Reducing Fatigue among Taxi/Rideshare Drivers

New Information Collection Request

Supporting Statement Part A –

Justification

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Table of Contents

Part A. Justification

Goal of the study: The goal of this study is to evaluate an online, interactive training on fatigue management tailored to taxi drivers and other for-hire rideshare drivers.

Intended use of the resulting data: The project findings could be used to prevent fatigue-related motor vehicle crashes impacting not only drivers but others sharing the streets, roads, and highways, including pedestrians and other motor vehicle and micro-mobility users. The findings would provide the evidence base for adaption and use of the training by company managers, labor associations and transportation regulators.

Methods to be used to collect: The proposed study is a longitudinal, randomized design comparing two interventions and a control over 5 study periods. One group of 60 drivers will receive both interventions: fatigue training and daily feedback on estimated fatigue score. A second group of 60 drivers will receive only the fatigue training. A third group of 60 drivers will receive neither intervention. All participating drivers will take a self-administered questionnaire, wear an actigraph to measure sleep quality, complete a sleep and activities diary, and take a sleep health and driving knowledge assessment. Drivers taking the training will be asked to complete an evaluation.

Subpopulation to be studied: 180 adult, licensed for-hire (e.g., taxi, rideshare) drivers in San Francisco, California.

How data will be analyzed: We will statistically compare across study groups and over 5 study periods: daily sleep duration and quality, alertness measures, self-rated sleepiness and fatigue, road safety behaviors and productivity.

A.1. Circumstances Making the Collection of Information Necessary

The mission of the National Institute for Occupational Safety and Health (NIOSH or the Institute), Division of Safety Research (DSR), is to identify, reduce, and prevent work-related injuries and deaths across all industries. Data collection for these purposes is authorized by the Occupational Safety and Health Act of 1970 (29 U.S.C. 657(g) (Attachment 1). As required by the Paperwork Reduction Act, NIOSH announced plans to collect information by publishing Notices in the Federal Register (Attachment 2).

Taxi drivers are ubiquitous, driving day and night, in urban, heavily trafficked streets and highways that are shared with commuters, drivers running errands, parents shuttling children, motorcyclists, bicyclists and pedestrians. In New York City, a typical taxi is driven 70,000 miles a year (NYCTLC, 2014). Among drivers in the taxi industry, the prevalence rate of motor vehicle crashes resulting in both fatal and nonfatal injuries and their associated costs ranks higher than most industries (BLS, 2016a,b; Chen, 2009; NETS, 2015). The severity associated with motor vehicle crashes in the taxi industry is higher than most industries for nonfatal injuries treated in emergency departments (Chen, 2009). The costs are in the tens of billions of dollars to employers and in disabling injury to drivers across all industries (NETS, 2015).

Fatigue among occupational drivers has been reported to contribute to at least 21% of fatal motor vehicle collisions and a likely substantial piece of an estimated $25 billion cost to employers in on-the-job crashes (AAA, 2013; NETS, 2015). In the driver-for-hire industry drivers are called upon at any time of day or night and the on-demand economy has created an additional workforce of drivers who likely already work other primary jobs. Fatigue ranks alongside inadequate seatbelt use, distracted driving, impaired driving and speeding as the leading modifiable direct contributors to motor vehicle crashes. The risk factors for fatigue are prevalent among taxi drivers – stress, long work hours, shift work, driving late at night or early in the morning, and inadequate rest breaks (Burgel, 2012). A recent field survey found a concerning level of drivers in two cities reported having driven while tired, having experienced difficulty driving due to tiredness or fatigue, and having nodded off while driving (Chaumont Menéndez, 2019). Fatigue and its associated motor vehicle crashes and related injuries are a threat to road safety in the most highly populated areas.

While fatigue is not limited to workers whose primary job duty is driving, targeting taxi drivers for public health research and action provides an opportunity to reduce fatigued driving in a high-risk worker population. With such high exposure to motor vehicle crash risk, an effective intervention designed to educate drivers about fatigue and help them identify and manage their fatigue could significantly reduce the burden of fatigue-related motor vehicle crashes.

Historically the driver-for-hire industry has lacked capacity and support to push for public health interventions to improve the health and safety of drivers. Public health interventions for

drivers-for-hire have been further stymied by tensions between the two segments of the industry, with taxi operators trying to force transportation network providers (TNPs) into pre-existing local regulatory frameworks. This is a workforce that is generally regulated at the municipal level and there is neither expertise nor resources for such safety efforts. Hours of service laws limiting the number of hours a taxi (or ride sharing) driver can drive in a 24-hour period have been enacted in at least a few cities (NYC, San Francisco, Houston) as a best practices measure. However, to our knowledge there is no educational component provided to the drivers that explain why the laws are in place, the science of sleep health, how to assess and improve your own sleep health, and countermeasures to sleepiness while driving. The necessity of an accessible fatigue management training demonstrated to be both effective and cost-effective cannot be overstated.

To meet the needs of for-hire drivers and the public, NIOSH has developed an online training program aimed at reducing driver fatigue in a cost-effective manner. The intervention will be an approximately 3-hour web-based interactive course on fatigue as developed in this study using previously validated training among nurses: Caruso CC, Geiger-Brown J, Takahashi M, Trinkoff A, Nakata A. [2015]. NIOSH Training Program for Nurses on Shift Work and Long Work Hours. (DHHS (NIOSH) Publication No. 2015-115). Cincinnati, OH: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. www.cdc.gov/niosh/work-hour-training-for-nurses. Before releasing the new online training for drivers, NIOSH must evaluate the training to obtain critical feedback and determine if parts of the training need editing to reinforce or modify sections of the content.

We propose to conduct a randomized controlled trial with three groups of 60 drivers each: one group receiving the training only, a second group receiving both the training and feedback in the form of a daily fatigue score, and a third (control) group receiving neither the training nor the fatigue score feedback. A survey evaluating the training (Attachment 4) for the 120 drivers who will take the training will be used to further improve the delivery of the key learning points, identify the strengths and weaknesses of the training, and identify barriers in this key workforce to improving their sleep health. All three participant groups will wear a wrist actigraph that passively records sleep and activity patterns and produces a personalized fatigue score. Study participants will also be asked to complete the online Work and Health Survey (Attachment 5), Sleep Health Knowledge Assessment (Attachment 6), and the brief daily sleep and activities diaries (Attachment 7).

Study activities and participant assignments are summarized as follows:

Overview of Study Design and Activities, by Participant Group			
Study Task / Data Collection Activity	Participant Group		
	Intervention: Fatigue Training Only (n=60):	Intervention: Fatigue Training + Daily Actigraph Feedback (n=60)	Control Group (n=60)
Online training (one-time)	x	x	
Online Training Evaluation Survey (one-time)	x	x	
Wrist actigraph (continuous passive data collection)	x	x	x
Daily feedback on wrist actigraph fatigue score		x	
Maintain daily sleep and activities diary (5 entries/day x 5 weeks = 175 entries)	x	x	x
Work and Health Survey (5 times over study period)	x	x	x
Knowledge Survey (5 times over study period)	x	x	x

The data collection and analysis plan is organized into 5 observation periods that include measurements before and after the training intervention and allow for comparisons over time. There are approximately 15 weeks of data collection per participant.

The study data collection schedule is summarized below:

O_1	O_2	I_{T+FS} O_3		O_4	O_5
O_1	O_2	$I_{T\ only}$ O_3		O_4	O_5
O_1	O_2	C_o O_3		O_4	O_5

−4	−3	−2	−1	0	1	2	3	4	5	6	7	8	9	10	11	12	13

Weeks
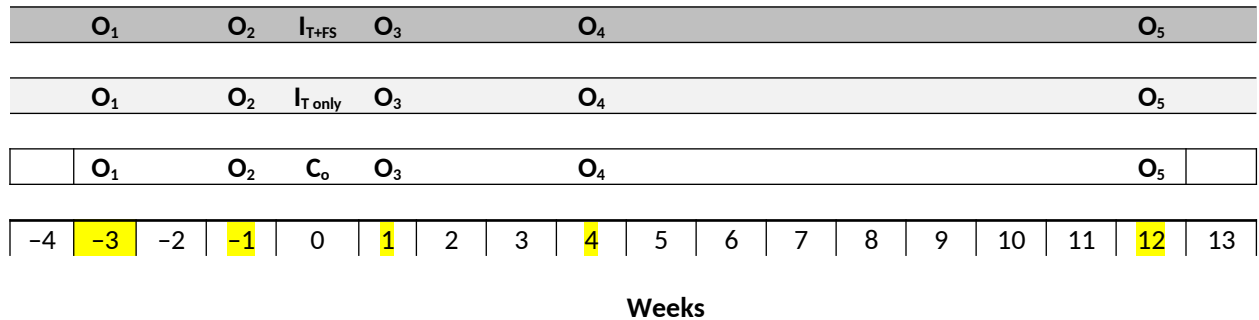
☐ Study Group 1

☐ Study Group 2

☐ Study Group 3

$O_\#$ = Observation period
C_O = Control
$I_{T\ only}$ = Intervention period for training only
I_{T+FS} = Intervention period for training plus fatigue score feedback

The study will be conducted in one major metropolitan area. We have company support and the regulator of one of the largest metropolitan areas in the U.S. (Attachment 3). Fatigue and driving has been a longtime concern of theirs.

OMB approval is requested for 2 years. This will allow CDC to work with the contractor and participants to identify the optimal period for initiating recruitment (after receipt of OMB approval); allow for rolling recruitment until the target number of participants is reached; and ensure that the data collection period accommodates all follow-up data collection for all participants.

A.2. Purpose and Use of the Information Collection

The research team will test the hypotheses that each intervention group experienced improved sleep quality, increased alertness, decreased sleepiness, improved road safety behaviors, and increased productivity compared to pre-intervention and compared to the control group. The research team will also test that these hypothesized changes persisted for 3 months post-intervention.

The specific questions to be answered with this research:

1) Are there improvements in taxi/rideshare drivers' sleep health, specifically sleeping patterns as measured by sleep quantity, timing and quality after completing the training program?

2) Were these improvements observed through at least 3 months after the training?

3) Are there improvements in taxi/rideshare drivers' reaction times and self-reported sleepiness levels after the training, and did this translate to increased road safety and productivity? Were these improvements observed throughout the 3 months post-training?

4) Are there greater improvements in taxi/rideshare drivers' sleep health, reaction times and self-reported sleepiness levels for drivers getting sleep score feedback compared to only receiving the training? Were these greater improvements observed throughout the 3 months post-training?

5) Was there an increase in sleep health and driving knowledge as measured by the knowledge assessments compared to before the training and compared to the control group? Did the knowledge changes persist through the 3 months after the training?

6) What are barriers to incorporating the knowledge gained from the training? What are things that can be improved upon in the training? What are things that were done well with the training?

7) Do responses on the survey items indicate the training is clear and readily understood by this population?

8) Do responses on the survey items indicate the training is persuasive?

9) Do parts of the training need editing to make the messages clearer? Was the length of the training appropriate?

10) Do participants report they incorporated the strategies in their personal life? Which ones?

The goal of this project is ultimately to educate this workforce so they can responsibly operate their vehicles for the good of public safety while still making a living. This project in its entirety will benefit not only drivers-for-hire but public safety (passengers, pedestrians, bicyclists, other drivers). The findings will improve the training and offer guidance on the effectiveness of the latest technology designed to measure fatigue by the drivers themselves. After taking the training, drivers for hire, including those hired by TNPs such as Uber and Lyft, are expected to adopt workplace strategies (e.g., driving schedules, scheduling patterns) and personal strategies (e.g., good sleep habits, effective use of fatigue countermeasures). In doing so drivers for hire will be increasing their sleep health, leading to safer road safety behaviors, reduced injury rates and increased productivity. The long-term goal of this project is to improve the life span and health of taxi drivers, who are gig economy workers with no retirement structure or healthcare plans through the company they contract with and need the daily work. There is an entire workforce that drives on demand, available 24/7 who may be operating on little to no sleep. The availability of a free, online learning tool will bridge a large gap in driver safety for workers who exclusively drive for a living. Access to this training will improve sleep health and road safety habits while also providing equitable access to the diverse population of drivers represented in this workforce where inclusion extends to all drivers having access to and understanding how sleep health relates to road safety.

Without this evaluation, we will not have the evidence needed to determine if the training was clear and persuasive and imparted knowledge that led taxi/rideshare drivers to make positive changes to their daily lives, to improve their sleep and improve their reaction times while reducing their sleepiness on the job.

A.3. Use of Improved Information Technology and Burden Reduction

There are two types of data collection activities the participants will be involved in: those resulting from answering surveys and those resulting from data generated simply by wearing an actigraph on the wrist. The actigraph is automated and records activity to estimate times of sleep and activity to generate an estimated fatigue score the driver can choose to monitor during the study periods. This is akin to periodically checking your watch to keep up on the time. The survey instruments are designed to support the collection of data needed to evaluate

the interventions with as much ease for the driver as possible. To the extent possible the contractors awarded the contract will create electronic surveys based on Word versions of the surveys we will provide them with. These include a Work and Health Survey needed to be completed at baseline of each study period – after study period 1 an abridged version will be used. Computerized skip patterns are incorporated throughout the survey to minimize participant burden. The Sleep Health Knowledge Assessments are straightforward questions needed to measure changes in knowledge, will be administered electronically, and will only involve the participant marking the correct answer from multiple choices. The daily sleep and activities diaries take a couple of minutes to complete and will be referred to and completed throughout the waking time. The sleep and activities diaries were designed by drivers in this workforce to fit into the shirt pocket and completed by hand throughout the day for ease of referral. The training evaluation will only be completed once for two-thirds of the participants and will be administered electronically.

Taken altogether these approaches will reduce the data entry burden to the participant and the data collection and processing burden to the research team.

A.4. Efforts to Identify Duplication and Use of Similar Information

There is no known online training tailored for drivers for hire, free or otherwise, available to this workforce. The project officer has performed multiple literature searches, regularly attends national transportation (Transportation Research Board) and transportation regulation (International Association of Transportation Regulators) conferences and has not encountered any similar research or product. Recent communication with Al LaGasse, CEO of The Transportation Alliance, revealed the lack of and need for such training for this workforce.

There is no known research study of any size that can be generalized to this workforce that has a unique combination of job tasks (exclusively driving), work scheduling, client availability (on demand, 24/7 for an unknown length of time), organizational structure (no set hours or break times) and employment agreement (independent contractor with no healthcare/retirement benefits). This workforce is also very diverse with respect to age, race/ethnicity, nativity, and educational attainment.

We have built upon foundational research that was conducted by the principal investigator in a previous funded project. Specifically, we conducted a cross-sectional survey of taxi drivers in Houston and Los Angeles to determine the extent to which drivers experience violence from passengers, motor vehicle crashes, and drowsy driving. The Work and Health Survey was adapted from the one we used in the cross-sectional survey. One publication from this research, Chaumont Menendez C et al [2019], reported on individual, business-related, and

work environment factors associated with driving tired among taxi drivers in two metropolitan U.S. cities. A second publication from this research, Chaumont Menendez C et al [2022], reported on the validity of the Occupational Driver Behavior Questionnaire (ODBQ) on measuring road safety behaviors in taxi drivers. The ODBQ has been included in the Work and Health Survey for the proposed data collection request.

So that our findings could be comparable with those focused on other workforces where shiftwork and working long hours are involved, we are using the following scales:

 The Epworth Sleepiness Scale measures excessive daytime sleepiness and has been previously validated: Johns, M. W. (1991). A new method for measuring daytime sleepiness: the Epworth sleepiness scale. Sleep, 14, 540-545.

The Pittsburgh Sleep Quality Index measures sleep quality and disturbances over the previous month: Buysse, D. J., Reynolds, C. F., III, Monk, T. H., Berman, S. R., & Kupfer, D. J. (1989). The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res, 28, 193-213.

The sleep and activities diary was adapted from a recent NIOSH study among police officers that used the following: Carney, Colleen E., et al. "The consensus sleep diary: standardizing prospective sleep self-monitoring." Sleep 35.2 (2012): 287-302.

Actigraphy will be used in the context of the sleep and activity diary to assess behavior changes. Actigraphy has been validated for use in clinical and research settings: Ancoli-Israel S, Martin JL, Blackwell T et al. [2015]. The SBSM Guide to Actigraphy Monitoring: Clinical and Research Applications. Behavioral Sleep Medicine, 13:supl 1, S4-S38.

The Fatigue Knowledge Survey will measure the knowledge of sleep health and strategies to reduce sleepiness and evidenced-based ways to promote alertness as related to work and health. The Fatigue Knowledge Survey was adapted from previous NIOSH studies and products. These items are part of the test to measure knowledge retained from an online training program for police officers: NIOSH, Caruso CC, Geiger-Brown J, Takahashi M, Trinkoff A, Nakata A. [2015]. NIOSH training for nurses on shift work and long work hours. (DHHS (NIOSH) Publication No. 2015-115). Cincinnati, OH: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. [www.cdc.gov/niosh/docs/2015-115/]

To our knowledge our research project will provide the only material available to drivers for-hire at no cost for use by municipal governments, companies, and labor groups. Having this training available on a NIOSH website accessible by multiple electronic platforms is considered the best way to sustainably offer such training due to NIOSH subject matter and technical expertise. Contracts with graphics and video production companies have already produced the training.

A.5. Impact on Small Businesses or Other Small Entities

The participants in this study will be taxi/rideshare drivers who are considered independent contractors of San Francisco companies that can be considered small businesses. One company, FlyWheel, has given us their full support to conduct this research they believe will help improve the health and productivity of their drivers. The surveys take a total of one hour to complete for each study period. The sleep and activities daily diaries take a couple of minutes to complete several times each waking period. The research team held the number of questions to the absolute minimum required to assess the training and provide a scientifically rigorous study design to make the conclusions needed about the training effectiveness. Participation in the study should not negatively affect the companies where the drivers work. The study does not impose any ongoing burden to small businesses.

A.6. Consequences of Collecting the Information Less Frequently

The respondents will respond to the information collection once. The research team has made every effort to design a scientifically rigorous study that will stand on its own and provide conclusive evidence on the effectiveness of the proposed interventions in this unique workforce. The study is a randomized controlled trial where two different interventions (one educational, the other behavioral) are evaluated. This study design is considered the gold standard in evaluating effectiveness of interventions. Such a study involves pre-intervention data collections periods, the interventions, and then several post-intervention data collection periods. Each data collection period will be measuring changes in items of the Work and Health Questionnaire that could change over time and, therefore, impact the interpretation of the findings. The Sleep Health Knowledge Assessments are needed both pre and post-training to evaluate changes in knowledge leading up to the training intervention, and then evaluate changes in knowledge after the training intervention and to see if the material was learned by the participants, when it was learned, and if the learning was maintained for at least 3 months after the training. The actigraph data, accompanied by the sleep and activities daily diaries for added validity for sleep quantity measurements, are needed for two data collection periods before the interventions to get a solid trend in baseline measurements of sleep patterns for a full 7 days. Three data collection periods after the interventions are needed to detect changes in sleep patterns to determine sleep quantity and quality. The data collection periods were timed to allow changes to occur and still provide meaningful measures of change. The 3rd data collection period is timed for a full 2 weeks after the intervention to assess immediate responses to the training but still provide time for changes in sleep habits to be implemented. The 4th data collection period is timed for a full 4 weeks after the intervention to assess less immediate but still proximal changes in sleep patterns and other outcome measures and to assess if changes made in the 3rd data collection are still there. The 5th data collection period is timed for a full 12 weeks post-intervention to assess the 'honeymoon' period (level of adoption)

of any changes in sleep patterns that have occurred and still detect those from participants who needed more time to implement them. It is assumed that if sleeping behaviors were adopted within 3 months of training and their adoption was maintained throughout the 3 months, then they can be considered a habit. Examining sleeping behavior changes throughout 3 months post-intervention also allows us to see if sleeping behaviors keep improving, are plateauing or are declining. Having post-intervention data collection periods longer than 3 months would make for a more time-intensive and expensive study while increasing the possibility of attrition and burden among the study participants. Gathering less data will not allow the research team to answer the research questions or make causal inferences, thus limiting the evidence-base of the usefulness and effectiveness of the training program. There are no technical or legal obstacles to reducing burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice was published in the *Federal Register* on July 20, 2020, Vol. 85, No. 139, pp. 43843-4 (**Attachment 2**).

- CDC/ATSDR received one substantive comment. The CDC/ATSDR response is provided (**Attachment 2a**).

A 60-day Federal Register Notice was published in the *Federal Register* on September, 17, 2021, Vol. 86, No. 178, pp. 51892-3 (**Attachment 2**).

- CDC/ATSDR received no substantive comments. The CDC/ATSDR response is provided (**Attachment 2a**).

A 60-day Federal Register Notice was published in the *Federal Register* on March, 10, 2023, Vol. 88, No. 47, pp. 15026-8 (**Attachment 2**).

- CDC/ATSDR received no substantive comments. There were four comments that were received. Some comments were positive affirmations or not responsive to the current request for comments. The CDC/ATSDR response is provided for one of the comments (**Attachment 2a**).

B. The project officer has experience in conducting OMB-approved research among taxi/rideshare drivers. Taxi drivers, management, rideshare drivers and management, and transportation industry regulators (fewer than 9) provided input into the study protocol and its data collection instruments. They reviewed the study protocol and data collection instruments for technical accuracy, literacy levels, and submitted questions for the data collection instruments if they thought additional questions were needed. The study team incorporated all of their comments.

All study instruments and the protocol have been peer reviewed (and suggestions incorporated) by drivers for hire, company management, transportation regulators, industry safety professionals, and sleep health researchers. The following external experts were consulted during 2018 to provide feedback about the methods for the study. They all approved the study methods and had just a few minor suggestions. The contact information and titles at the time of the consultations are listed below.

- Laura Barger, PhD, Assistant Professor in Medicine, Harvard Medical School; Associate Physiologist, Division of Sleep and Circadian Disorders, 530.753.2876, lkbarger@hms.harvard.edu

- Erin Flynn-Evans, PhD,MPH, Director, NASA Ames Research Center Fatigue Countermeasures Laboratory, 650.279.3459, erin.e.flynn-evans@nasa.gov

- Barbara Burgel, RN, PhD, FAAN, FAAOHN, Professor of Clinical Nursing, Emeritus, University of California at San Francisco School of Nursing, 415.476.1381, Barbara.burgel@gmail.com.

- Charles Rathbone, BS, Retired taxi driver and company manager, 415.500.2431, Charles.rathbone@sonic.net

- Edward Escobar, Founder, Alliance for Independent Worker, Labor organization for gig workers, 415.992.0061, theAllianceorg@outlook.com.

- Jarvis Murray, Esq, Administrator, For-Hire Policy and Enforcement Division, Los Angeles Department of Transportation, 213.972.8470, jarvis.murray@lacity.org.

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A.9. Explanation of Any Payment or Gift to Respondents

The research team will provide the study participants with an incentive after completing each data collection period: a $40 gift card. There are 5 one-week data collection periods that can total to $200 in incentives for completing the study. The staggered incentive of a $40 gift card after the completion of each data collection period will promote retention to endpoint while encouraging continued participation. This will be provided to show appreciation for the time they will spend completing the questionnaires and knowledge test at the beginning of each data collection period, wearing the actigraph for 10-days throughout each data collection period, and completing the daily sleep and activities diaries several times a day throughout

each data collection period. Additionally, the drivers who are invited to watch the 3-hour training and complete an evaluation of the training will be provided a gift card for $53.40 as an incentive. The research team has found similar incentives were useful for participation in their previous studies of taxi drivers.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The collection contains PII with demographic information in the survey (i.e., Study-ID, Name). The Privacy Impact Assessment (PIA) determination was approved January 20, 2023 by NIOSH's ODIT and the Information Systems Security Officer (ISSO) determined in conjunction with the CDC Privacy Office that the Privacy Act applies. The applicable Privacy Act Systems of Record Notice (SORN) is 09-20-0147, "Occupational Health Epidemiological Studies and EEOICPA Program Records."

The DLO will plan to utilize the following systems: Research Electronic Data Capture (REDcap) and NIOSH Edge Computing Platform (NCEP). REDCap and NCEP include the in-place technical, physical, or administrative controls (safeguards).

SSN is used within the project and is requested for participants who want a completion bonus for their participation and receive a gift card after completing each data collection period. SSN is necessary to provide participants with the appropriate IRS form needed to file for their taxes as required by law. SSN is currently contained within the spreadsheet in the CDC MUST. The DLO will migrate all PII involved with the project to the NCEP.

The Research Electronic Data Capture (REDcap) and NIOSH Edge Computing Platform (NCEP) System Security Plan (SSP) define the process for handling security incidents. The system's team and the Cybersecurity Program Office (CSPO) share the responsibilities for event monitoring and incident response. Direct reports of suspicious security or adverse privacy related events to the component's Information Systems Security Officer (ISSO), CDC helpdesk, or to the CDC Security Incident Response Team (CSIRT). The CDC CSPO reports to the HHS Computer Security Incident Response Center (CSIRC), which reports incidents to US-CERT as appropriate.

NIOSH study key personnel (NIOSH employees only) record a unique study identification number for each participant (generated by the participant) to allow study staff to match the surveys, diary, and actigraph files for each participant. NIOSH will file and retrieve IIF by the study identification number (ID). NIOSH will collect, store and process IIF in using the NIOSH IT & Informatics Services approved Virtual Volume (housed within the EDGE Computing Platform). As is standard and required by law, the consent forms will contain: the authority of collecting the data, the purpose for collecting the data, with whom CDC will share identifiable information, the voluntary nature of the information collection, and the effect upon the respondent for not participating. NIOSH study key personnel (NIOSH employees only) will store the list that matches the study identification number and name within the NIOSH IT & Informatics Services approved Virtual Volume that is only accessible by NIOSH study key

personnel (NIOSH employees only). NIOSH study key personnel (NIOSH employees only) will destroy the list that matches the participant's name and identification number after the study has been completed. NIOSH study key personnel (NIOSH employees only) will collect participant name and preferred contact information the study participant decides to share to contact the participant during the study. NIOSH will own the data without identifiers. The respondent will be informed about all the security measures for privacy protections in the consent form and accompanying consent presentation (**Attachment 9b**). In addition, the respondent will be informed that his or her response is voluntary and there are 5 short questions at the end of each baseline questionnaire per data collection period that asks if the respondent understands participation is voluntary.

To summarize: All data will be collected, stored, and processed using CDC approved systems. Data are collected through the REDCap system hosted within CDC and required for CDC surveys (this means it is CDC approved). All data, including any PII such as SSN, will only be stored on the NIOSH IT & Informatics Services approved Virtual Volume (housed within the EDGE Computing Platform). The data will only be accessed using the Windows Analytical preconfigure virtual workspace environment and the provisioned software (these are all CDC-approved). Research data without PII will be collected at multiple time points ("collection periods") during the study and therefore must be linked by a study ID (identification number) assigned by the project officer during the individual participant consent process. The study ID is separately stored in a spreadsheet with corresponding PII (e.g., Name, SSN) in the CDC-approved storage. This spreadsheet will only be used by the project officer in order to remunerate the study participant for their time after each completed data collection period. No PII will be used for analysis or shared beyond this remuneration task. Any reference to the 'Cloud' is meant to be interpreted as the FedRAMP, CDC approved system as it is housed within the EDGE Computing Platform.

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

IRB Approval

NIOSH IRB determined this study is an activity that is: (1) research; (2) involves human subjects; (3) is not exempt from the regulations governing human subjects research. NIOSH IRB approved the study in May 2022. See **Attachment 10**.

Sensitive Questions

There are very few questions asked that are considered sensitive. We are using standard and validated approaches taken from OMB-approved national surveys to ask these questions.

Again, the respondent will be informed their response to these questions are completely voluntary.

For the Work and Health Survey (**Attachment 5**): We will be asking the driver's gender and have adopted the questions recommended by the GenIUSS group's best practices for gender identity. The study is meant to be inclusive of all taxi/rideshare drivers driving in a city that has historically represented, welcomed, and promoted the LGBTQ community. Consistent with the CDC Health Equity Guide our goal is to make every effort for inclusiveness in our research.

We will be asking about race and ethnicity in the demographic section towards the end of the Work and Health surveys because we need to evaluate effectiveness of the training and sleep scores by race and ethnicity to strive for an intervention that is equally effective for all drivers. The questions used to establish race/ethnicity are taken from the Bureau of Census and are found in the 2nd to last section of the Work and Health Survey under 'Demographics'. We have preserved the questions for assessing race/ethnicity in the two-question format to align with OMB guidance.

Additionally we will administer the Patient Health Questionnaire-4 (PHQ-4) for mental health as it is related to sleep quality and is an important potential confounder for the analyses. Both of the race/ethnicity questions and the PHQ-4 will be at the end of the Work and Health survey administered baseline for each data collection period. We will ask very general questions about substance use, such as alcohol and other drugs, as they affect the dependent variables (fatigue levels and alertness) and will impact the effectiveness of the intervention by a potential confounder in many of the analyses. Questions on substance use are taken from the national Behavioral Risk Factor Surveillance System.

For the Sleep and Activities Diary (**Attachment 7**): We will ask for participants to report daily quantities of substance use, such as alcohol and other drugs, as they affect the outcomes in the statistical analyses and are crucial for controlling.

For the Informed Consent form (**Attachment 9a**): We will ask for participants to provide their Social Security number ONLY IF they want a completion bonus for their participation and receive a gift card after completing each data collection period so we can provide them with the appropriate IRS form needed to file for their taxes as required by law.

A.12. Estimates of Annualized Burden Hours and Costs

OMB approval is requested for 2 years. The target number of total participants is 180, assigned to a control group (n=60), and two intervention groups (n=120) who will take the fatigue training. For purposes of burden annualization and estimation in the table below, the number of respondents for each group is one half of the total number of respondents for that group.

Only participants who complete the training will be asked to complete the one-time online Fatigue Training Evaluation Survey (Attachment 4). Data collection is the same for all other components. Each respondent (participating taxi/rideshare driver) will complete 5 data

collection periods that consist of: a Work and Health survey (Attachment 5, 45 minutes), the Sleep Health Knowledge Assessment (Attachment 6, 15 minutes), and the Sleep and Activities diary (Attachment 7, 5 minutes, 5 times per day). The number of responses per respondent includes total responses per data collection period multiplied by the 5 data collection periods. In the case of the Sleep and Activities diary, respondents will provide entries 5 times per day, for 7 days, for 5 weeks ("data collection periods") for a total of 175 responses.

All participants will wear an actigraph that permits continuous, passive data collection. It will take 10 minutes to receive and fit the actigraph for each participant (Attachment 8).

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Taxi and Rideshare Drivers	Fatigue Training Evaluation Survey	60	1	15/60	15
	Actigraph Training and Fitting	90	1	10/60	15
	Sleep & Activities Diary (including Psychomotor Vigilance Test)	90	175	5/60	1,313
	Work & Health Survey	90	5	45/60	338
	Knowledge Survey	90	5	15/60	113
Total					1,794

The following table provides the estimated annualized burden costs for the licensed taxi drivers participating in the study. To obtain these estimates we used the Department of Labor National Occupational Employment and Wage Estimates United States website to determine appropriate wage rates for taxi drivers (53—3050). We used the mean hourly wage rate of $17.21 for the estimates presented in the table below (total respondent costs rounded up to the nearest whole number). The total estimated annualized burden cost is $30,875.

Estimated Annualized Burden Costs

Respondent		Form Name	No. of Respondents	No. of Responses per Respondent	Total Burden Hours	Hourly Wage Rate	Total Burden Cost
		Fatigue Training Evaluation Survey	60	1	15	$17.21	$258
		Actigraph Training and Fitting	90	1	15	$17.21	$258
		Sleep & Activities Diary (including Psychomotor Vigilance Test)	90	175	1,313	$17.21	$22,597
		Work & Health Survey	90	5	338	$17.21	$5,817
		Knowledge Survey	90	5	113	$17.21	$1,945
							$30,875

A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

The research team anticipates no other costs to participants or record keepers.

A.14. Annualized Cost to the Federal Government

The data collection phase includes an estimated $278,000 contract for external partners through a competitive bid process. The contract includes assisting with finalizing the IRB protocol based on the valid technologies used for the data collection, virtual planning meetings, a site visit, recruitment of 180 drivers, and 5 one-week data collection periods with a training intervention between the 2nd and 3rd data collection periods. Government personnel effort will be about $125,000. This includes 50% effort by the Project Officer (Cammie Chaumont

Menendez) and 25% effort by the Co-Project Officer (Christina Socias-Morales). Total government cost will be about $403,000. Over the 2-year OMB approval period, the annualized cost to the federal government is $201,500.

A.15. Explanation for Program Changes or Adjustments

This is a new data/information collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Table A.16.1 provides the estimated timeline for the data collection, analyses and publication of the results. As soon as OMB provides the approval the research team will begin the data collection procedures (starting at the participant recruitment phase).

Table A.16.1

Project Time Schedule	
Activity	Time Schedule
Letters sent to respondents	Immediately after OMB approval
Recruit and consent participants	Immediately after OMB approval
Complete data collection	8-14 months after OMB approval
Analyze the data	9-24 months after OMB approval
Publications	12-36 months after OMB approval

The research team will score the scales present in the Work and Health survey, provide descriptive summary statistics for each intervention group (training + actigraph feedback, training only and control group) and include them in analyses as potential covariates. The Sleep and Activities Diaries will be used to validate the actigraphy data by indicating when the time to bed and wake up occurred to calculate sleep latency, sleep duration, time awake, and sleep efficiency. These will be compared across intervention groups and over time across data collection periods for pre-post comparisons and time-dependent changes. Additionally, the activities and medicines data will be included in the statistical modeling process as potential covariates. Moreover, the subjective sleepiness scales in the sleep and activities diaries will serve as an outcome variable and be plotted throughout the day. Daily sleepiness patterns will be compared across intervention groups and over time. Finally, reaction times recorded on the sleep and activities diaries will serve as an outcome variable and will be plotted throughout the day. Daily reaction time patterns will be compared across intervention groups and over time. Reaction times data will validate the sleepiness scale data.

Separate statistical models will be constructed to predict reaction times and sleepiness scale data. They will be modeled on fatigue scores as a measure of the validity of the fatigue scores. They will also be modeled (in separate models) on sleep latency, duration and efficiency. Temporal changes over a shift and workweek will be compared over all data collection periods and across intervention groups.

The Knowledge Survey will be scored and compared across interventions pre- and post-training to assess changes in knowledge in response to the training and compared to the control group. Examining the scores by intervention group for 3 data collection periods post-training will determine if the knowledge is retained and detect any dissemination of knowledge into the control group.

Responses to the Training Evaluation will be summarized and synthesized to improve the training by addressing acceptance of the training, training effectiveness, barriers preventing drivers for hire from using information included in the training and providing input as to who their influencers are and sleep health behavioral changes made.

The following table shells are examples of how the data collected will be presented and are not the full list of ways the data will be used and disseminated as the research is likely to lead to new opportunities for analysis and hypothesis development beyond the primary analyses, revisions for clarity in manuscripts, and opportunities for dissemination that present themselves (e.g., presentations for industry and scientific conferences, fact sheets, and blogs).

One of the first tables to be constructed is the number of participants and completed surveys, actigraphy, and sleep and activities diaries by intervention group and data collection period to understand the completeness of the data collection activities (see Table A.16.2).

Table A.16.2

Number of Study Participants by Group and Data Collection Period with Completed Data Collection Instruments					
	Data Collection Periods				
	Pre-Intervention		Post-Intervention		
Group by Survey	1	2	3	4	5
Work and Health	(Example)				
Training + Fatigue Score Feedback	60 (60)	X (X)	X (X)	X (X)	X (X)
Training only	60 (0)	X (X)	X (X)	X (X)	X (X)
Control	60 (0)	X (X)	X (X)	X (X)	X (X)
Knowledge					
Training + Fatigue Score Feedback	60 (60)	X (X)	X (X)	X (X)	X (X)
Training only	60 (60)	X (X)	X (X)	X (X)	X (X)
Control	60 (60)	X (X)	X (X)	X (X)	X (X)
Sleep and Activities					

Diaries					
Training + Fatigue Score Feedback	60 (420)	X (X)	X (X)	X (X)	X (X)
Training only	60 (420)	X (X)	X (X)	X (X)	X (X)
Control	60 (420)	X (X)	X (X)	X (X)	X (X)
Actigraph Daily Data Collection					
Training + Fatigue Score Feedback	60 (420)	X (X)	X (X)	X (X)	X (X)
Training only	60 (420)	X (X)	X (X)	X (X)	X (X)
Control	60 (420)	X (X)	X (X)	X (X)	X (X)

All of the potential covariates, found in the Work and Health Survey and Sleep and Activities Diaries, will be included in bivariate analyses with the outcomes examined before model building processes occur. As the statistical models are finalized and the covariates selected to remain in the final model as determined by the a priori process are included the distribution of the selected covariates will be summarized and presented in a table by pre- and post-intervention status and intervention group (see Table A.16.3).

A multilevel statistical model is designed to test the two hypotheses: (1) study participants in Study Group 1, after completing the online fatigue training and receiving thrice daily feedback on their fatigue score derived from their actigraph, will experience less fatigue as indicated by changes in their fatigue scores compared to the control group (Study Group 3), and (2) study participants in Study Group 2, after completing the online fatigue training only, will experience less fatigue, as indicated by changes in their fatigue scores, compared to the control group.

Table A.16.3

Distribution of Covariates (Mean Scores) by Pre- and Post-Intervention and Group						
				Intervention Group		
		Intervention Phase		Training + Fatigue Score Feedback	Training only	Control
(Examples)	Overall	Pre	Post			
Daily nap frequency	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
ESS score	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
General (poor) health	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
Covariate 4	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
Covariate 5	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
Covariate n	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX

Testing these two hypotheses with the proposed statistical model requires the following variables: one dummy variable for the first intervention group (I_{T+FS}) (control group is the

referent), one dummy variable for the second intervention group (I_T) (control group is the referent), one variable indicating study phase (0=pre-intervention, 1=post-intervention), one variable indicating time of shift (0=beginning, 1=middle, 2=end), and one variable indicating time of work week (1-7 for each day of 7-day workweek). Interaction terms will be created and added to the model to describe fatigue changes for a specific intervention group for a specific time of shift or time of work week. The variables indicating time of shift and time of work week will be tested early in the analysis process to see if they are significantly associated with fatigue. Time of work week may not follow any pattern in describing fatigue, but time of shift is expected to follow a U-shaped curve. If either variable is found to be significantly associated with fatigue, it will be incorporated into the interaction terms. For example, if time of shift is significant with fatigue changes, a three-way interaction term comprised of the intervention group dummy variable, study phase and time of shift variable would describe fatigue changes throughout the day for the online fatigue training with fatigue score feedback group post-intervention compared to the control group.

The working statistical model is described as:

$$\text{Fatigue}_{ij} = \beta_{0ij}\text{constant} + \beta_{1j}\text{covariates} + \beta_{2j}T{+}FS + \beta_{3j}T + \beta_{4ij}\text{Study Phase} + \beta_{5ij}T{+}FS*\text{Study Phase} + \beta_{6ij}T*\text{Study Phase}$$

where Level 1 (within-person variable) is designated by i, Level 2 (between-person variable) is designated by j, the constant term is 1, and β_{1j}*covariates* refers to a vector of covariates that are selected in a process described *a priori* (as follows). Every variable included in the Work and Health survey will comprise the list of potential covariates for the final model and will be included in model-building processes. Covariates will be included in the final model if they meet a set of criteria: they must be significantly associated with the outcome, fatigue, they must not be strongly correlated with another covariate also selected for the model, and if they were not evenly distributed between the study groups. All covariates meeting these criteria will be added to the model and a stepwise backwards selection procedure would be followed where those not statistically significant at $p > 0.20$ will be removed. The difference in the -2ln(likelihoods) comparing the full model with the model missing only the two interaction terms will be used to test the study hypotheses. To test differences in fatigue levels throughout the day or work week the distance between predicted levels for the intervention group and control groups pre- and post-intervention will be compared. They will be calculated as linear combinations of the standardized estimated coefficients present in the final model (additional interaction terms will be added to reflect the within day or throughout workweek trends if significant). Wald tests will be used to assess their significance. The final model variables and their parameters (including standard errors) for both models will be presented in a table, along with the difference in -2ln(likelihoods) that describes significance of interventions. The findings of the fatigue scores pre- and post-intervention will also be presented in a figure, with average fatigue scores designated by study group for each study phase. If there are within-day changes or within-work week changes that were significant, those will be in a figure as well to visually depict the fatigue changes in as straightforward a manner as possible. To test the difference in effect of the two intervention groups, specifically, the effectiveness of the contribution of receiving feedback on fatigue scores, the differences between the interaction effects will be

tested. All analyses will be done using the latest version of SAS. See Table A.16.4 for how the results of the statistical modeling will be presented.

Table A. 16.4

Multi-Level Models Including and Excluding the Main Effect Parameters		
Variable	Model 1 β (Std. Error)	Model 2 β (Std. Error)
Covariate 1	X.XX (X.XX)	X.XX (X.XX)
Covariate 2	X.XX (X.XX)	X.XX (X.XX)
Covariate 3	X.XX (X.XX)	X.XX (X.XX)
Covariate 4	X.XX (X.XX)	X.XX (X.XX)
Covariate 5	X.XX (X.XX)	X.XX (X.XX)
Covariate n	X.XX (X.XX)	X.XX (X.XX)
Training + Fatigue Score Feedback group	X.XX (X.XX)	X.XX (X.XX)
Training only group	X.XX (X.XX)	X.XX (X.XX)
Intervention phase (post- compared with pre-)	X.XX (X.XX)	X.XX (X.XX)
Training + Fatigue Score Feedback group*Intervention	X.XX (X.XX)	X.XX (X.XX)
Training only group*Intervention	X.XX (X.XX)	X.XX (X.XX)
Time of day of alertness levels	X.XX (X.XX)	X.XX (X.XX)
Time of day of alertness levels*Intervention	X.XX (X.XX)	X.XX (X.XX)
Training + Fatigue Score Feedback group*time of day	X.XX (X.XX)	X.XX (X.XX)
Training only group*time of day	X.XX (X.XX)	X.XX (X.XX)
Training+Fatigue Score FB grp*Intervention*time of day	X.XX (X.XX)	X.XX (X.XX)
Training only group*Intervention*time of day	X.XX (X.XX)	X.XX (X.XX)
Intercept term	X.XX (X.XX)	X.XX (X.XX)
Level 1 variance	X.XX (X.XX)	X.XX (X.XX)
Level 2 variance	X.XX (X.XX)	X.XX (X.XX)
-2 ln(likelihood)	X.XX (X.XX)	X.XX (X.XX)
Difference in -2 ln(likelihoods) = X.XX		

*asterisks will indicate significance levels at $p < 0.05$.

Finally, using the statistical models separate figures depicting fatigue levels (Fatigue Score) and alertness levels (recorded on diaries) throughout the day before and after the training intervention will be graphed by intervention group and study phase (pre- vs post-intervention).

The knowledge scores will also be graphed pre and post intervention by intervention group to depict differences and sustained knowledge through each post-intervention period, which will be tested using a series of paired t-tests.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is appropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

References

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List of Attachments

Attachment 1. Authorizing Legislation (Occupational Safety and Health Act)

Attachment 2. 60-day Federal Register Notice

Attachment 2a. Public Comments and Response

Attachment 3. Letters of Support from Taxi Company

Attachment 3b. Letter of Support from Regulator

Attachment 3c. Letter of Support from Medical Sleep Expert

Attachment 4. Fatigue Training Evaluation Survey 01497

Attachment 4a. Fatigue Training Evaluation Survey

Attachment 5. Work and Health Survey 01497

Attachment 5a. Work and Health Survey

Attachment 6. Sleep Knowledge Survey 01497

Attachment 6a. Sleep Knowledge Survey

Attachment 7. Sleep and Activities Diary 01497

Attachment 7a. Sleep and Activities Diary

Attachment 8. Wrist Actigraph

Attachment 9a. Informed Consent

Attachment 9b. Informed Consent Instruction Slides

Attachment 9c. Informed Consent Flyer

Attachment 10. IRB Approval