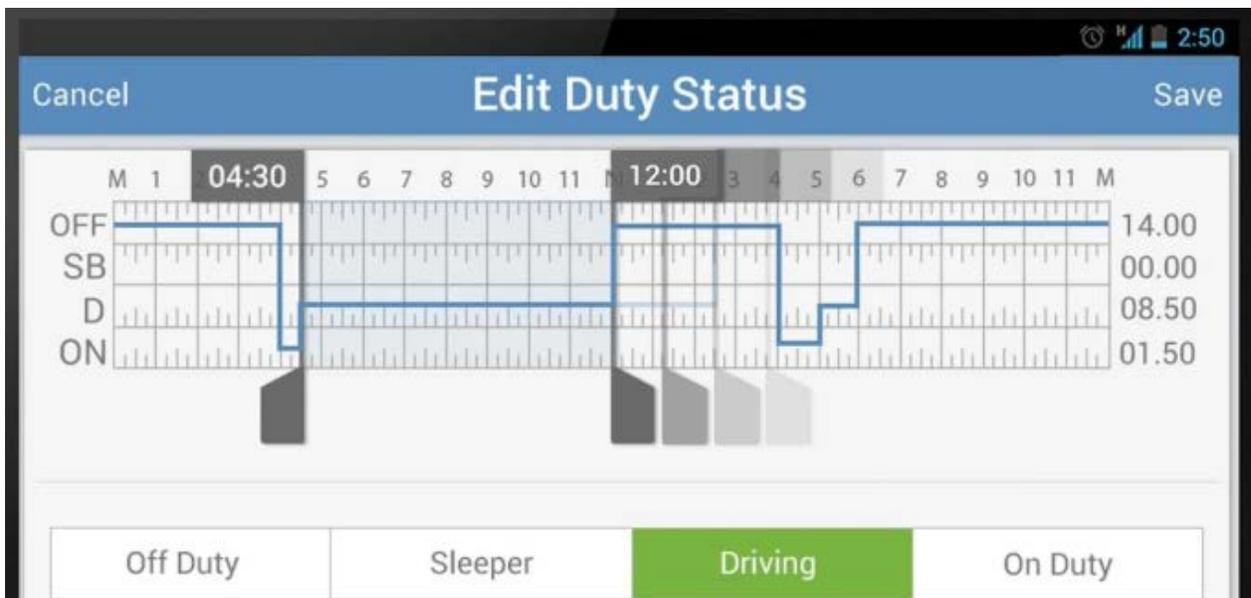


Figure 8. Screenshot. KeepTruckin app.

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3. PROCEDURES

Below is a description of the procedures and methods necessary to successfully complete this study. The aim was to provide these methods in chronological order (as they will be initiated during this study), but there may be some overlap of activities.

3.1 INSTITUTIONAL REVIEW BOARD (IRB)

The Virginia Tech Transportation Institute (VTTI) study team will submit a protocol to the Virginia Tech IRB and the University of Pennsylvania IRB. The protocol will include all necessary non-disclosure agreements, confidentiality certifications, and documents needed to conduct this study (see Appendix A for the preliminary IRB application). This work plan will be the basis for those applications. Of critical importance will be the creation of the Informed Consent Form (ICF) (see Appendix D for the preliminary ICF). The ICF will be given to all potential participants. The ICF will outline the study objectives and methods, any possible risks, compensation, and the rights of the participant (including freedom to withdraw from the study at any time, for any reason, without penalty). No human subjects' activities will take place until IRB approval is received.

3.2 RECRUITMENT

A sample size formulated to be closely aligned with the primary study hypotheses involving comparisons of safety and fatigue outcomes between restarts with 1 night compared to at least 2 nights. Specifically, based on (largely) within-driver comparisons, 199 drivers are required for at least 80 percent statistical power to detect a mean difference as small as one-fifth of one (within-driver) standard deviation. Effect sizes of this magnitude have potentially important public health policy implications (see sample size discussion below). The study team is taking a conservative approach of adopting the higher of the two results and estimating up to a 10 percent participant attrition rate. A participant will be included in the statistical analyses and count toward the total sample size if the participant completes at least one complete set of data from the beginning of one restart period to the beginning of the next restart period. If the attrition rate at the beginning of the study appears to exceed 10 percent, then the study design allows for an increase in the sample size to accommodate up to a 25 percent attrition rate. The study team will closely monitor subject attrition and complete a second round of recruiting in the fourth week as necessary to meet the analysis target of $N = 207$, to maintain statistical power.

In order for the results to be generalizable to the widest range of driving operations, as shown in Table 3, drivers will be sampled from small, medium, and large carriers involved in short-haul, regional, and long-haul operations on different truck types, including flat-bed, refrigerated, tank, and dry-van. Each of the subgroups in Table 3 will be represented to the extent feasible. As stated in the Statute, "The study shall include fleets of all sizes (i.e., small, medium, and large) and operations (including long-haul, regional, and short-haul) in various sectors of the industry (including flat-bed, refrigerated, tank, and dry-van) *to the extent practicable.*" The study team will generate weekly recruitment reports that detail how many carriers and drivers have been contacted and recruited relative to the industry segmentation plan in Table 3. The goal is to

attempt to obtain participants in each cell noted in Table 3; however, the final sample may not reflect the total cell counts noted in Table 3 due to insurmountable circumstances. In order to maximize statistical power, the study will oversample drivers who regularly drive/work close to HOS weekly limits, complete most drives at night, and are likely to be observed under more than one restart condition.

Table 3. Industry segmentations in the sampling plan.

Operation	Carrier Size	Flat-bed	Refrigerated	Tank	Dry-van	Total
Long-haul	Small	8	8	5	28	49
Regional	Small	5	5	3	17	30
Short-haul	Small	5	5	3	18	31
Long-haul	Medium	2	2	1	5	10
Regional	Medium	1	1	1	3	6
Short-haul	Medium	1	1	1	4	7
Long-haul	Large	5	5	4	20	34
Regional	Large	3	3	2	11	19
Short-haul	Large	4	4	2	11	21
Total		34	34	22	117	207

Below are the operational definitions for the industry segmentation noted in Table 3:

- Carrier Size:
 - Small: 1–20 power units.
 - Medium: 21–100 power units.
 - Large: greater than 100 power units.
- Type of Operation:
 - Short-haul: the driver normally operates within a 100 air-mile radius of the driver’s home terminal.
 - Regional: the driver normally operates more than 100-air mile radius and up to 250 air-miles radius of the home terminal. The trip normally involves a single day, out and back to the home terminal.
 - Long-haul: the driver normally operates beyond a 250 air-mile radius of the driver’s home terminal. The driver operates away from home terminal for multiple days and involves single or multiple loads.
- Industry Sector (definitions used in the Fatality Analysis Reporting System and General Estimates System):
 - Flat-bed: flat surface above rear tires; may have a front bulkhead and stake or strap accommodations.
 - Refrigerated: a refrigerated and insulated box trailer.
 - Tank: cylindrical for liquid transport.

- Dry-van: fully enclosed with hard or soft sides and side and/or rear doors.
- Participating drivers will be asked to sign a consent form which includes their responsibility to maintain a valid Commercial Driver’s License (CDL) during the course of their study participation.

3.2.1 Carriers

The study requires recruitment of carriers and individual driver participants from participating carriers. In order to meet the objectives of the sampling plan, the study must include small, medium, and large carriers involved in short-haul, regional, and long-haul operations on different truck types (flat-bed, refrigerated, tank, dry-van)—a total of 36 industry segmentations. FMCSA will assist when needed and contact chief executives from a variety of industry and driver organizations to solicit their involvement in the study. These include the American Trucking Associations, National Association of Small Trucking Companies, Women in Trucking, Owner-Operator Independent Drivers Association, Trucking Safety Alliance, and the Teamsters. The study team will follow up with each contact lead provided by FMCSA and will also leverage their extensive industry experience and relationships with various trucking companies in order to recruit carriers.

3.2.2 CMV Drivers

After carriers have provided a commitment to support the study, the study team will work closely with senior management and operational personnel to review company HOS data to identify drivers meeting the following criteria:

1. Hold a valid Class A CDL during the course of participation.
2. Regularly drive/work close to HOS weekly limits.
3. Complete most drives at night.
4. Regularly take a minimum 1-night restart.

The study team will also ask potential participants if they plan on continuing to work under the above conditions. If, within a given industry segment, the study team is unable to identify drivers meeting the above criteria, it will identify drivers from that carrier whose HOS data indicate that they drive the longest hours, the most night driving hours, and take the most frequent 1-night restarts relative to the other drivers at that carrier.

Every effort will be made to coordinate with the dispatchers and carrier operational staff to advertise the study to drivers who meet the study criteria. In support of driver recruitment, two standardized posters will be created (one directed at carriers and one directed at drivers) that provide details about the study.

3.3 DRIVER RETENTION

An intensive approach will be adopted to maximize participant retention and compliance with study protocols. Most study measures will be collected in near-real-time and reviewed daily to detect missing, spurious, or corrupt data, or device hardware or software failures. When a

protocol deviation is detected, a member of the study team will contact the participant to understand the source of the problem and provide corrective feedback. Immediate feedback is key to set consistent demand characteristics throughout the entire data collection phase of the study.

Drivers will be reimbursed for their efforts in support of the study. Driver compensation will be based on completion rates of study activities on a pro rata basis according to the following schedule (subject to approval by IRB).

Participants completing all elements of the study for the full 5 months may receive up to a total of \$2,165. Payments will be disbursed every 30 days via check. The payment is structured as follows:

- \$25 for attending the initial briefing and sign-up of the study.
- \$25 for completing a health assessment questionnaire during the initial briefing.
- Up to \$1,540 for 22 duty cycles. A duty cycle is defined as a work week (i.e., up to 7 consecutive days of driving). Drivers will be asked to complete three PVT tests per day and may receive the following payment:
 - \$3 per assessment × three assessments per day = up to \$9 per day.
 - \$9 per day × 7 days in duty cycle + \$7 bonus for completing all assessments in a duty cycle = up to \$70 per duty cycle.
 - 22 duty cycles × \$70 per duty cycle = \$1,540.
- Up to \$550 for 22 restart periods. A restart period is defined as non-driving time required before starting a new duty cycle. Drivers will be asked to complete three PVT tests per day and may receive the following payment:
 - \$3 per assessment × three assessments per day = up to \$9 per day.
 - If all assessments are completed during a restart period, regardless of the number of days, drivers will receive \$25 for that restart period.
 - If all assessments are NOT completed during a restart period, drivers may receive up to \$9 per day, with a maximum of \$18 for any restart period.
 - 22 restart periods × \$25 per restart period = \$550.
- \$25 for attending the debriefing meeting at the end of the study.

If a participant elects to withdraw from the study or if their employment ends, that participant will be compensated for participation up to that time.

3.4 PARTICIPANT BRIEFING

3.4.1 Pre-Study Briefing

At the pre-study briefing, participants will undergo the process of informed consent and receive a full explanation of all of the study procedures. Participants will be asked to confirm that they

have a valid CDL. Participants will be assigned a smartphone and actigraph device. A digital photograph will be taken of the participant's face to assist with identification when looking at the video data. Participants will complete the background survey using the assigned study smartphone. A member of the study team will assist with collecting anthropometric measures (height, weight, and neck circumference). Participants will complete a 1099 tax form that will be used for subject reimbursement. Participants will have an opportunity to ask questions.

3.4.2 Weekly Debriefs

Throughout the study, members of the study team will interact (by phone and possibly email as well, if indicated as a preference from the driver) with drivers on an as-needed basis and during weekly scheduled debriefs. The purpose of this contact is to receive clarifications from drivers regarding data that do not align, to ask questions, and to provide feedback about missing data, study equipment problems, or study procedures that were not followed correctly. Examples of such scenarios include:

- Sleep diary inputs do not align with actigraphy-based sleep estimates.
- Timestamp on smartphone-based study measures does not align with driver HOS logs (possibly due to time-zone shifts or incorrect clock time on phone).
- Participant fails to complete one or more of the study assessments.
- Data fail to upload via the mobile data link.
- Driver-initiated questions related to the study or the study equipment.

In addition, study participants will be asked to predict whether their next restart will be a 1-night or 2-night restart. The general category of the reason for this selection (operational imperative versus driver preference) will also be elicited. This will allow for comparisons between driver predictions and actual restart conditions. This will be done as a measure of selection bias (see Section 4.6—Addressing Selection Bias).

3.4.3 Final Debriefing

The final participant debriefing will occur following the data collection period or if the participant exits the study early. Participants will meet with a member of the study team to return study equipment (i.e., smartphone, actigraph watch). The study team will receive clarifications from drivers regarding data that do not align, ask questions, and provide feedback about missing data, study equipment problems, or study procedures that were not followed correctly (see examples above). In addition, study participants will have an opportunity to ask questions about the study or express any concerns.

3.5 VEHICLE INSTALLATION

The vehicles of the participating drivers will be installed with a Lytx VER. Installation will take place after the participant briefing. Lytx will arrange for the installation of the VERs. The installation process is fairly easy and is estimated to take approximately 30–60 minutes. As shown in Figure 1, the VER will be installed in such a location so that it does not impede the

driver's view of the forward roadway. As shown in Figure 2, the VER will be mounted in such a way as to provide a good view of the forward roadway and the driver (from the driver's lap to the top of the driver's head), thereby allowing data analysts to code fatigue and/or engagement in any non-driving tasks (e.g., texting, eating, etc.).

3.6 DATA COLLECTION

Once participants have signed the ICF, received their assigned smartphones, and their vehicles have been fully installed with the required equipment (VER and possibly an ELD), data collection will begin. Participating drivers will drive an instrumented vehicle for up to 5 consecutive months. Below is a description of how the data will be collected, reduced, and transmitted.

3.6.1 Onboard Monitoring System (OBMS) Data

The technology vendor will be responsible for all data collection and reduction. The video and quantitative data from all instrumented trucks will be automatically sent to the technology vendor via cellular transmission. The received data will be reviewed, reduced (i.e., data analysts will mark the presence of specific variables pertaining to the event), and uploaded to a secure server. All video and kinematic data will be destroyed before the end of the project.

3.6.1.1 Data Reduction

Data analysts undergo an extensive 5-week training regimen prior to reducing "real" data. Lytx currently sees 97 percent reliability with a 95-percent confidence interval using their standard data reduction protocols. To ensure the enhanced fatigue reduction is meeting these criteria, the study team will request the first 500 events (SCEs, spurious baselines, or random baselines) be reduced by 2 reductionists and 1 trainer (observed by a total of 3 people) and the results sent to the research team to calculate reliability. At the quarter point of data reduction (25 percent of events reduced), the study team will evaluate reliability on events reviewed multiple times using Lytx's current reliability plan of 3 percent of all events (SCEs, spurious baselines, or random baselines) reduced by two reductionists and 3 percent of those twice-reviewed events reduced by trainer (event reduced by three people total). Reliability at both checkpoints is expected to be more than 90 percent with a 95-percent confidence interval. If reliability is less than expected, the study team will work with Lytx to identify and improve those variables with lower reliability. When coding the data, the Lytx data analysts will be blind to or not know what type of restart each of the subjects had taken.

Once the data are received, a trained data analyst will review the data. The data analyst will review the data to determine if it represented a valid SCE or a spurious trigger value (e.g., hit a pothole in the street, driving on a bumpy road, etc.). Spurious events, though normally not reduced, will receive the same reduction as SCEs. Data reduction involves reviewing the video and recording the trigger type, outcome, root cause, demeanor, risky behaviors, and adverse weather conditions (if necessary). An enhanced fatigue coding (see below) will also be applied to every SCE and spurious baseline. The date, time, fleet number, and driver identification (ID) number will be automatically tagged to the SCE and spurious baseline. Data analysts will

complete their reduction of the SCEs and spurious baselines approximately 24–48 hours from the time the data were recorded by the VER in the instrumented truck.

3.6.1.2 Fatigue-Coded Epochs from OBMS

Data analysts at Lytx will be trained to perform an enhanced analysis of fatigue. At present, Lytx characterizes fatigue as a binary variable (fatigue or no fatigue) using a combination of facial characteristics and the amount of time the driver is blinking during the SCE. This can be viewed as an acute measure of fatigue. Lytx also codes if the driver was asleep (a driver that is coded as asleep is not coded as fatigued). The enhanced measure of fatigue will be similar to observer rating of drowsiness (ORD) and Lytx’s current operational definition of fatigue. A valid measure of ORD requires longer than 12 seconds of video; thus, the enhanced analysis of fatigue will include many of the operational definitions of ORD, but it will not be ORD. This enhanced assessment of fatigue, which is not part of Lytx’s standard data reduction protocol, will be performed on SCEs and spurious baselines.

The procedure for measuring ORD was developed and first used by Wierwille and Ellsworth.⁽⁴⁸⁾ That study demonstrated ORD could have good intra- and inter-rater reliability and that the measure correlated highly ($r = +0.7$ to 0.9) with eye closure measures such as PERCLOS (percentage of time that the eyes were closed 80 percent or more) and AVECLOS (mean percent eye closure). Data analysts will be instructed to watch the driver’s face and body language in the 8 seconds prior to the incident flag (12 seconds in the random baselines) during SCEs and spurious baselines (as the precipitating event is likely to alert the driver). As described by Wierwille and Ellsworth,⁽⁴⁹⁾ signs indicative of drowsiness include rubbing face or eyes, facial contortions, moving restlessly in the seat, and slow eyelid closures (see Figure 9). Data analysts will be trained to look for these signs of drowsiness and make subjective but specific assessments of the level of drowsiness. After watching the video data, data analysts will record a fatigue score.

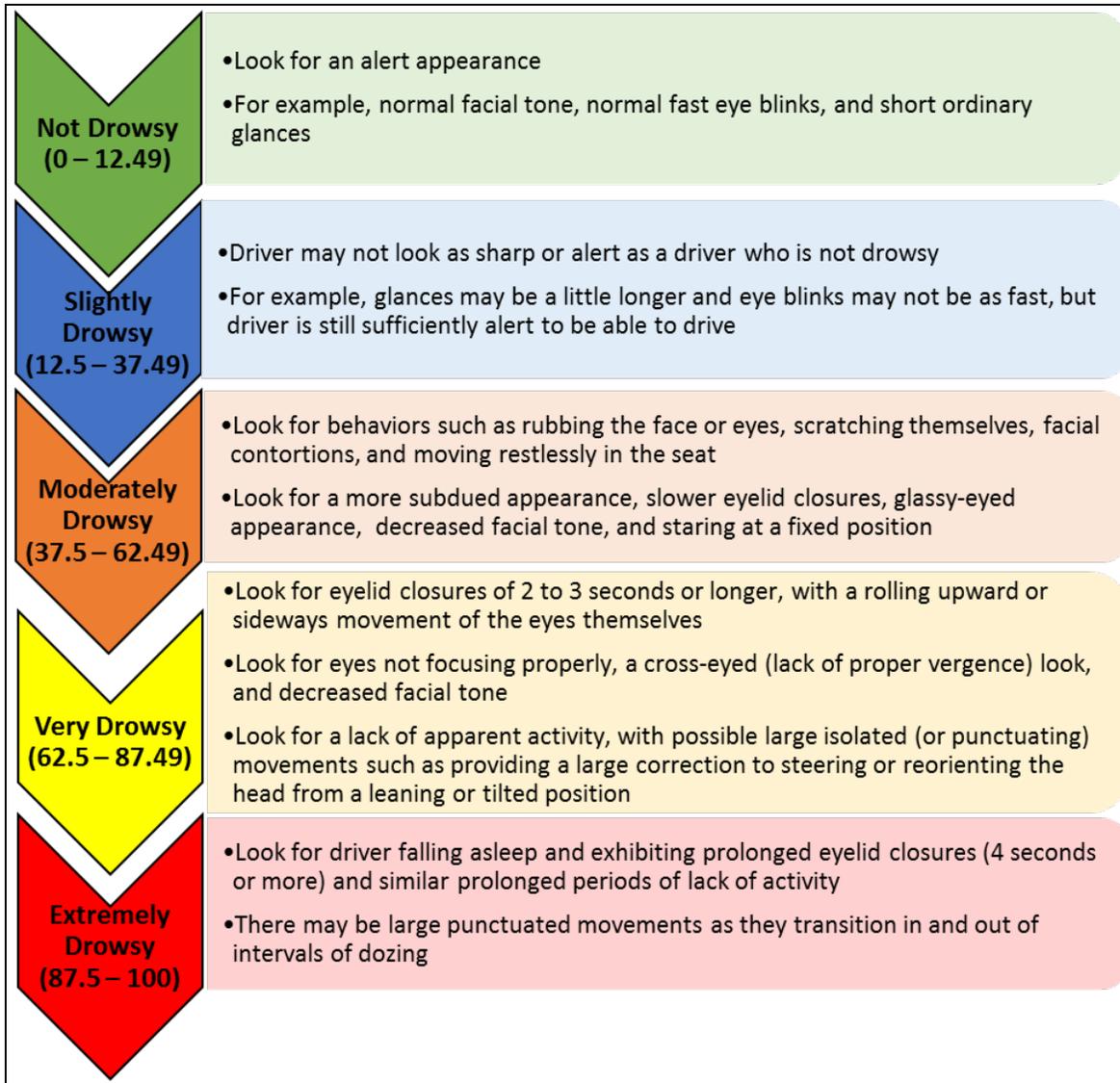


Figure 9. Diagram. Observer rating of drowsiness (ORD) rating scale.

3.6.1.3 Data Transmission

Once data reduction and reliability has been completed, the reduced data set will be sent to the study team for analysis. This reduced data set will be sent in an Excel or SQL file via a secure file transfer protocol (ftp) portal. The data set will be stored on a secure, password-protected server. Included in the data set will be the categorical reduction for each spurious baseline and SCE, including:

- A unique time/date.
- GPS location of the event.
- Carrier ID number.

- Unique driver ID number.
- Unique event ID number.
- Trigger type.
- Severity (if a SCE, including, crash, near-crash, or crash-relevant conflict).
- The categorical reduction (including the standard Lytx protocol and the enhanced fatigue analysis).
- The maximum kinematic values.

A separate data key will be sent that provides information on the identity of the driver and carrier and definitions of the variables included in the data set.

3.6.2 Smartphone App Data

Participants will use the Pulsar custom SleepFit data collection app throughout the 22 duty cycles (5 months) at the following time points:

- At beginning of duty period before driving, on a smartphone (approximately 10 minutes):
 - Fill out confidential sleep/wake/duty diary.
 - Perform 3-minute reaction time test.
 - Rate fatigue.
- During break from driving about halfway through duty period, on a smartphone (approximately 5 minutes):
 - Perform 3-minute reaction time test.
 - Provide subjective ratings related to perceived stress, fatigue, difficulty of drive, and degree of drive hazards.
- At end of duty period after driving, on a smartphone (approximately 10 minutes):
 - Perform 3-minute reaction time test.
 - Rate fatigue.
 - Fill out confidential sleep/wake/duty diary.

Participants will also use the app during restart days to provide the same measures at a time within 2 hours of waking, about midway through the waking period, and within 2 hours of sleeping. The app detects motion and does not allow participants to do the smartphone-based PVT while the vehicle is in motion. For team drivers, the study team will provide instructions to the off-duty driver in the sleeper berth to complete assessments at the same time as his or her driving partner before the drive, after the drive, and when taking a break.

3.6.2.1 Data Transmission and Reduction

Pulsar custom SleepFit data (PVT-B, sleep diary, caffeine log, and questionnaire data) will be collected and transmitted in real-time via secure mobile data link to a server. Raw PVT-B data, sleep diary and caffeine log entries, and questionnaire data will be parsed and secondary metrics

calculated. Data quality control analyses will include programmatic scripts and manual review to detect missing, spurious, or corrupt data, and device hardware or software failures. Weekly data quality reports will be generated to support weekly participant telephone debriefings and for review by FMSCA and the PRP. In the previous field study,⁽⁵⁰⁾ a PVT completion rate of 84 percent (i.e., 84 percent of the possible PVT-B opportunities were completed) was achieved based on an approach that involved rapid feedback to participants when data problems were detected.

After the data quality control process is completed, de-identified data will be formatted and transmitted for statistical analysis for PVT-B and questionnaire data flow, respectively. See Figure 10 and Figure 11 for the data collection and quality control steps for questionnaire data collected via the SleepFit Android app on the smartphone. Data will be automatically uploaded and securely transferred to the research team to support near real-time data collection, quality control, and variables extraction.

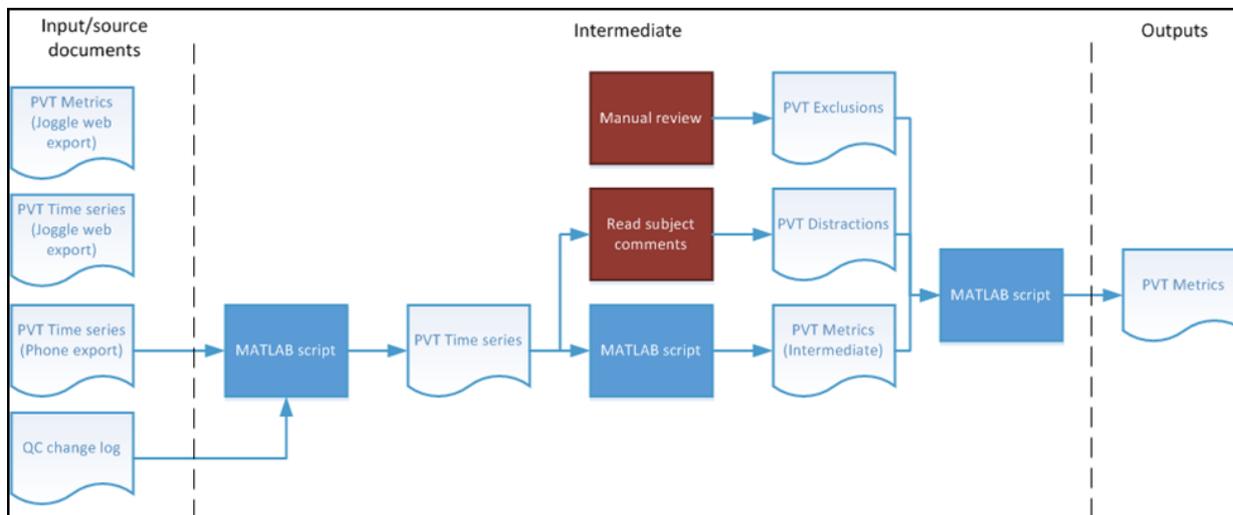


Figure 10. Schematic diagram. Data collection and quality control steps for PVT-B data collected via the SleepFit Android app on the smartphone.

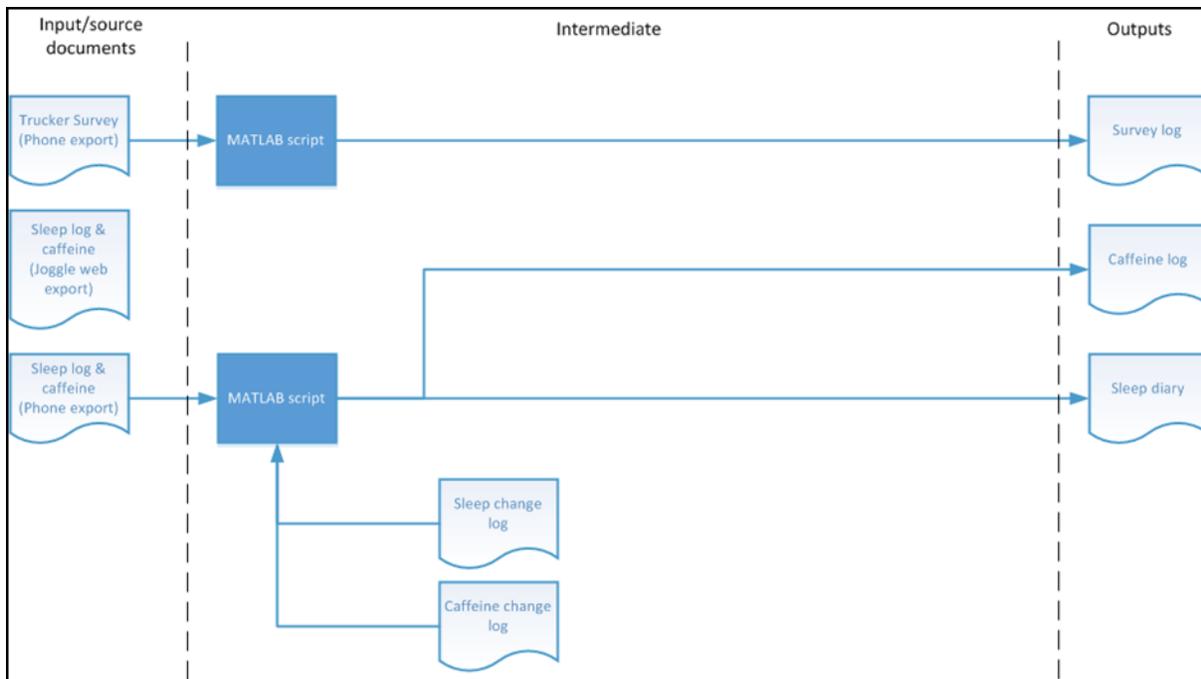


Figure 11. Schematic diagram. Data collection and quality control steps for questionnaire data collected via the SleepFit Android app on the smartphone.

3.6.3 Electronic Logging Device (ELD) Data

ELD data will be collected using a variety of approaches based on which ELD solution is deployed by the carrier. Most large carriers use enterprise-grade ELD solutions, such as Omnictrac or Peoplenet. In cases where a carrier has not yet adopted an ELD solution, one will be provided during the study (delivered on the same smartphone that participants will be using to complete daily PVTs, maintain sleep diaries and caffeine logs, and complete questionnaires). As described in Section 2.4.3, BigRoad and KeepTruckin are two candidate products that deliver ELD solutions via smartphone apps.

3.6.3.1 Data Transmission and Reduction

The study team will develop an ELD data flow plan for each carrier based on technology used and carrier-specific work flow. The goal is to collect ELD data as frequently as possible in a manner that has the smallest impact for carriers. ELD data will be collected and variables related to driver status will be extracted (timing and duration of driving, work, break, off-duty, and restart) to provide the primary independent study measure in the aggregate analysis (see Figure 12).

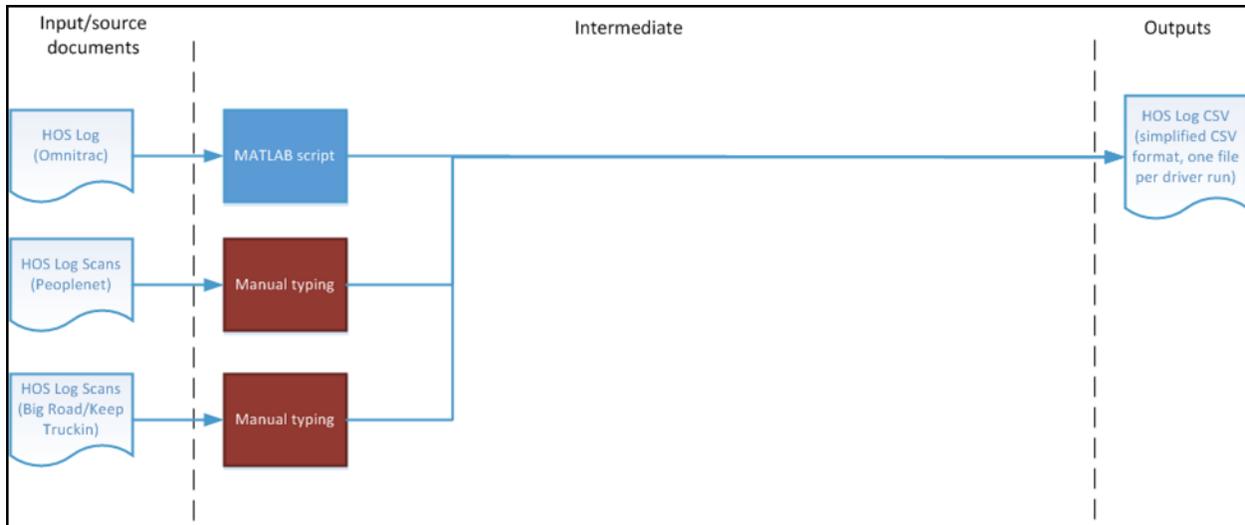


Figure 12. Schematic diagram. Data collection and quality control steps for ELD data collected via various means depending on the solution deployed for each carrier.

3.6.4 Actigraph Data

Participants will wear actigraph watches (www.actigraphcorp.com) on their wrist during the field study to measure sleep timing and quantity. These devices provide objective 24-hour sleep/wake measurements, including TST, sleep efficiency, and ambient light (on some models). The rechargeable battery lasts 7–14 days with wireless transmit mode enabled. Each participant will receive a universal serial bus charger with an alternating current wall adapter and 12-volt cigarette lighter adapter to enable charging in the vehicle (approximately 2 hours to charge). Participants will be instructed to remove and charge their actigraph watch once per week (e.g., every Wednesday). Participants will receive friendly reminders by the study team. Because data are uplinked in near-real time (e.g., daily), the study team will know if there is a problem with the device (e.g., dead battery) and contact the participant to troubleshoot the problem.

3.6.4.1 Data Transmission and Reduction

Actigraph data will be transmitted in real-time via secure mobile data link to the investigators' server. Raw actigraph data will be parsed and secondary metrics calculated. Data quality control analyses will include programmatic scripts and manual review to detect missing, spurious, or corrupt data, and device hardware or software failures. Weekly data quality reports will be generated to support weekly participant telephone debriefings and for review by FMSCA and the PRP. See Figure 13 for data collection and quality control steps for sleep data collected via wrist-worn actigraph devices. Data will be automatically uploaded and securely transferred to the investigators to support real-time data collection, quality control, and variable extraction.

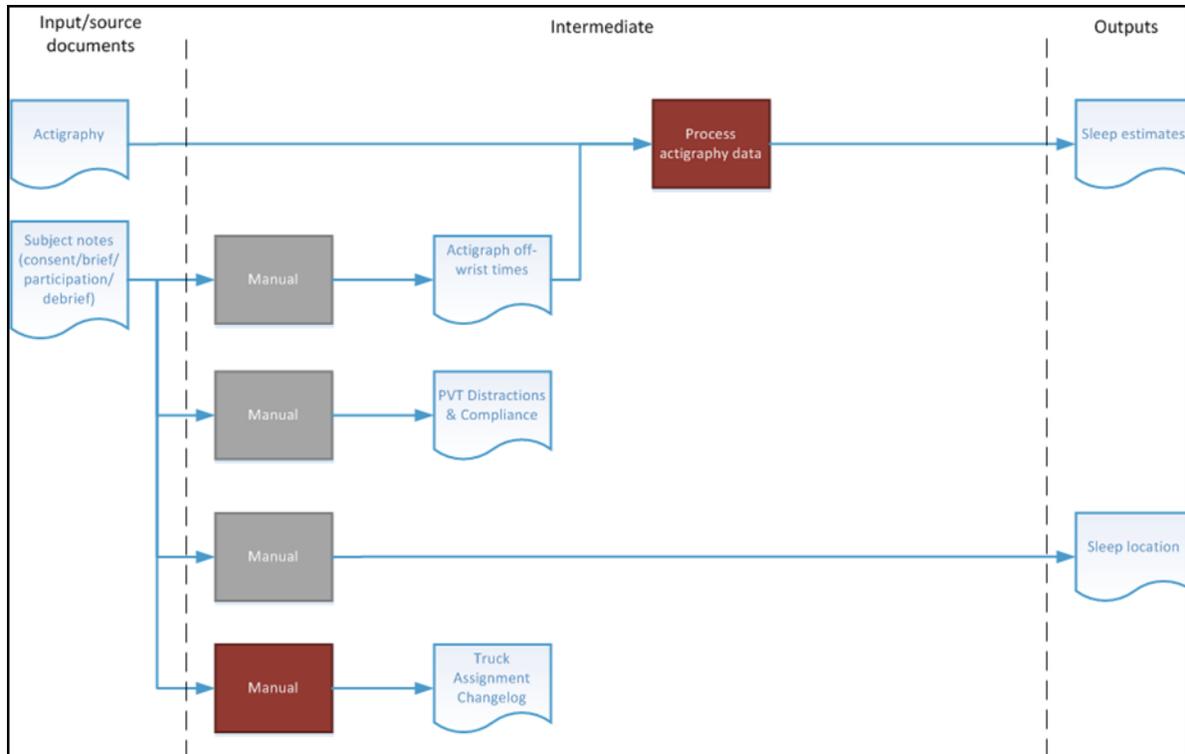


Figure 13. Schematic diagram. Data collection and quality control steps for sleep data collected via wrist-worn actigraph devices.

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4. SAMPLING PLAN AND DATA ANALYSES

The study will use a naturalistic approach defined as an “unobtrusive observation or observation taking place in a natural setting”⁽⁵¹⁾ to evaluate the impacts of Sections 395.3(c) and 395.3(d) of Title 49, Code of Federal Regulations. Specifically, the potential effects of a the 1-night restart duty cycle relative to a 2-or-more-night restart duty cycle and the potential effects of taking a restart in less than 168 hours versus at least 168 hours will be evaluated relative to selected operational, safety, health, and fatigue outcomes. A stratified convenience sample spanning the industry in terms of fleet size (small, medium, and large), type of operation (long-haul, regional, and short-haul), and industry sector (flatbed, refrigerated, tank, and dry-van) will be enrolled to enhance the generalizability of study findings. Participants will be observed over the course of 5 months, which will result in up to 22 restart/duty cycles. In order to maximize statistical power for testing key hypotheses, participants will be prescreened according to whether or not it is expected that the participant’s schedule is, or is not, likely to include at least one restart duty cycle of both types (1 night and 2 or more nights). Web-based screening questionnaires to be completed by potential enrollees will evaluate aspects of commercial driving related to the relative likelihood of taking 1-night versus 2-or-more-night restarts as well as the relative likelihood of taking a restart in less than 168 hours versus 168 hours or more. This will facilitate enriching the sample with drivers expected to be observed under multiple conditions as illustrated in Table 4. Pre-study estimates of a, b, c, and d as defined in the table below will be tracked and used as an aid in sample enrichment. The study team will make extra efforts to identify drivers for each of the cells in Table 4, but as this is a naturalistic study, the study team will not be able to ensure equal numbers of drivers in each cell because some cells are rare (e.g., a 2-night restart in less than 168 hours and greater than 70 hours of work per week). The mixed model analytic plan can handle some degree of inequality in the cell.

Table 4. 2-by-2 cross-tabulation of duty cycles per CMV driver by provisions to be evaluated in primary analyses.

<i>Section 395.3(d)</i>	<i>Section 395.3(c)</i>		Number of Restart/ Duty Cycles
	1-night	≥2-night	
≥ 168 hours (<70 hours/week)	a	b	R₁
< 168 hours (≥70 hours/week)	c	d	R₂
Number of Restart/Duty Cycles	C₁	C₂	N_k
Notes: N _k = total number of restart/duty cycles contributed by driver K. C ₁ = number of restart/duty cycles for driver K with 1-night restarts. C ₂ = number of restart/duty cycles for driver K with ≥2-night restarts. R ₁ = number of restart/duty cycles for driver K with ≥168 hours. R ₂ = number of restart/duty cycles for driver K with >168 hours. a = number of restart/duty cycles for driver K with 1-night restart and ≥168 hours. b = number of restart/duty cycles for driver K with 2-night restart and ≥168 hours. c = number of restart/duty cycles for driver K with 1-night restart and <168 hours. d = number of restart/duty cycles for driver K with 2-night restart and <168 hours.			

Within driver comparisons derive their enhanced statistical power by filtering out between driver “nuisance” variance (e.g., age, medical conditions, personality, etc.). This is an observational study in which participants self-select their experimental condition. However, the study is designed to focus on within-driver comparisons in order to strengthen causal inferences to be derived on the basis of study data. Nonetheless, even participants with only one type of duty cycle (and who complete at least one duty cycle) will contribute to the analyses using the mixed-effects statistical models to be employed. The mixed model analytic plan can handle some degree of inequality in the cell frequencies and drivers with less than all four types of restarts will be included and will contribute to the analyses.

4.1 OVERALL STUDY HYPOTHESES

The study hypothesis (H_0) is that driver performance and safety is the same for CMV drivers operating under the old HOS rules (R_O) or the new HOS rules (R_N). The alternative hypothesis (H_A) is that driver performance and safety are not the same for CMV drivers operating under the old HOS rules (R_O) versus the new HOS rules (R_N). This is:

$$H_0: R_O = R_N \text{ versus } H_A: R_O \neq R_N.$$

The focus of this study will be on within-driver comparisons in order to improve statistical precision and to strengthen the causal inferences to be supported on the basis of results from this study. Therefore, these hypotheses can be expressed for each provision as:

$$H_0: \delta_{1-2} = 0 \text{ versus } H_A: \delta_{1-2} \neq 0 \text{ [for Section 395.3(c)]}$$

$$H_0: \delta_{1-2} = 0 \text{ versus } H_A: \delta_{1-2} \neq 0 \text{ [for Section 395.3(d)]}$$

Where δ_{1-2} for Section 395.3(c) is the true mean difference within driver between restarts with 1 night compared to 2 or more nights (controlling for hours between restart category and other factors) and where δ_{1-2} for Section 395.3(d) is the true mean difference within driver between restarts within less than 168 hours compared to 168 hours or more controlling for 1 night versus 2-or-more nights. δ_{1-2} will be estimated through mixed-effects models that account for within-driver and other correlations, account for the sampling plan, and accommodate inclusion of relevant covariates. Importantly, when estimating main effects comparing 1 night versus 2-or-more nights, statistical models will account for whether or not the restart occurred in less than 168 hours and vice-versa. Effect modification of δ_{1-2} will be formally addressed by assessing the impact of preexisting conditions (e.g., obstructive sleep apnea) that may interact with driver fatigue and safety relative to the restart schedule. This will be done by evaluating the significance of interactions between relevant preexisting conditions and the type of restart duty cycle.

It is important to acknowledge that as a consequence of operational factors and regulations, it is expected that the numbers of restart/duty cycles falling in cells c and d in Table 4 may be relatively small. This may impact on the interpretation of the relative importance of the provisions in Section 395.3(c) and Section 395.3(d) and reduce the scope of statistical analyses possible for addressing the impact of Section 395.3(d). Nonetheless, the sampling plan is

designed to maximize the study's ability to evaluate the impact of both provisions and both will be evaluated to the extent possible using similar statistical methods.

4.2 SAMPLING UNIT

The sampling unit for analysis is the individual restart/duty cycle. Each sampling unit will be defined on the basis of the ELD as falling into one of the cells described in Table 4. All drivers contributing at least one restart/duty cycle that meets minimum data quality criteria will be included in the analyses. Therefore, individual drivers will contribute from 1 to up to 22 sets of restart/duty cycle sampling units. It is expected that operational, safety, health, and fatigue outcomes determined from restart/duty cycles from the same driver will be correlated. Some of these correlations will be explainable by observed between-driver factors. However, unobserved variables are likely to result in residual within-driver correlation. All statistical models used for inferential purposes will account for these correlations. Each sampling unit for each participant will be categorized as either a 1-night restart/duty cycle or a 2-or-more-night restart duty cycle and as less than 168 hours between restarts and 168 hours or more. Initial descriptive analyses will involve averaging over each participant's 1-night restart duty cycles and separately averaging over each participant's 2-or-more-night restart duty cycles and then computing paired within-driver differences. These simple summaries will be appropriately weighted (e.g., by exposure time defined as hours driven and/or total work hours) to standardize sampling units. Sampling units will be subjected to three phases of analysis:

1. **Detailed assessment of each sampling unit by driver and condition.** This will include both tabular and graphical descriptions of data over days within sampling unit and for selected time-of-day blocks. These analyses will be used in statistical screening for quality assessment as well as to provide detailed views of key outcomes for each driver in an organized fashion.
2. **Simplified data analysis using summary statistics by driver and condition.** For example, the total number of SCEs and total number of hours driving will be determined for each driver by condition. These simple summaries will be appropriately weighted (e.g., by exposure time defined as hours driven and/or total work hours) to standardize sampling units. The distribution of within-driver differences in SCE rates under each restart condition will be evaluated. If SCE risk was independent of condition, then 50 percent of these differences are expected to be positive.
3. **Generalized mixed-effects modeling.** State-of-the-art statistical modeling designed to account for correlations within drivers and over time. The model will be used to test primary and secondary hypotheses, and to evaluate effect modification.

The within-participant summaries filter out residual between-driver variance. In addition to within-driver descriptive summaries, descriptive analyses of the distributions of outcomes and duty-cycle-specific covariates will be performed for each of the cells described in Table 4. As needed to enhance interpretation of results, correlations of outcomes among sampling units within drivers can be described using intra-class correlation (ICC) coefficients derived from mixed-effects variance components models. These analyses can be used to identify driver characteristics responsible for observed driver heterogeneity.

4.3 SAMPLE SIZE DISCUSSION

The statistical power of comparisons among outcomes between 1-night restart duty cycles and 2-or-more-night restart duty cycles (and between less than 168 hours versus 168 hours or more) depends heavily on the magnitude of the average within-driver difference in outcomes. Negative binomial (i.e., gamma-Poisson), generalized mixed-effects models (i.e., random effects negative binomial), and linear mixed-effects models will be the primary statistical models for inferential purposes depending upon the nature of the outcome variable. Multi-event duration models (i.e., frailty models) and random effects logistic regression are among other candidate statistical models to be considered. All of these approaches are designed to properly account for correlations within drivers and, where appropriate, correlations over time. They also permit accounting for the sampling plan by including design variables among model covariates. The simplest statistical test consistent with the (largely) within-driver nature of the primary comparison is a paired *t*-test. For a paired *t*-test that evaluates within-subject comparisons between two conditions, the magnitude of the expected difference is measured by the mean difference divided by the standard deviation of differences. This value is known as the “effect size.” Whether an effect size for an expected or observed difference is “small,” “medium,” or “large” depends on the nature of the outcome and the implications of differences of specific magnitudes. As a starting point, Cohen’s convention for a “small” effect size in clinical research for mean differences is a mean difference equal to one-fifth of the standard deviation of the paired differences. Rather than simply specifying a “small” or “medium” effect size, it is better to evaluate available information to define more meaningful target effect sizes expressed in terms of units meaningful for the outcomes of interest. Therefore, an evaluation of effect sizes that are likely to be important and are to be reasonably expected in the study will be conducted as part of the development of the final statistical analysis plan. Nonetheless, it is useful to at this stage to evaluate sample size requirements for what Cohen refers to as a “small” effect size, since these potentially could have important public health policy implications.

Using nQuery Advisor 7.0, Module MOT1-1, a sample size of 199 will have 80 percent power to detect an effect size of 0.2 using a paired *t*-test with a 0.05 two-sided significance level. The target *N* of 207 will be used in the study. In the prior restart study, 117 drivers were enrolled and 106 completed the study, resulting in an attrition rate of 10.4 percent. Therefore, the target sample size was increased by approximately 10 percent to account for attrition of drivers when evaluating SCEs that are unobtrusively collected. If the attrition rate at the beginning of the study appears to exceed 10 percent, then the study design allows for an increase in the sample size to accommodate up to a 25 percent attrition while still enrolling 207 drivers. Experience from Van Dongen & Mollicone⁽⁵²⁾ also indicates that for outcomes requiring driver actions (e.g., PVT-B), missing data is not likely to compromise statistical power. In Van Dongen & Mollicone,⁽⁵³⁾ there were 3,780 test opportunities. Among these opportunities, test bouts were completed on 3,169 (84 percent) occasions. Mixed-effect models to be used will account for the sampling by fleet size and type of operation and other relevant covariates. The effects of these covariates will be evaluated as part of the modeling process.

4.4 ROLE OF STRATIFIED SAMPLING PLAN

As stated in the Statute, “The study shall include fleets of all sizes (i.e., small, medium, and large) and operations (including long-haul, regional, and short-haul) in various sectors of the industry (including flat-bed, refrigerated, tank, and dry-van) *to the extent practicable*” (p. 1, italics added). The study is powered to compare outcome differences associated with 1-night and 2-or-more-night restart duty cycles. The study is not powered to formally test whether restart duty cycle effects vary across type of operation or fleet size with the sample size of $N = 207$ drivers. Rather, these differences will be assessed in descriptive “poolability” analyses using appropriate summary statistics. The sampling plan will insure that there are enough drivers from different types of operations to be able to show that study conclusions are generally consistent across various subpopulations and so findings are generalizable to the industry. Moreover, “medium” effect sizes (0.5 standard deviations) are likely to be detected within fleet size strata and type of operations strata. For example, only 38 drivers are needed for 85 percent power to detect medium effect sizes using a paired t -test with a 2-sided $\alpha=0.05$. Specific contrasts will statistically pool over (say) fleet sizes in order to compare among (say) types of operations and vice versa. In general, the focus of comparisons across sampling strata will be to evaluate whether or not it can be confidently concluded that results (relative to restart schedules) are generalizable across drivers from different fleet sizes and different types of operations.

4.5 SUMMARY OF KEY STATISTICAL MODELS

Statistical analyses of primary and secondary outcomes will involve the use mixed-effects models. The following is a summary of key models to be used:

- Negative binomial (or gamma-Poisson) model:
 - “The Poisson-gamma/negative binomial model is probably the most frequently used model in crash-frequency modeling.”⁽⁵⁴⁾
 - Residual (over-dispersion) variance is assumed to be distributed across drivers as a gamma distribution.
 - The Statistical Analysis System (SAS) procedure “Proc Genmod”⁽⁵⁵⁾ will be used to estimate parameters for the negative binomial for the generalized estimating equation (GEE) approach.
- Random-effects generalized linear model with negative binomial “link” function:
 - The random-effects model is similar to the negative binomial model but is capable of accounting for multiple sources of variability. For example, in specific analyses, units of analysis may be subdivided to account for time of day. In such cases, “Both over-dispersion and serial correlation need to be addressed in a modeling framework to produce efficient estimates.”⁽⁵⁶⁾
 - The SAS procedure “Proc GLMMIX” will be used to estimate parameters for this model using restricted maximum likelihood (REML).
- Mixed model for repeated measures:⁽⁵⁷⁾

- The mixed model approach provides considerable flexibility relative to hypothesis testing and accounting for heterogeneity of the trucking operation.
- The SAS procedure “Proc Mixed” will be used to estimate parameters for this model.

The primary safety outcome will be the number of SCEs captured via OBMSs, which have proven to be feasible and informative of risk. SCEs meet the criterion of being valid surrogate endpoints for crash risk.⁽⁵⁸⁾ There are a number of candidate statistical models for evaluation of SCEs, including models originally developed to assess crash risk under various conditions.⁽⁵⁹⁾ Based on the study design and statistical considerations, two candidate statistical models emerge for evaluating SCEs. These include the negative binomial (or gamma-Poisson) model and the related random-effects model.

The SAS procedure “Proc Genmod”⁽⁶⁰⁾ can be used to estimate parameters for the negative binomial and random-effects models. As stated by Lord and Mannering, “The Poisson-gamma/negative binomial model is probably the most frequently used model in crash-frequency modeling.”⁽⁶¹⁾ In this model, the rate of SCEs is reflected in the Poisson parameter, lambda. Lambda is formulated as a function of covariates that can pertain to between-driver differences (e.g., BMI) and within restart/duty cycle variables such as time of day. Residual (over-dispersion) variance is assumed to be distributed across drivers as a gamma distribution. The random-effects model is similar to the negative binomial model but is capable of accounting for multiple sources of variability. For example, in specific analyses, units of analysis may be subdivided to account for time of day. In such cases, “Both over-dispersion and serial correlation need to be addressed in a modeling framework to produce efficient estimates.”⁽⁶²⁾

These models naturally account for exposure time within each restart/duty cycle. Exposure time will be assessed based on ELDs and defined as hours of driving time, since these data will be available. The ELDs also provide total hours worked and hours working, but not driving, and hours in a sleeping berth. Within-duty-cycle covariates will include the fraction of work hours that were spent driving. It is expected that this fraction may modify the rate at which risk accumulates over exposure time and that the magnitude of effect modification will depend on the industry segment that the driver is working in. For example, some drivers may be involved in heavy lifting, which could have differential effect on risk accumulation compared to less strenuous non-driving work efforts. These factors will be evaluated through the statistical model described above.

Most other outcomes are continuous. For these outcomes, mixed models for repeated measures will be employed to account for correlations within drivers and where applicable, over time.⁽⁶³⁾ In a matrix equation, this model can be expressed as:

$$\mathbf{Y}_i = \mathbf{X}_i\boldsymbol{\beta} + \mathbf{Z}_i\mathbf{u} + \mathbf{e}_i$$

where $\boldsymbol{\beta}$ is a vector of fixed-effect regression parameters including the overall mean μ , the effect of 1 versus 2-or-more nights restart (θ), a vector of driver and sampling unit covariates $\boldsymbol{\tau}$, and a vector of covariate by restart type interaction effects $\boldsymbol{\eta}$. \mathbf{X} is a design matrix for the fixed effects, \mathbf{Z} is a design matrix for the random effects of driver (\mathbf{u}), and \mathbf{e} is the error vector with $E(\mathbf{e}) = \mathbf{0}$ and $\text{Var}(\mathbf{e}) = \sigma_e^2\mathbf{V}$. \mathbf{V} may be specified to optimally account for the specific kind of covariance-correlation structure appropriate for a specific longitudinal setting. Parameters will be estimated

using SAS “Pros Mixed.”⁽⁶⁴⁾ Information criteria, such as the Akaike Information Criterion,⁽⁶⁵⁾ will be used to evaluate the optimal covariance structure by comparing models identical in the fixed effects part of the model with increasingly more complex covariance structures. The mixed-effect generalized linear model has similar formulation, but the “left-hand” side of the equation is tied to the “right-hand” side of the equation by way of nonlinear “link” functions. Parameters for generalized linear models will be estimated using the SAS procedure “Proc GLMMIX.”

The mixed-model approaches to be employed provide considerable flexibility in testing hypotheses of scientific interest while accounting for heterogeneity from multiple sources. Specific models will be parameterized to address systematic variation over 24-hour cycles of sleeping and waking between sampling units with different restart options. These data will be recorded for each driver expressed in the driver’s home terminal time. This will make it possible to statistically compare repeated-measures data between duty cycles, both within and between drivers.

Data reduction plans specific to each individual outcome variable and covariate from each variable domain will be developed in close collaboration between study team partners. For example, data collected in small intervals such as 1-minute intervals will be aggregated into 1-hour bins for each hour of the day across days in each duty cycle for each driver. It is likely that the study team will construct multiple reduced data sets organized according to time resolution and for varying analysis needs. These analyses sets are considered to be intermediate data sets. Final statistical programming and analysis data set creation will be developed by Biomedical Statistical Consulting. Further statistical screening of the intermediate data sets and the final analysis data sets will be performed on a regular basis with results reviewed and summarized by the Scientific Leader in collaboration with the Statistical Leader in order to further monitor the accumulation of data needed to meet the primary and secondary study objectives.

For example, outcomes, such as PVT measurements, are determined less frequently and at discrete time points rather than continuously, as are SCEs. Data on PVT lapses of attention will be aggregated in 4-hour bins spanning the 24 hours of the day, and collapsed (again, not averaged) across days in each duty cycle for each driver. Other outcomes, such as subjective sleepiness scores on the KSS, will be similarly analyzed. Additionally, measurements taken during the restart breaks themselves will be separately analyzed. Graphical representations of modeling results will be generated to represent the distributions of averages over drivers and duty days (or restart days) as a function of time of day under each restart duty cycle type. These graphs will be derived from the statistical analyses using the predicted population marginal means and their standard errors.

4.6 ADDRESSING SELECTION BIAS

The PRP was concerned about potential confounding from selection bias associated with CMV driver choices between 1-night restart and 2-night restart and whether such choices are based on drivers’ preferences or fleet scheduling. The PRP acknowledged the statutory requirements of the study, but also noted that an ideal study design would involve randomization of drivers to only 1-night restarts or 2-or-more-night restart conditions. Although the project calls for a

naturalistic observational study, the study team agreed to focus its recruitment efforts on drivers likely to take a 1-night restart on a regular basis versus drivers likely to take a longer restart and to monitor screened drivers according to the cells described in Table 4. It is expected this approach will enrich the amount of information collected during this study for testing the primary study hypotheses. This will be achieved by increasing the likelihood that drivers will be observed under both 1-night and 2-or-more-nights restart conditions and to the extent possible under both of these conditions stratified by less than 168 hours versus 168 hours or more.

Specifically, the study team indicated they expected that many drivers volunteering for the study will have varying restart schedules that include both 1-night and 2-night restarts which will permit within-subjects data analyses. This will result in greater statistical power and precision with potential for enhancing the validity of the inference. FMCSA also agreed that most drivers will have mixed restart schedules during the 5-month data acquisition period. Primary statistical analyses will be based on mixed-effects modeling which can accommodate CMV drivers with both types of restart or only one type. The primary analyses will be supported by ancillary analyses designed to address the issue of self-selection bias posed by the PRP. To this end, questions have been added to the weekly driver interviews to prospectively assess whether the driver intends to utilize a 1-night or 2-night restart for the following duty cycle. To the extent possible, a similar strategy will be implemented to assess the impact of less than 168 hours between restarts versus 168 hours or more.

The general category of the reason for drivers' predictions of type of restart (operational imperative versus driver preference) will also be elicited. This will allow for comparisons between driver predictions and actual restart conditions. The assessment of selection bias will include an evaluation of the degree to which driver intentions are associated with the actual restart conditions observed. Similarly, the safety, sleep health, and fatigue outcomes from the prior duty cycle will be evaluated with respect to their association with actual restart condition on the subsequent duty cycle. These analyses will also account for pre-study baseline driver characteristics. The added weekly questions, as well as the predictive modeling of choices between 1-night and 2-night restarts, will be investigated as to their utility in addressing the selection bias concern of the PRP. These may have usefulness in analyses designed to address selection bias in a fashion similar to observational studies that utilize propensity score approaches for this purpose.

5. INDEPENDENT REVIEW PANEL

5.1 FMCSA INDEPENDENT REVIEW PANEL

In the regular course of business, FMCSA utilizes an independent peer review when conducting research activities. At the project's outset, the panel evaluates the clarity of the research questions, the validity of the research methodology, and the quality of the data collection plan. The peer review panel will also evaluate the draft final report and comment on the strength of the analyses and the appropriateness of the study conclusions. The Consolidated and Further Continuing Appropriations Act, 2015, requires that the initial plan and final report of FMCSA's CMV Driver Restart Study be subject to an independent peer review team. The USDOT Office of Inspector General (OIG) must review the selection of the independent review panel. The table below displays the panel members selected by FMCSA and their areas of expertise. The peer review team members will communicate their project reviews and inquiries directly with FMCSA staff.

Table 5. Peer Review Panel (PRP) team members.

Name	Area of Expertise	Professional Affiliation
Dr. Tom Balkin	Sleep medicine, operations research	Walter Reed Army Institute of Research
Dr. Edward Hitchcock	Human subject research, fatigue	Centers for Disease Control, National Institute for Occupational Safety and Health
Dr. Joel Greenhouse	Statistics/Methodology	Carnegie Mellon University
Dr. Eloise Kaizar	Statistics/Methodology	Ohio State University

5.2 SELECTION PROCESS AND CRITERIA

FMCSA selected the members of the independent peer review team based on their scientific and medical expertise. To identify a broad pool of potential team members, FMCSA reached out to the National Academy of Sciences Committee on National Statistics, the American Statistical Association, and several Federal research agencies, such as NIH, for advice on independent experts who could serve on the panel. FMCSA met to review the candidates and narrowed the list to four experts. These individuals represent expertise in statistics, human subject research design, and medical research. FMCSA also gave due consideration to each individual's independence and ability to objectively review the study, based on a review of their publicly available biographical materials, academic vitae, and résumés. Two of the members are Federal scientists who are required to abide by government-wide ethics and conflict of interest rules. As Federal employees, they do not have ties to industry or other outside groups which could impair their ability to make objective professional judgments regarding the study plan. Two other peer review team members hold academic positions and have experience with national scientific study panels and grant-funded research. A review of their professional backgrounds does not indicate any financial or other ties to industry or other outside groups which could impair their ability to review the study plan and findings objectively. Each of the four peer review panel members

came highly recommended by professional colleagues. Each member is required to sign a nondisclosure/conflict of interest statement.

In selecting the peer review panel members, FMCSA followed the overall guidance issued by the Office of Management and Budget's (OMB) *Final Information Quality Bulletin for Peer Review* (issued December 16, 2004).⁽⁶⁶⁾ FMCSA also followed the policies employed by the National Academy of Sciences to ensure independence and avoidance of conflicts of interest. For further information on this topic, see National Academy of Sciences, *Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the Development of Reports*, May 2003.⁽⁶⁷⁾ The National Academy of Sciences defines conflict of interest as "any financial or other interest that conflicts with the service of an individual on the review panel because it could impair the individual's objectivity or could create an unfair competitive advantage of a person or organization" (National Academy of Sciences, May 2003).⁽⁶⁸⁾

5.3 PROCESS INTEGRITY

The comments provided by the review panel will be posted on the FMCSA Web site for public access. Drafts of documents and other materials provided to the peer review panel that are intended solely for the purposes of a peer review, and not for public dissemination, will include the following disclaimer:

THIS INFORMATION IS DISTRIBUTED SOLELY FOR THE PURPOSE OF PRE-DISSEMINATION PEER REVIEW UNDER APPLICABLE INFORMATION QUALITY GUIDELINES. IT HAS NOT BEEN FORMALLY DISSEMINATED BY THE FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION. IT DOES NOT REPRESENT AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY.

5.4 ROLES AND RESPONSIBILITIES

FMCSA provided the peer review team with the project's draft work plan and methodological design for their review and comment. The team members attended the project kick-off meeting in February 2015 and provided comments to FMCSA. FMCSA evaluated the comments and modified the draft work plan as necessary. Once data collection begins, the peer review team will be informed of any significant issues that could change the research design. FMCSA will provide the peer review team with copies of the draft final report for their review and comment.

FMCSA will make the peer review team's comments available on the Agency's Web site. The study contractor will be responsible for managing the peer review meetings and providing appropriate remuneration for non-Federal peer review team members. The remuneration is intended to cover a portion of the team member's time and the amount will be in accordance with similar prior Agency projects. The team will provide their comments and project-related inquiries directly to FMCSA. The Peer Review Charge provides the specific activities assigned to the peer review team. As recommended by OMB guidelines, FMCSA will engage the peer

review team for early involvement in the research study process to benefit from their expert review of the research design and methodology.

The peer review team's evaluation of the initial study plan included a review of the study hypothesis, soundness of the research methodology, adequacy of the technology used to measure safety performance and driver fatigue, data collection protocol, and analysis plan. The review team also commented on the study's performance measures to properly evaluate the study outcomes. The independent review of the final report will include an evaluation of whether the findings in the report are supportable in view of the statistical evidence provided and whether the report addresses all the items in the initial study plan.

5.5 KEY MILESTONES FOR THE INDEPENDENT PEER REVIEW PANEL

- Peer Review Panel established – January 2015.
- Peer Review Panel information submitted to OIG – February 2015.
- Project Kick-off – February 2015.
- Peer Review Panel reviews Study Plan prior to submission to OIG – February 2015.
- Peer Review Panel reviews draft Report prior to submission to OIG – October 2015.

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6. PROJECT TASKS

Below is a description of how the 11 tasks will be successfully completed by the study team.

6.1 TASK 1: KICK-OFF MEETING AND DEVELOPMENT OF DRAFT DETAILED WORK PLAN

The study team will write a draft work plan (the current document) for the project, providing details for each of the project tasks. The draft work plan specifies the field research in detail and provides a basis for the IRB submission in Task 3. FMCSA has constituted a PRP consisting of independent experts in the area to review the scientific aspects of this study. A kick-off meeting will be held at FMCSA Headquarters to review and address key elements of the draft work plan with FMCSA personnel, VTTI representation, and the PRP. This work plan includes a detailed project timeline, sampling design, driver recruitment plan, analysis plan, and discussion of technology to be used to collect the required driver fatigue, health, and performance data. The study team will adjust the work plan as necessary based on feedback received from the PRP, FMCSA, and USDOT OIG.

Deliverables: Draft detailed work plan, PowerPoint briefing for kick-off meeting, and letter reporting on kick-off meeting outcomes.

6.2 TASK 2: DEVELOP AND FINALIZE PROJECT WORK PLAN

The study team will work with FMCSA and the PRP to develop a final work plan for each stage of this project. The work plan will include potential literature review sources, detailed data collection and statistical analysis plans, project milestones, and target completion dates.

Deliverable: Final work plan.

6.3 TASK 3: OBTAIN INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL

The study team will submit a protocol to the Virginia Tech IRB and University of Pennsylvania IRB. The protocol will include all necessary non-disclosure agreements, confidentiality certifications, and documents needed to conduct a study that involves human subjects.

Deliverables: IRB application, documentation of subsequent IRB approval.

6.4 TASK 4: SECURE PARTICIPATION BY RECRUITED CARRIERS/DRIVERS AND INITIATE STUDY

The study team will recruit carriers to participate and cooperate in this study with the goal of recruiting a mix of large, medium, and small companies. The study team will work with carrier senior management and operational staff to identify drivers who regularly (1) maximize work and driving hours, and (2) work at night. The study team will recruit up to 207 drivers, and

assume up to a 10 percent attrition rate, with the goal of sampling drivers involved in long-haul, regional, and short-haul operations and to the extent practical, further segment recruitment efforts to achieve a mix of different truck types including flat-bed, refrigerated, tank, and dry-van. As directed by FMCSA, a driver that has at least one duty cycle will be considered a valid participant and that data will not be discarded. If the attrition rate at the beginning of the study appears to exceed 10 percent, then the study design allows for an increase in the sample size to accommodate up to a 25 percent attrition rate.

Deliverable: Weekly status reports detailing carriers contacted, number of drivers recruited, challenges faced, and prospect for resolution of any issues.

6.5 TASK 5: LITERATURE REVIEW

The study team will conduct a literature review with an emphasis on new studies on the need for recovery from fatigue and the effectiveness of the 34-hour restart, significant findings from international research relating to commercial vehicle driver fatigue, and significant findings, domestically and internationally, relating to driver fatigue and the need for an adequate recovery period. Significant findings on the effectiveness and measurable safety benefits of an adequate recovery period (include related sources, such as military, Federal Aviation Association, transit, and Federal Railroad Administration).

Deliverable: Report containing literature review.

6.6 TASK 6: CONDUCT THE CMV DRIVER RESTART FIELD STUDY

The study team will conduct a naturalistic field study with up to 207 drivers, with at least 1 duty cycle, who regularly maximize work and driving hours and work at night (see recruitment targets in sampling plan). If the attrition rate at the beginning of the study appears to exceed 10 percent, then the study design allows for an increase in the number of drivers sampled to accommodate up to a 25 percent attrition rate. Details of the final study will be decided based on feedback from FMCSA and the PRP in Tasks 1 and 2. This study will have at least the following key elements:

1. Drivers will be followed while driving normal revenue-producing routes through at least 2 and up to 22 duty cycles to document changes in performance pre- versus post-restart.
2. Drivers will be compared to themselves and each other in a mixed within-/between-subjects design focused on the number of biological nights in the restart period.
3. Rest/activity patterns will be measured through continuous actigraphic recording.
4. OBMS data will be used to measure the total number of SCEs and the number of fatigue-related events.
5. Participants' performance on a PVT-B along with subjective ratings using a smartphone with custom software.

The study team will obtain informed consent from participants, distribute smartphones to facilitate collection of PVT-B, ELD, and questionnaire data, and distribute actigraph devices to

facilitate collection of actigraph data. The study team will install the DriveCam system VEs in participant vehicles to facilitate collection of SCEs and fatigue-related events. The study team will coordinate with carriers to collect ELD data in cases where the carrier is already using an ELD technology.

Deliverables: Weekly written reports on the number of drivers participating in this study and the status of the data generated by each driver. Reports will include a discussion of any limitations in completing this study and any other pertinent factors.

6.7 TASK 7: DATA REDUCTION AND ANALYSES

The study team will follow the analysis plan outlined above. This will include the primary statistical testing, which involves within-subject and between-subject comparisons of driver performance in all restart/duty cycles with a 1-night restart to all restart duty/cycles with 2-or-more-nights restart. The study team will evaluate sleep, alertness, and driving safety metrics (e.g., SCEs and fatigue-related events) within and between subjects. Data collected in this study will be stored on secure, password-protected servers.

Deliverable: Written reports describing the data reduction procedures, including assumptions made, errors identified and removed, and the characteristics of the final data set, (e.g., size, number of variables, and value labels).

6.8 TASK 8: DRAFT FINAL REPORT, DRAFT RESEARCH BRIEF, AND REPORT TO CONGRESS

The study team will prepare a draft final report that details the methodology used, data relied upon, and the study results. The study will also prepare a draft two-page research brief. USDOT will submit a summary report to Congress.

Deliverables: Draft final report, 2-page draft research brief, and 10-page draft summary report to Congress which addresses the study methodology, data collected, and findings.

6.9 TASK 9: PRESENT AND SUBMIT FINAL REPORT TO FMCSA AND THE PEER REVIEW TEAM

The study team will deliver a PowerPoint presentation to FMCSA and the PRP detailing the rationale for the project, its methodology, and key findings. At the request of FMCSA, the study team will deliver up to four additional presentations during the course of the project to provide status updates and descriptions of current findings.

Deliverables: PowerPoint presentation and delivery of compiled draft final report.

6.10 TASK 10: SUBMIT REVISED FINAL REPORT

The study team will prepare a final report that addresses comments and changes proposed by FMCSA and the PRP.

Deliverables: Final report and letter addressing comments from FMCSA and peer review panel.

6.11 TASK 11: FOLLOW-UP BRIEFINGS TO AGENCY, OIG, AND CONGRESS

The study team will prepare a PowerPoint briefing presentation and deliver up to four post-study release briefings to the Agency, the USDOT OIG, and Congressional staff, as requested, detailing the rationale for the project, its methodology, and key findings.

Deliverables: PowerPoint briefing presentation, handouts, and up to four briefings.

APPENDIX A: INSTITUTIONAL REVIEW BOARD PROTOCOL¹

Section 1: General Information

1.1 DO ANY OF THE INVESTIGATORS OF THIS PROJECT HAVE A REPORTABLE CONFLICT OF INTEREST? (<http://www.irb.vt.edu/pages/researchers.htm#conflict>)

- No
 Yes, explain:

1.2 WILL THIS RESEARCH INVOLVE COLLABORATION WITH ANOTHER INSTITUTION?

- No, go to question 1.3
 Yes, answer questions within table -->

IF YES
<p>Provide the name of the institution [for institutions located overseas, please also provide name of country]:</p> <p>University of Pennsylvania Pulsar Informatics Biomedical Statistical Consulting</p>
<p>Indicate the status of this research project with the other institution's IRB:</p> <p><input checked="" type="checkbox"/> Pending approval <input type="checkbox"/> Approved <input type="checkbox"/> Other institution does not have a human subject protections review board <input checked="" type="checkbox"/> Other, explain:</p> <p>The University of Pennsylvania will sign a letter of reliance allowing Virginia Tech to be the IRB of record for the data collection and data sharing portion of this study. The University of Pennsylvania will submit their own IRB application to cover their analysis of de-identified driving and non-driving data.</p> <p>Pulsar Informatics will also sign a letter of reliance allowing Virginia Tech to be the IRB of record covering all of their research activities in this study.</p> <p>Staff from Biomedical Statistical Consulting will sign Individual Investigator Agreements allowing Virginia Tech to be the IRB of record for their analysis activities.</p>
<p>Will the collaborating institution(s) be engaged in the research? (http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html)</p> <p><input type="checkbox"/> No <input checked="" type="checkbox"/> Yes</p>

¹ While the appendices of the IRB Protocol document are not included in this final scope and methodology plan, they can be provided upon request.

<p>Will Virginia Tech's IRB review all human subject research activities involved with this project?</p> <p><input type="checkbox"/> No, provide the name of the primary institution: <input checked="" type="checkbox"/> Yes</p> <p><i>Note: primary institution = primary recipient of the grant or main coordinating center</i></p>
--

1.3 IS THIS RESEARCH FUNDED?

- No, go to question 1.4
 Yes, answer questions within table -->

IF YES
<p>Provide the name of the sponsor [if NIH, specify department]:</p> <p>Federal Motor Carrier Safety Administration</p>
<p>Is this project receiving federal funds?</p> <p><input type="checkbox"/> No <input checked="" type="checkbox"/> Yes</p> <p>If yes,</p> <p>Does the grant application, OSP proposal, or "statement of work" related to this project include activities involving human subjects that are <u>not</u> covered within this IRB application?</p> <p><input checked="" type="checkbox"/> No, all human subject activities are covered in this IRB application <input type="checkbox"/> Yes, however these activities will be covered in future VT IRB applications, these activities include: <input type="checkbox"/> Yes, however these activities have been covered in past VT IRB applications, the IRB number(s) are as follows: <input type="checkbox"/> Yes, however these activities have been or will be reviewed by another institution's IRB, the name of this institution is as follows: <input type="checkbox"/> Other, explain:</p> <p>Is Virginia Tech the primary awardee or the coordinating center of this grant?</p> <p><input type="checkbox"/> No, provide the name of the primary institution: <input checked="" type="checkbox"/> Yes</p>

1.4 DOES THIS STUDY INVOLVE CONFIDENTIAL OR PROPRIETARY INFORMATION (OTHER THAN HUMAN SUBJECT CONFIDENTIAL INFORMATION), OR INFORMATION RESTRICTED FOR NATIONAL SECURITY OR OTHER REASONS BY A U.S. GOVERNMENT AGENCY?

For example – government / industry proprietary or confidential trade secret information

- No
 Yes, describe:

1.5 DOES THIS STUDY INVOLVE SHIPPING ANY TANGIBLE ITEM, BIOLOGICAL OR SELECT AGENT OUTSIDE THE U.S?

No
 Yes

Section 2: Justification

2.1 DESCRIBE THE BACKGROUND, PURPOSE, AND ANTICIPATED FINDINGS OF THIS STUDY:

The purpose of this study is to evaluate the efficacy of the 34-hour restart rule, as described in the Hours-of-Service (HOS) Regulations. Starting July 1, 2013, the HOS rule allowed commercial motor vehicle (CMV) drivers to restart their 7/8 consecutive day schedule by taking 34 or more consecutive hours off duty; however, the 34 or more consecutive hours must include two periods from 1 a.m. to 5 a.m. This study will evaluate the operational, safety, health and fatigue impacts of the restart provisions.

To do this, driving data and various forms of non-driving data (described in more detail in section 5.1 below) will be collected for a time period of up to five months for each driver.

This project is being conducted by a large research team consisting of several different organizations. VTTI will serve as the prime institution and will oversee management of the study, as well as conduct some analysis of the de-identified event-based data. Lytx will provide the data recorder and will lead the collection of driving data and the coding of this data into a de-identified format. Lytx is a technology vendor who provides this type of service as part of their business, and thus are not considered to be engaged in the research, per OHRP guidance (and confirmed via communication with the Virginia Tech IRB office). Participants in this study may be current clients of Lytx, or may become new clients of Lytx. Pulsar is considered to be the main data collector for this study and will be the main point of contact for participants. They will lead the recruiting process as well as meet with participants to provide consent. They will also lead the collection of the non-driving data (described in more detail in Section 5.1). The University of Pennsylvania serves as the Technical Lead on this project and will also be involved in the data analysis. Finally, Biomedical Statistical Consulting will take the lead in the data analysis.

We want to provide some comparisons to previous commercial vehicle naturalistic driving studies conducted by VTTI. Previous studies collected continuous data, with identifying data being retained for further (future) analysis. The current study will collect event-based data (so only a fraction of the typical amount of data is being collected). In addition, the data are coded more quickly than usual into a de-identified format, and the identifying data are only being retained for a relatively short period of time (in accordance with Lytx's usual data retention business policies). Finally, only de-identified data will be retained for further and future analysis. For all of these reasons, we feel that the study has less legal and breach of privacy risk (long-term and short-term) than many of our previous studies.

The other major difference is that drivers will be asked to complete tasks daily. The tasks will take up to 30 minutes per day to complete. In accordance with the requirement to complete study tasks, participants will be compensated according to how many of these tasks they complete. Although total study compensation is higher than normal for a typical naturalistic driving study, we feel it is quite reasonable when the driver's time is factored in. These calculations are presented in the Compensation section.

2.2 EXPLAIN WHAT THE RESEARCH TEAM PLANS TO DO WITH THE STUDY RESULTS:

For example - publish or use for dissertation

The collected data will be analyzed and included in a technical report to be delivered to the sponsor and briefed to congress.

A de-identified data set will be posted online for public use.

Section 3: Recruitment

3.1 DESCRIBE THE SUBJECT POOL, INCLUDING INCLUSION AND EXCLUSION CRITERIA AND NUMBER OF SUBJECTS:

Examples of inclusion/exclusion criteria - gender, age, health status, ethnicity

Multiple commercial motor vehicle (CMV) fleet companies, and owner-operator drivers, will be recruited to participate in this effort, providing approximately 250 vehicles to be instrumented with the Lytx OnBoard Monitoring System (OBMS). For this research study, as many as 300 participants will be selected across all fleets and will each drive one instrumented vehicle for up to five months.

All participants must drive a commercial vehicle as part of their daily work duties, and have a valid Class-A Commercial Driver's License (CDL). Participants will be recruited from the following categories: long haul, regional, short-haul, small carrier, medium carrier, large carrier, flat-bed trailer, refrigerated trailer, tank trailer, and dry-van trailer (see Appendix A). It is also requested that participants be nighttime drivers who take one to two restart breaks during the workweek and drive more than 60 hours/week. Participants will be volunteers; participation is not compulsory.

3.2 WILL EXISTING RECORDS BE USED TO IDENTIFY AND CONTACT / RECRUIT SUBJECTS?

Examples of existing records - directories, class roster, university records, educational records

No
 Yes

IF YES
<p>Are these records private or public? (highlight one)</p> <p><input type="checkbox"/> Public</p> <p><input checked="" type="checkbox"/> Private, describe the researcher's privilege to the records:</p> <p>The research team will be working with the fleets to recruit participants.</p>
<p>Will student, faculty, and/or staff records or contact information be requested from the University? (highlight one)</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Yes, visit the following link for further information: http://www.policies.vt.edu/index.php (policy no. 2010)</p>

3.3 DESCRIBE RECRUITMENT METHODS, INCLUDING HOW THE STUDY WILL BE ADVERTISED OR INTRODUCED TO SUBJECTS:

There will be several steps involved in the recruitment process. Rick Gobbell, an expert in the trucking industry, will help us connect with fleets and owner-operator drivers who may be interested in participating in this study. He hosts a 1-hour radio show twice a month where he will be announcing the study (Appendix B) and directing potential participants to a recruiting website (www.RestartStudy.com) where drivers may provide information about themselves (Appendix C). As noted in section 3.1, participants will be recruited from various parts of the trucking industry (long haul, regional, short-haul, small carrier, medium carrier, large carrier, flat-bed trailer, refrigerated trailer, tank trailer, and dry-van trailer), therefore, it is necessary to obtain this information from potential participants while recruiting. The analysis needs of this study require a certain number of participants in given cells (see Appendix A), therefore, when certain cells have already obtained the needed sample size, drivers will no longer be recruited for that particular cell.

Potential participants who fill out this form, and meet the study needs noted above, will be contacted and given detailed information about the study (Appendix B). Their physical location will also play a role in their eligibility as it may not be logistically feasible to work with certain drivers given their location. At this time, it has not been decided what geographical locations will be included, or excluded, in the study.

The questions from Appendix C may also be asked to potential participants over the phone, or email, if a driver has shown interest in the study but has not provided this information through the recruiting website. For example, drivers may have just provided their name and contact information through the FMCSA website listed below.

Pulsar will lead the recruitment process and will contact any driver who expresses interest in participating and who fits the criteria for the study, to confirm their eligibility. Recruitment posters (Appendix D) will also be distributed to drivers at fleet locations who are interested.

Finally, FMCSA has also set up a website where interested participants may obtain more information: <http://www.fmcsa.dot.gov/safety/research-and-analysis/commercial-motor->

vehicle-driver-restart-study. It is expected that there will be a link to the above mentioned recruiting website (www.RestartStudy.com) from the FMCSA website.

3.4 PROVIDE AN EXPLANATION FOR CHOOSING THIS POPULATION:

Note: the IRB must ensure that the risks and benefits of participating in a study are distributed equitably among the general population and that a specific population is not targeted because of ease of recruitment.

The purpose of this study is to evaluate the efficacy of the 34-hour restart rule, which applies to CMV drivers. Therefore, all participants must be CMV drivers and hold a Class-A CDL. They must also be nighttime drivers who work more than 60 hours/week and take one to two restart periods per workweek. They must also fit into one of the nine cells of the sampling matrix (Appendix A)

Section 4: Consent Process

For more information about consent process and consent forms visit the following link:
<http://www.irb.vt.edu/pages/consent.htm>

If feasible, researchers are advised and may be required to obtain signed consent from each participant unless obtaining signatures leads to an increase of risk (e.g., the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting in a breach of confidentiality). Signed consent is typically not required for low risk questionnaires (consent is implied) unless audio/video recording or an in-person interview is involved. If researchers will not be obtaining signed consent, participants must, in most cases, be supplied with consent information in a different format (e.g., in recruitment document, at the beginning of survey instrument, read to participant over the phone, information sheet physically or verbally provided to participant).

4.1 HIGHLIGHT ALL OF THE FOLLOWING THAT APPLY TO THIS STUDY'S CONSENT PROCESS:

- Verbal consent will be obtained from participants
- Written/signed consent will be obtained from participants
- Consent will be implied from the return of completed questionnaire. Note: The IRB recommends providing consent information in a recruitment document or at the beginning of the questionnaire (if the study only involves implied consent, skip to Section 5 below)
- Other, describe:

We are requesting a waiver of informed consent to collect data from secondary drivers who may end up driving the instrumented vehicle. No data will be retained for these drivers; as soon as it is determined that a trip file is from an unconsented driver, the data will be deleted.

4.2 PROVIDE A GENERAL DESCRIPTION OF THE PROCESS THE RESEARCH TEAM WILL USE TO OBTAIN AND MAINTAIN INFORMED CONSENT:

Study participants will attend a face-to-face meeting with researchers from the research team. At this time, participants will be asked to review and sign the Informed Consent Form (ICF) (Appendix E for participants who will provide electronic log data through the Smartphone app, and Appendix F for participants who will not provide electronic log data). Participants will be given as much time as needed to thoroughly read the ICF and have all questions

answered before signing. Once all questions have been answered, both the participant and researcher will sign two copies of the ICF (one copy for the participant and one copy for VTTI's records). Pulsar will lead the consent process. They will make a digital scan of the ICF to store securely at their facilities. They will then package and send the original ICF to VTTI, where it will be kept in a locked file cabinet.

4.3 WHO, FROM THE RESEARCH TEAM, WILL BE OVERSEEING THE PROCESS AND OBTAINING CONSENT FROM SUBJECTS?

Daniel Mollicone, Christopher Mott, Kevin Kan, Matthew van Wollen, Jami Bilger, Steve Bruneau, Aaron Unice, and Vionna Lo will be involved in the consent process from Pulsar Informatics. Rich Hanowski, Jeff Hickman, Rebecca Hammond, Devon Moeller, and Mark Golusky may also be involved from VTTI. Anyone else assigned to this task by the project PI will be added to the IRB protocol as needed.

4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?

In a private area of a driver lounge/break room or other meeting room/area at the participating fleet location.

4.5 DURING WHAT POINT IN THE STUDY PROCESS WILL CONSENTING OCCUR?

Note: unless waived by the IRB, participants must be consented before completing any study procedure, including screening questionnaires.

Consent will occur after explanation of the study's purpose and after participants have had any questions answered. Consent will be obtained prior to any data collection activities.

4.6 IF APPLICABLE, DESCRIBE HOW THE RESEARCHERS WILL GIVE SUBJECTS AMPLE TIME TO REVIEW THE CONSENT DOCUMENT BEFORE SIGNING:

Note: typically applicable for complex studies, studies involving more than one session, or studies involving more of a risk to subjects.

Participants will be given a copy of the ICF to review during their meeting with a member of the research team and will be given as much time as needed to review, ask questions, and sign the ICF at the time of the meeting.

___ Not applicable

Section 5: Procedures

5.1 PROVIDE A STEP-BY-STEP THOROUGH EXPLANATION OF ALL STUDY PROCEDURES EXPECTED FROM STUDY PARTICIPANTS, INCLUDING TIME COMMITMENT & LOCATION:

Participants will be given a copy of the ICF to review during their meeting with a member of the research team and will be given as much time as needed to review, ask questions, and sign the ICF. Following informed consent, participants will be asked to complete a W9

(pencil-and-paper – Appendix G) and a Background Questionnaire (Smartphone app on Smartphone provided to the participant for the study – Appendix H). Researchers will ask participants if they may use a flexible measuring tape to measure the participant's neck circumference. This is preferred so we may get an accurate and consistent measurement across all participants. Researchers will also take a digital picture of each participant to be used to identify them in the driving data. The initial meeting is expected to last approximately 45 minutes.

Data collection for this study will last up to five months per participant. Event-based data will be recorded using the Lytx DC3P video event recorder (VER). A VER will be installed on the inside of the front windshield of each vehicle and will collect event-based data (8 seconds before, 4 seconds after) for hard braking, hard acceleration, hard swerve maneuvers, and contact with other objects. In addition, events will be recorded each time the participant exceeds the posted speed limit by 5 mph. Participants will be expected to drive their normal revenue-producing routes and will not be expected to drive any additional or different routes for the purposes of this study. Some participants may already be a client of Lytx and have a VER installed in their vehicle and data that is being collected in baseline mode (i.e., data is being transferred back to Lytx for review but is not being transferred to their employer for coaching). In these cases, the previously installed VER would be used for data collection for these participants.

During the participation time, participants will be asked do various tasks each day (on both driving days, and non-driving days) using a Smartphone provided to them for the course of the study. The Smartphone will have a data plan only, and no calling capabilities. The Smartphone will have the Participant ID (number only, nothing to indicate that it is part of a study) labeled on the outside of the phone, as well as connected to the data (described below) on the phone.

At the beginning of each duty period (i.e., after sleep and before driving begins), participants will be asked to perform a three-minute PVT test (reaction time) on the Smartphone provided to them for the duration of the study, rate their level of drowsiness, indicate their caffeine use for the day, fill out a sleep/wake/duty diary, and indicate their perceived stress. Approximately halfway through their duty period during a time when they are not driving, participants will be asked to perform a second three-minute PVT test and rate their level of drowsiness on the Smartphone. Finally, at the end of their duty period, after they have finished driving, they will be asked to perform a third three-minute PVT test, rate their level of drowsiness, and fill out the sleep/wake/duty diary on the Smartphone. The same tasks will be expected to be completed on non-driving days: the first within two hours of waking, the second approximately halfway through the waking period, and the third within two hours of going to bed. It is expected that all of these tasks combined will not take more than 30 minutes of a participant's time each day. Participants will practice entering this data into the Smartphone app during the initial meeting with a researcher. Participants will be asked to charge the Smartphone approximately once per day to maintain charge.

Participants will also be asked to wear an actigraph wristwatch for the duration of the study. The actigraph watch will be provided to participants for the duration of the study and will

monitor sleep patterns. Data from this device will be downloaded automatically and will not require any additional time from the participant; however, participants will be asked to charge the watch once every seven days to maintain data collection. Pulsar will monitor the data coming in from the watch and if it appears the watch has not been charged, a researcher will contact the driver and ask him/her to charge the watch at their earliest convenience.

Additionally, the research team will attempt to obtain electronic log information from the fleet via their dispatching devices. However, if this information is not available it will be collected from participants via a Smartphone app. The participant will be required to enter their driving/non-driving data into the app, similar to what they currently do with paper and electronic logs. The participant will be required to send the data to Pulsar through the app on a regular basis.

Researchers will also attempt to call (and/or email) participants approximately once per week to ask if there are any questions and to encourage participants to continue to complete the necessary tasks (listed above) if they are not regularly being completed. Pulsar will also discuss any tampering to the VER at this time, such as covering the camera lens. It is expected that these phone calls will take no more than 10 minutes each.

Finally, participants will meet with a researcher at the end of their participation for a 30-minute debriefing meeting. Participants will be asked to return the actigraph watch and Smartphone at this time. Researchers will also ask participants to provide feedback relating to missing data, study equipment problems or when study procedures were not followed correctly. In addition, study participants will have an opportunity to ask questions about the study or express any concerns.

5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

Participants will be asked to complete one questionnaire (Appendix G) at the beginning of their data collection, during the same meeting when they sign the ICF. These questions will be administered on a Smartphone app and will be transferred wirelessly to Pulsar, who will store the data on a secure server. Electronic copies of the de-identified coded questionnaire data will be sent to other members of the research team who will be required to keep such files on a secure limited access server.

Participants will also be asked to have a digital picture taken of them to identify them later in the event-based data. Pictures will be taken on a digital camera and will be copied to a password-protected computer and/or a secure server on a regular basis. These pictures will be labeled with the participant's vehicle number only and will be sent to Lytx via email or through an ftp server. Lytx will never have access to participant names or contact information.

Encrypted, event-based data will be recorded using the Lytx DC3P video event recorder (VER). A VER will be installed inside the front windshield of each vehicle and will collect event-based data (8 seconds before, 4 seconds after) for hard braking, hard acceleration, hard

swerve maneuvers, and contact with other objects. In addition, events will be recorded each time the participant exceeds the posted speed limit by 5mph. This data will be recorded for up to five months for each vehicle and will be wirelessly transferred back to Lytx (at the end of each day, dependent on cell phone signal) for review and reduction. All VER data will be archived to tape backup after 90 days of being transferred to Lytx and will be deleted at the end of the study.

The VER has two camera views: one of the participant's face, and one of the forward roadway. The VER also has three accelerometers (y-, x-, and z-axis) that trigger the above noted hard braking, hard acceleration, and hard swerve maneuvers as well as GPS that allows linking to digital maps to determine speeding events.

Each participant will also be asked to wear an actigraph watch, and to conduct daily PVT tests, drowsiness assessments and sleep/wake/duty diaries as described above in section 5.1. An actigraph watch will be provided to them for the duration of the study and will be worn at all times. Data from the watch will be automatically transferred to a Smartphone app which will then automatically, and remotely, transfer the data back to Pulsar. The PVT tests, drowsiness assessments, caffeine diary, sleep/wake/duty diaries, and perceive stress assessments will also be conducted on the Smartphone and will automatically be transferred to Pulsar on a regular basis. All data will be stored at Pulsar on a secure server. De-identified versions of this data will then be sent to other members of the research team for analysis.

Finally, electronic log information will be collected from each participant to provide information on their driving/non-driving hours. The research team will first attempt to obtain this information directly from the fleet without having to involve the participant, but if the data is not available, the data will be collected directly from the participant through a Smartphone app. The driver will be required to transfer this data from the app to Pulsar on a regular basis.

5.3 DOES THE PROJECT INVOLVE ONLINE RESEARCH ACTIVITIES (INCLUDES ENROLLMENT, RECRUITMENT, SURVEYS)? Highlight the appropriate answers.

View the "Policy for Online Research Data Collection Activities Involving Human Subjects" at <http://www.irb.vt.edu/documents/onlinepolicy.pdf>

- No**, go to question 6.1
 Yes, answer questions within table -->

IF YES	
Identify the service / program that will be used:	
<input type="checkbox"/>	www.survey.vt.edu, go to question 6.1
<input type="checkbox"/>	Blackboard, go to question 6.1
<input type="checkbox"/>	Center for Survey Research, go to question 6.1
<input checked="" type="checkbox"/>	Other
IF OTHER:	
Name of service / program:	
1.	Cell phone app as described in Section 5.2 above.
2.	URL: www.restartstudy.com

This service is...

- Included on the list found at:
<http://www.irb.vt.edu/pages/validated.htm>
- Approved by VT IT Security
- An external service with proper SSL or similar encryption (https://) on the login (if applicable) and all other data collection pages.
- None of the above (note: only permissible if this is a collaborative project in which VT individuals are only responsible for data analysis, consulting, or recruitment)

Section 6: Risks and Benefits

6.1 WHAT ARE THE POTENTIAL RISKS (E.G., EMOTIONAL, PHYSICAL, SOCIAL, LEGAL, ECONOMIC, OR DIGNITY) TO STUDY PARTICIPANTS?

We have checked the more than minimal risk box in section 7.3 as we usually do for naturalistic studies not protected by a Certificate of Confidentiality because of the increased legal risk. However, because the data are event-based rather than continuous, and because the identifying data will be deleted quickly and are not being retained for long term use, we feel that the risk is lower than for most of our naturalistic commercial driving studies.

The following may be considered risks to the participant while participating in this study:

- The risk of filling out the questionnaires is minimal and similar to completing office paperwork.
- The risk that if the provided phone is lost or stolen, or confiscated by law enforcement or an employer, that these other persons will be able to view the research data and learn a drivers participant number.
- The risk of a crash associated with driving a truck as they usually do.
- The risk of being detained or arrested, or of having the vehicle impounded if the participant drives into an area where cameras are not allowed, including international border crossings, certain military and intelligence locations, and certain manufacturing facilities.
- As noted in section 5.1 above, some participants may already have a VER installed in their vehicle collecting data as part of an existing contract between their fleet and Lytx. For participants who do not already have a VER installed in their vehicle, there is an additional risk not encountered in everyday driving. While driving the vehicle, cameras will record video of the participant, their actions, and surrounding traffic. In the event of an accident, there is a risk that the video, and vehicle parametric data could be obtained in conjunction with a government inquiry, or in litigation or dispute resolution. However, under normal circumstance the participant's identity and the company the participant works for will be kept confidential.
- Because this is a federal study, the data may be considered as federal records, and there is a chance that someone not affiliated with the study may request identifying data. Such requests will be evaluated on a case-by-case basis.

6.2 EXPLAIN THE STUDY'S EFFORTS TO REDUCE POTENTIAL RISKS TO SUBJECTS:

- All data collection equipment will be mounted such that, to the greatest extent possible, it will not pose a hazard in any foreseeable way. The participant will be instructed to follow his/her company's safety protocol and will be free to withdraw from the study at any time. The participant will not be liable for VER equipment damage in a vehicular crash. The participant's participation (or withdrawal) will not have an influence on their status as an employee with their current company.
- The data collection apps on the provided Smartphone will not operate while the vehicle is in motion.
- All vehicle data (video and parametric) will be encrypted at the time it is collected (e.g., when the file is written) and will not be decrypted until it is loaded onto a Lytx server. Once the data arrives at Lytx, it will be stored on a secure server. There will be limited access to identifiable (e.g., video and GPS) data, this is explained in more detail in section 8.4 below. In addition, the participant's name will not be stored with their data, only a Participant ID number (e.g., Participant 001) so that it is not possible to identify a participant from their parametric data.
- If the provided Smartphone is lost or stolen, we will perform a remote data wipe. However, the research data will be viewable up to that point.
- Identifying video data will be archived 90 days from the time it is received from Lytx, and will be deleted at the end of the study. This should minimize the risk of someone unaffiliated with the study being provided access to identifying study data.

6.3 WHAT ARE THE DIRECT OR INDIRECT ANTICIPATED BENEFITS TO STUDY PARTICIPANTS AND/OR SOCIETY?

There are no direct benefits to the participants for the data collection portion of this study, other than they will have the opportunity to be involved in this very important research study. The results of this study will be briefed to congress and will be used to modify, as needed, the current CMV HOS regulations.

Section 7: Full Board Assessment

7.1 DOES THE RESEARCH INVOLVE MICROWAVES/X-RAYS, OR GENERAL ANESTHESIA OR SEDATION? Highlight the appropriate answer.

- No
 Yes

7.2 DO RESEARCH ACTIVITIES INVOLVE PRISONERS, PREGNANT WOMEN, FETUSES, HUMAN IN VITRO FERTILIZATION, OR MENTALLY DISABLED PERSONS? Highlight the appropriate answers.

- No, go to question 7.3
 Yes, answer questions within table -->

IF YES	
This research involves:	
<input type="checkbox"/> Prisoners	
<input type="checkbox"/> Pregnant women	<input type="checkbox"/> Fetuses <input type="checkbox"/> Human in vitro fertilization
<input type="checkbox"/> Mentally disabled persons	

7.3 DOES THIS STUDY INVOLVE MORE THAN MINIMAL RISK TO STUDY PARTICIPANTS? Highlight the appropriate answer.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily activities or during the performance of routine physical or psychological examinations or tests. Examples of research involving greater than minimal risk include collecting data about abuse or illegal activities. Note: if the project qualifies for Exempt review (<http://www.irb.vt.edu/pages/categories.htm>), it will not need to go to the Full Board.

- No
- Yes

IF YOU ANSWERED “YES” TO ANY ONE OF THE ABOVE QUESTIONS, 7.1, 7.2, OR 7.3, THE BOARD MAY REVIEW THE PROJECT’S APPLICATION MATERIALS AT ITS MONTHLY MEETING. VIEW THE FOLLOWING LINK FOR DEADLINES AND ADDITIONAL INFORMATION:
<http://www.irb.vt.edu/pages/deadlines.htm>

Section 8: Confidentiality / Anonymity

For more information about confidentiality and anonymity visit the following link:
<http://www.irb.vt.edu/pages/confidentiality.htm>

8.1 WILL PERSONALLY IDENTIFYING STUDY RESULTS OR DATA BE RELEASED TO ANYONE OUTSIDE OF THE RESEARCH TEAM? Highlight the appropriate answer and fill in text as required.

For example – to the funding agency or outside data analyst, or participants identified in publications with individual consent

- No
- Yes, to whom will identifying data be released?

The collected data is divided into two categories: 1) driving data – video, GPS, and parametric data collected from the Lytx VER, and 2) non-driving data – questionnaires, actigraph, PVT, and electronic log data collected while the vehicle is not in motion. Lytx will be the data collector for the driving data, and Pulsar Informatics will be the data collector for the non-driving data.

Only Lytx project personnel will have access to the driving data (as defined above) that personally identifies participants or that could be used to personally identify participants, and they will not have access to participants’ names, contact information, or the research participant ID number. The encrypted data will be securely transferred back to Lytx where it will be reviewed and only a de-identified data set will be provided to the rest of the research team for analysis. No identifying data collected during this study will be released to anyone else from the research team, the research sponsor, or outside of the research team, unless subpoenaed by court order.

Only Pulsar Informatics project personnel will have access to identifying information (e.g., the key code that ties the participant’s name with their participant ID) for the non-driving data (as defined above). Other team members will have access to de-identified data (e.g.,

participant ID only) both during the course of the study, and once the study is over. The project sponsor, and any outside researchers, may have access to the de-identified data set that will be posted online at the end of the study.

Because this is a federal study, the data may be considered as federal records, and there is a chance that someone not affiliated with the study may request identifying data. Such requests will be evaluated on a case-by-case basis.

8.2 WILL ANY STUDY FILES CONTAIN PARTICIPANT IDENTIFYING INFORMATION (E.G., NAME, CONTACT INFORMATION, VIDEO/AUDIO RECORDINGS)? Highlight the appropriate answer and fill in text as required.

Note: if collecting signatures on a consent form, select "Yes."

- No**, go to question 8.3
- Yes**, answer questions within table -->

IF YES
<p>Describe if/how the study will utilize study codes:</p> <p>A unique participant ID number will be given to each participant (i.e., Participant 001). All questionnaires, actigraph, PVT, electronic logs and video/parametric data will be tagged with this participant ID.</p>
<p>If applicable, where will the key [i.e., linked code and identifying information document (for instance, John Doe = study ID 001)] be stored and who will have access?</p> <p><i>Note: the key should be stored separately from subjects' completed data documents and accessibility should be limited.</i></p> <p>Lytix will use a unique-to-them participant ID number to identify participants and will not have access to the research participant ID. An excel spreadsheet will be created connecting the Lytx participant ID to the research participant ID which will be stored in a limited access folder, on a secure network at Pulsar. Other members of the research team will only have access to the research participant ID. The key code will be deleted upon completion of the study.</p>
<p>The IRB strongly suggests and may require that all data documents (e.g., questionnaire responses, interview responses, etc.) do not include or request identifying information (e.g., name, contact information, etc.) from participants.</p> <p>If you need to link subjects' identifying information to subjects' data documents, use a study ID/code on all data documents.</p>

8.3 WHERE WILL DATA BE STORED?

Examples of data - questionnaire, interview responses, downloaded online survey data, observation recordings, biological samples

The driving data collected during this study will be stored securely at Lytx facilities for up to 90 days from the time it is transferred to Lytx. De-identified driving data will be sent to other members of the research team for analysis, and will be stored on secure limited access network servers at each location.

Actigraph, PVT, and electronic log files will be stored at Pulsar on a secure network server. De-identified data sets of each will be sent to other members of the research team for analysis and such files will be stored on secure network servers at each location. Digital images of each participants face will be stored on secure network servers at Pulsar, and sent securely to Lytx for identification purposes only. The original copies of the ICF will be mailed to VTTI and will be stored in a locked file cabinet within a locked storage room, or office. Pulsar will keep a digital scan of each ICF which will be kept on a secure network server.

8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

As previously noted, the collected data is divided into two categories: 1) driving data – video, GPS, and parametric data collected from the Lytx VER, and 2) non-driving data – questionnaires, actigraph, PVT, and electronic log data. Lytx will be the data collector for the driving data, and Pulsar Informatics will be the data collector for the non-driving data.

Only Lytx project personnel will have access to the driving data (as defined above) that personally identifies participants or that could be used to personally identify participants. This encrypted data will be securely transferred back to Lytx where it will be reviewed and only a de-identified data set will be provided to the rest of the research team. Identifying driving data will be stored for up to 90 days from the time it was transferred to Lytx, and then will be deleted. Identifying digital pictures of participants will be deleted at the end of the study. Identifiable data may only be released by a court ordered subpoena. Other team members will have access to de-identified data (from both of the above noted sources) both during the course of the study, and once the study is over. The project sponsor, and any outside researchers, may have access to the de-identified data set that will be posted online at the end of the study.

Because this is a federal study, the data may be considered as federal records, and there is a chance that someone not affiliated with the study may request identifying data. Such requests will be evaluated on a case-by-case basis.

Only Pulsar Informatics project personnel will have access to identifying information (e.g., the key code that ties the participant's name with their participant ID) for the non-driving data (as defined above). Other team members will have access to de-identified data (e.g., participant ID only) both during the course of the study, and once the study is over. The

project sponsor, and any outside researchers, may have access to the de-identified data set that will be posted online at the end of the study.

8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING THE STUDY DATA

All driving data will be archived to tape after 90 days from the time it is transferred to Lytx, and will be deleted at the end of the study. Note that the tape archive is virtually inaccessible (data can only be restored by highly compensated experts while it is in archival mode). The key code tying the driving data to the non-driving data will be deleted upon the completion of the study. De-identified data will be posted online for public use and will be kept indefinitely.

8.6 DOES THIS STUDY REQUEST INFORMATION FROM PARTICIPANTS REGARDING ILLEGAL BEHAVIOR? Highlight the appropriate answers.

- No, go to question 9.1
 Yes, answer questions within table -->

IF YES
Does the study plan to obtain a Certificate of Confidentiality? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes (Note: participants must be fully informed of the conditions of the Certificate of Confidentiality within the consent process and form) <i>For more information about Certificates of Confidentiality, visit the following link: http://www.irb.vt.edu/pages/coc.htm</i>

Section 9: Compensation

For more information about compensating subjects, visit the following link:
<http://www.irb.vt.edu/pages/compensation.htm>

9.1 WILL SUBJECTS BE COMPENSATED FOR THEIR PARTICIPATION? Highlight the appropriate answers and fill in text as required.

- No, go to question 10.1
 Yes, answer questions within table -->

IF YES
What is the amount of compensation? Participants may receive up to \$2,165 if they participate for the full five months and if their work schedules allow for all 22 duty cycles. Payments will be disbursed every 60 days via check. Participants will be paid for the following: <ul style="list-style-type: none">• \$25 for attending the initial briefing and signing up for the study

- \$25 for completing a health assessment questionnaire during the initial briefing
- Up to \$1,540 for 22 duty cycles. A duty cycle is defined as a work week (i.e., 5 consecutive days of driving). Participants will be asked to complete three PVT tests per day and may receive the following payment:
 - \$3 per assessment × 3 assessments/day = up to \$9/day
 - \$9/day × 7 days in duty cycle + \$7 bonus for completing all assessments in a duty cycle = up to \$70/duty cycle
 - 22 duty cycles × \$70/duty cycle = \$1540
- Up to \$550 for 22 restart periods. A restart period is defined as non-driving time required before starting a new duty cycle. Participants will be asked to complete three PVT tests per day and may receive the following payment:
 - \$3 per assessment × 3 assessments/day = up to \$9/day
 - If all assessments are completed during a restart period, participants will receive a \$6 bonus for that restart period. Participants may receive up to \$25 for that restart period, regardless of number of days.
 - If all assessments are NOT completed during a restart period, participants will receive up to \$9/day, with a maximum of \$18 for any restart period.
 - 22 restart periods × \$25 restart period = \$550
- \$25 for attending the debriefing meeting at the end of the study

For calibration purposes, if each participant was paid \$30 per hour for completion of research activities, the daily activities are expected to take ~30 minutes (\$15). Five months x 30 days x \$15 would equal \$2250, which is very close to the maximum amount possible for this study.

Will compensation be prorated?

Yes, please describe:

See above. Participants will be paid based on what has been completed during their participation in the study.

No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study?

Unless justified by the researcher, compensation should be prorated based on duration of study participation. Payment must not be contingent upon completion of study procedures. In other words, even if the subject decides to withdraw from the study, he/she should be compensated, at least partially, based on what study procedures he/she has completed.

Section 10: Audio / Video Recording

For more information about audio/video recording participants, visit the following link:
<http://www.irb.vt.edu/pages/recordings.htm>

10.1 WILL YOUR STUDY INVOLVE VIDEO AND/OR AUDIO RECORDING?

Highlight the appropriate answers and fill in text as required.

No, go to question 11.1

X Yes, answer questions within table -->

IF YES
This project involves: <input type="checkbox"/> Audio recordings only <input type="checkbox"/> Video recordings only <input checked="" type="checkbox"/> Both video and audio recordings
Provide compelling justification for the use of audio/video recording: Video data allows researchers to perform detailed analyses of driving behaviors and driver drowsiness that are unavailable via any other means. For example, standard variables used in analyzing driver drowsiness include Observer Rating of Drowsiness (ORD) which requires observing the participants eyes and facial movements. In determining event causation, it is also important to classify and understand the external driving environment leading up to the incident. Video data collected from the cameras aimed toward the vehicle exterior accomplish this, providing researchers with information about visibility conditions, positions of other vehicles, potential distractions outside the vehicle, etc. Audio recordings are collected during each event in case the participant says something relevant to the conflict. The event-based video and audio data being collected are the standard Lytx data collected for their clients.
How will data within the recordings be retrieved / transcribed? Encrypted, event-based driving data will be transferred to Lytx via cellular service. The data will then be reviewed by trained data analysts during the data reduction process.
How and where will recordings (e.g., tapes, digital data, data backups) be stored to ensure security? All video and audio data will be recorded digitally. During this study, encrypted, event-based driving data will be transferred to Lytx via cellular service. The data will be transferred to a secure server at Lytx upon arrival.
Who will have access to the recordings? As noted in Section 8.4 above, identifiable video and audio data will be accessed by Lytx personnel only. No other team members, research sponsors, or anyone outside of the research team will have access to these recordings. Video and audio recordings will not be used for any type of meeting or conference.
Who will transcribe the recordings? The identifiable video and audio data will be transcribed by Lytx.
When will the recordings be erased / destroyed?

All identifying video and audio driving data will be deleted after 90 days from the time it is transferred to Lytx. The de-identified public dataset derived from the video and audio data that will be posted online and will be retained indefinitely.

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APPENDIX B: RECRUITMENT POSTER



ATTENTION DRIVERS Do you drive at night? Work more than 60 hrs a week?
Use the restart provision? Take one night restarts at least some of the time?

Get involved in the Hours of Service Driver Restart Study

and earn up to \$2,165 while you work.

Participate in a 5-month, on-the-job research study to compare fatigue and safety performance levels of drivers who take two nighttime rest periods during their 34-hour restart break compared to those who take less than two nighttime rest periods during their restart break.

www.RestartStudy.com

Answer questions and provide your contact details online to be considered for the study.
Must be an active truck driver whose work hours require the use of the Restart provision in the Hours of Service regulations.
Virginia Tech's Institutional Review Board reviewed and approved the study for human subject participation.

What you will do:

For the 5 month study period:

1. Drive a truck equipped with a camera facing inward and a camera facing the road to monitor driving patterns.
2. Wear a wrist activity monitor.
3. Complete a 5 min. health background survey.
4. Dedicate no more than 30 minutes a day to:

Complete sleep diary and caffeine log

Perform smartphone based assessments

Track hours of service using an ELD (Electronic Logging Device)

You will receive up to \$2,165 for completing all components during the 5-month study.

What we will do:

1. Meet with you before and after the study and answer all of your questions.
2. Provide all equipment.
3. Collect data about work and rest patterns, driving performance, and your level of alertness.
4. Arrange a weekly phone call during the study to answer any questions and provide feedback related to the data collection.
5. Provide payment monthly to reimburse you for your time.

YOUR DATA IS CONFIDENTIAL

Your data will not go on your medical or employment record, be shared with anyone at your company or be shared with the government.

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APPENDIX C: RECRUITMENT QUESTIONNAIRE

Driver: Name: _____
Address: _____
E-mail address: _____
Cell Phone #: _____
Best time to call: _____

Employer: Name: _____
Employer's Address: _____
DOT Number displayed on the door of your vehicle: _____
Motor Carrier's Phone Number: _____
Supervisor name: _____
Your immediate supervisor's phone number: _____

How many drivers work at your company?

- 1-20
- 21-100
- 101+

What type of vehicle do you drive?

- Flat-bed
- Refrigerated
- Tank
- Dry-Van
- Other

What geographic area do you regularly operate in?

- Within 100 mile radius from where you report for duty
- More than 100 miles but less than 250 mile radius from where you report for duty
- More than 250 miles from your normal work reporting location

How many miles do you normally drive each week?

- Less than 2,000 miles
- More than 2,000 miles but less than 3,000
- More than 3,000 miles but less than 4,000
- More than 4,000 miles

How many miles did you drive in 2014: _____

Which of the 395.3(b) weekly hour of service rule do you operate under?

- The 7 day 60 hour rule ()
- The 8 day 70 hour rule ()

How often does any part of your driving occur at night (between 1am and 5am)?

- 0 days per week
- 1 day per week
- 2 days per week
- 3 days per week
- 4 days per week
- 5+ days per week

How many hours do you normally log as on duty-not driving and driving each seven day period?

- Less than 50 hours
- More than 50 hours
- More than 60 hours
- Near or more than 70 hours

How often do you use the restart provision?

- Once per month
- Two times per month
- Three times per month
- Four times per month

When you use the restart provision, does your 34 hours usually include?

- A single night off duty
- Two nights off duty

APPENDIX D: INFORMED CONSENT FORM

Informed Consent for Participants in Research Projects Involving Human Participants

Title of Project: Commercial Motor Vehicle (CMV) Driver Restart Study

Investigators: Daniel Mollicone – Pulsar Informatics, Inc.
Richard Hanowski – Virginia Tech Transportation Institute

I. Purpose of this Research/Project

This study will look at the effectiveness of the 34-hour restart rule, as described in the Hours-of-Service (HOS) Regulations. This will help us better understand driver behavior and driving patterns. Data from this study will be used in a confidential way to understand commercial vehicle driving. This Informed Consent Form is to explain your role in this study.

II. Procedures

If you agree to participate in this study, you will be asked to do the following:

1. Read and sign this Informed Consent Form.
2. Fill out a W9 form.
3. Complete a Heath Assessment Questionnaire (on the Smartphone provided to you for this study) at the beginning of your participation time. A researcher will take a measurement of your neck circumference during this time.
4. Allow a researcher to take a digital photo of your face – this will be used to identify you as the correct participant when looking at the video data.
5. Drive an instrumented vehicle for up to 5 months on your normal route(s). The vehicle instrumentation includes a camera that records your face and upper body in the driver's seat and a second camera facing out the front of the truck at the forward road. Video is recorded in 12-second snippets (8 seconds before, 4 seconds after) surrounding an event of interest such as hard braking or acceleration, hard lateral swerves, and speeding (5 mph over the posted speed limit). The corresponding vehicle data is also collected at the same time (how hard you brake, your speed, GPS location, etc.).
6. Wear an actigraph watch for up to 5 months. This watch is to be worn at all times (unless swimming) and will monitor your sleeping patterns. You will be required to charge the watch battery once per week in order to keep it running.
7. Complete the following assessments three times a day, on both working days and non-working days. On working days, you will complete each assessment prior to the start of your first driving period, approximately halfway through the total driving period for your day, and at the end of your driving period. On non-working days, you will complete each assessment within two hours of waking, approximately halfway through you day, and within two hours of going to bed. During each of the described time periods, you will complete:
 - a. A psychomotor vigilance test (PVT) that requires you to look at the Smartphone screen and tap the screen when you see a counter appear at random (chance) intervals during the 3-minute test. This test measures your reaction time.

- b. A drowsiness assessment, caffeine diary, perceived stress diary, and a sleep/wake/duty diary on the provided Smartphone.

These assessments will take approximately 30 minutes each day. You will also be required to charge the Smartphone approximately once per day in order to keep it running.

8. Enter your driving/non-driving hours into an electronic log app on the Smartphone.
9. Participate in a brief (approximately 5 – 10 minute) phone call with a researcher, once a week, to review your assessments.
10. Attend a 30-minute debriefing meeting at the end of your participation to return the actigraph watch and Smartphone. You will also be asked to provide your feedback from the study to a member of the research team at this time.

For this study we will be collecting data from up to 300 commercial-vehicle drivers like you. The starting day of data collection is determined by the date when you start driving an instrumented vehicle.

III. Risks and Discomforts

There are some risks and discomforts to which you may be exposed to in volunteering for this research. These risks include:

1. The risk of a crash associated with driving a commercial vehicle as you usually do.
2. The risk of completing the questionnaires is minimal and similar to completing office paperwork.
3. The risk that if the provided Smartphone is lost or stolen, or confiscated by law enforcement or your employer, that these other persons will be able to view your research data and learn your participant number.
4. If you do not already have a Lytx Video Event Recorder (VER) in your vehicle, there may be stress associated with being recorded while driving (the video will show your face, and a forward view and your actions in response to the driving situation).
5. If you drive into an area where cameras are not allowed, including international border crossings, certain military and intelligence locations, and certain manufacturing facilities, there is a risk that you may be detained or arrested or that your vehicle may be impounded.
6. There is an additional risk not encountered in everyday driving. While you are driving the instrumented vehicle, cameras will record video of you, your actions, and surrounding traffic. In the event of an accident, there is a risk that the video and vehicle parametric data could be obtained in conjunction with a government inquiry or in litigation or dispute resolution. Even if you are not in any accidents, there is a risk of someone outside of the study requesting your data. However, under normal circumstances your identity and the company you work for will be kept confidential.

The following precautions will be taken to ensure minimal risk to the participants:

1. You will be instructed to follow your company's safety policies.
2. The Smartphone apps you will use during the study will not operate while the vehicle is moving.

3. Your participation in (or withdrawal from) this study does not have any influence on your status as an employee with your current company.
4. All data collection equipment will be mounted such that, to the greatest extent possible, it will not pose a hazard in any foreseeable way.
5. If your provided Smartphone is lost or stolen, we will perform a remote data wipe.

IV. Benefits

There are no direct benefits to you for the data collection portion of this study, other than you will have the opportunity to be involved in this very important research study. The results of this study will be briefed to congress and will be used to modify, as needed, the current CMV HOS regulations.

V. Extent of Confidentiality

The data gathered in this experiment will be treated with confidentiality. Shortly after participating, your name and the company you work for will be separated from the data and replaced with a number. That is, your data will not be attached to your name, but rather to a number (e.g., Participant 001, Location A). It is possible that the Institutional Review Board (IRB) may view this study's collected data for auditing purposes. The IRB is responsible for the oversight of the protection of human subjects involved in research.

While you are driving the vehicle, a camera will record 12-second snippets (8 seconds before, 4 seconds after) surrounding an event of interest such as hard braking, hard acceleration, hard lateral swerve, or speeding (5 mph over the posted speed limit). Video of your face and out the front of your truck will be recorded during this 12 seconds, as well as audio. An example is shown below.

All data will be encrypted at the time of data collection and will be decrypted only once it arrives back at Lytx and will be stored on a secure server. Access to the video and audio will be limited to Lytx personnel only.



If you are involved in a crash while participating in this study, the data collection equipment in your vehicle will likely capture the events leading up to the event. You are under NO LEGAL OBLIGATION to voluntarily mention the data collection equipment or your participation in this study at the time of a crash or traffic offense.

We will do everything we can to keep others from learning about your participation in the research. We may disclose information about you as required by law, in conjunction with a government inquiry, or in litigation or dispute resolution. You should understand that this informed consent does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.

Each data file will be coded for driver behavior and environmental and roadway conditions. The data will be archived 90 days from the day it is transferred to Lytx and deleted at the end of the study. The coded dataset (with no information that could be used to identify you) will be posted online at the end of the study for public use.

VI. Compensation

You may receive up to \$2165 if you participate for the full five months of this study, if your driving schedule allows for the 22 duty cycles, and if you complete all assessments as requested. You will receive a payment at the end of each month of participation. Payment will be by check, mailed to your home approximately 2 – 3 weeks after the end of each month of participation. The payment is as follows:

- \$25 for attending the initial briefing and sign up of the study
- \$25 for completing a health assessment questionnaire during the initial briefing
- Up to \$1540 for 22 duty cycles. A duty cycle is defined as a work week (i.e., 5 consecutive days of driving). You will be asked to complete three PVT tests per day and may receive the following payment:
 - \$3 per assessment × 3 assessments/day = up to \$9/day
 - \$9/day × 7 days in duty cycle + \$7 bonus for completing all assessments in a duty cycle = up to \$70/duty cycle
 - 22 duty cycles × \$70/duty cycle = \$1540
- Up to \$550 for 22 restart periods. A restart period is defined as non-driving time required before starting a new duty cycle. You will be asked to complete three PVT tests per day and may receive the following payment:
 - \$3 per assessment × 3 assessments/day = up to \$9/day
 - If all assessments are completed during a restart period, you will receive a \$6 bonus for that restart period. You may receive up to \$25 for that restart period, regardless of number of days.
 - If all assessments are NOT completed during a restart period, you will receive up to \$9/day, with a maximum of \$18 for any restart period.
 - 22 restart periods × \$25 restart period = \$550
- \$25 for attending the debriefing meeting at the end of the study

If you elect to withdraw from the study or if your employment is terminated, you will be compensated for your participation up to that time. You will be asked to return the actigraph watch and Smartphone if you end your participation early.

VII. Freedom to Withdraw

Participation in this research is voluntary. You are free to withdraw at any time without penalty. If you withdraw, are dismissed from the study, or if your employment is ended, we will retain data collected before that time, but delete any data collected in the interval between when we become aware of the withdrawal/dismissal and before we are able to remove the data collection equipment. If you withdraw from the study, or if your employment is terminated, you will be paid for your participation up to that time. Withdrawal from this study will not adversely affect your employment status.

VIII. Approval of Research

This research project has been approved, as required, by the Institutional Review Board for Research Involving Human Participants at Virginia Polytechnic Institute and State University. You should know that this approval has been obtained and is valid for the dates listed at the bottom of this form.

IX. Participant's Responsibilities

I voluntarily agree to participate in this study. I have the following responsibilities:

1. You will be instructed to follow your company's safety policies.
2. You will maintain a valid Commercial Driver's License throughout the course of the study
3. To follow the experimental procedures as well as I can.
4. To inform the experimenters if I incur difficulties of any type.

X. Participant's Permission

I have read and understand the Informed Consent and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent for participation in this project.

If I participate, I understand that I may withdraw at any time without penalty.

Participant's name (print)

Signature

Date

Experimenter's name (print)

Signature

Date

Should I have any questions about this research or its conduct, I may contact:

Daniel Mollicone, *Co-Investigator*
Richard Hanowski, *Principal Investigator*

(215) 520-2630, daniel@pulsarinformatics.com
(540) 231-1513, rhanowski@vti.vt.edu

If I should have any questions about the protection of human research participants regarding this study, I may contact:

Dr. David Moore, Chair Virginia Tech Institutional Review Board for the Protection of Human Subjects
Telephone: (540) 231-4991; Email: moored@vt.edu

Participants must be given a complete signed copy (or duplicate original) of the informed consent.

APPENDIX E: BACKGROUND SURVEY QUESTIONNAIRE

Background Survey

Please answer all questions as accurately as possible.

All information is confidential.

Boxes should get a checkmark or an "X". Example:

Blank lines allow you to input your answer as a number or text response.

A-C. Gender? male female Married? yes no Age? _____years

1. What is your height? _____feet _____inches
2. What is your weight? _____pounds 3. Neck Circumference? _____inches
4. Has a physician informed you that you have any of the following conditions? (Please mark all that apply to you.)
 Sleep apnea Diabetes High blood pressure Insomnia
5. Do you use any of the following? (Please mark all that apply to you)
 CPAP for sleep apnea Medication for diabetes
 Medication for high blood pressure Medication for insomnia

6. What is your usual caffeine consumption during a daily work shift? (Check all that apply to a typical daily work shift.)

No caffeine consumed in a daily work shift. (If you take caffeine, fill out next line)

Indicate average number consumed per daily work shift

Coffees Cola drinks Energy drinks Caffeine pills Tea (not herbal)

7. Do you use tobacco products during a daily work shift? (Check all that apply to a typical daily work shift.)

No tobacco products used in a daily work shift. (If you use tobacco, fill out next line)

Indicate average number used per daily work shift

Cigarettes cigars chew tobacco smoke pipe Nicotine gum

8. How often do you experience pain of any kind during a typical daily work shift? (Check only 1 box)

0-5% of shift 5-25% of shift 25-50% of shift 50-75% of shift 75% of shift

9. Have you participated in a Fatigue Management Program (FMP)?

Check a box: yes no

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LIST OF ACRONYMS, ABBREVIATIONS, AND SYMBOLS

Acronym	Definition
AVECLOS	mean percent eye closure
BMI	body mass index
CPAP	Continuous Positive Airway Pressure
CMV	commercial motor vehicle
DHS	Department of Homeland Security
ELD	electronic logging device
FMCSA	Federal Motor Carrier Safety Administration
FS	fatigue scale
ftp	file transfer protocol
GEE	generalized estimating equation
GPS	global positioning system
HOS	hours of service
ICF	Informed Consent Form
ID	identification
IRB	Institutional Review Board
KSS	Karolinska Sleepiness Scale
NASA	National Aeronautics and Space Administration
NIH	National Institutes of Health
NSBRI	National Space Biomedical Research Institute
OIG	Office of Inspector General
OBMS	onboard monitoring system
OMB	Office of Management and Budget
ORD	observer rating of drowsiness
PDF	portable document format

Acronym	Definition
PERCLOS	percentage of time that the eyes were closed 80 percent or more
PRP	Peer Review Panel
PVT	Psychomotor Vigilance Test
PVT-B	Brief Psychomotor Vigilance Test
REML	restricted maximum likelihood
SAS	Statistical Analysis System
SCE	safety-critical event
SQL	Structured Query Language
SS	stress scale
TST	total sleep time
USDOT	U.S. Department of Transportation
VER	video event recorder
VTTI	Virginia Tech Transportation Institute

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