

## Information Collection Request Supporting Statement: Section A

### The EMS Sleep Health and Fatigue Education Study

The National Highway Traffic Safety Administration (NHTSA) proposes to collect information from Emergency Medical Services (EMS) personnel about their shift work schedules and self-rated fatigue, and to determine the impact of a fatigue mitigation intervention that delivers education and training directly to EMS personnel that operate ambulances on the roadway. The overarching goals of this project are to 1) enhance our understanding of the relationships between shift work, sleep, and fatigue in EMS operations, and 2) determine if providing education and training to EMS personnel on the importance of sleep health and dangers of fatigue impact diverse indicators of sleep, fatigue, and safety. The research team will accomplish these goals by collaborating with up to 30 EMS organizations and their personnel in an experimental research study to test a novel education and training program that stresses the importance of sleep and dangers of fatigue, tailored to EMS personnel.

Members of the research team will coordinate recruitment and enrollment of EMS organizations and individual EMS personnel. Recruitment will be limited to EMS organizations and affiliated personnel located in the United States, inclusive of Alaska and Hawaii. The research team will use webinars, conference calls, and a website to advertise the research study to those that may be interested. Participation in this research study will be voluntary.

#### **A.1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.**

##### ***a. Circumstances making the collection necessary***

NHTSA was established to reduce the number of deaths, injuries, and economic losses resulting from motor vehicle crashes on the Nation's highways. As part of this statutory mandate, NHTSA is authorized to conduct research as a foundation for the development of traffic safety programs. Few safety programs exist for EMS personnel who operate ambulances and other rescue vehicles in emergency situations. Every minute of every day in the United States, more than 35 patients are transported in ambulances to the hospital.<sup>1</sup> A 2015 NHTSA study found that on average there are 4,500 crashes per year involving ambulances, and these crashes result in an average of 33 deaths per year.<sup>2</sup> Fatigue and/or sleep deprivation are likely contributors to ambulance crashes.<sup>3</sup> More than half of EMS personnel report fatigue, poor sleep, or inadequate

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<sup>1</sup>Pitts SR, Niska RW, Xu J, Burt CW. National Hospital Ambulatory Medical Care Survey: 2006 emergency department summary. Natl Health Stat Report. 2008 Aug 6;(7):1-38. PubMed PMID: 18958996.

<sup>2</sup>Smith N. A National Perspective on Ambulance Crashes and Safety: Guidance from the National Highway Traffic Safety Administration on ambulance safety for patients and providers. Link: <https://www.ems.gov/pdf/EMSWorldAmbulanceCrashArticlesSept2015.pdf>. Last accessed on January 2, 2018.

<sup>3</sup>Walker D, J. P. Ambulance wreck on Martha Berry Highway leaves 1 dead (Reported on June 16, 2017). [http://www.northwestgeorgianews.com/rome/news/police\\_fire/ambulance-wreck-on-martha-berry-highway-leaves-dead/article\\_f493d010-5297-11e7-b585-8727e42016fc.html](http://www.northwestgeorgianews.com/rome/news/police_fire/ambulance-wreck-on-martha-berry-highway-leaves-dead/article_f493d010-5297-11e7-b585-8727e42016fc.html). Rome News-Tribune. Rome, GA. Last Updated: June 16, 2017. Accessed December 6, 2017.

DeFeciani E. Ambulance crashes into tree on Duanesburg road, patient killed (Reported on May 24, 2017). <http://cbs6albany.com/news/local/ambulance-crashes-into-tree-on-duanesburg-road>. WRGB Albany News. Albany, NY. Last Updated: May 24, 2017. Accessed December 6, 2017.

Staff. Driver who caused fatal ambulance-involved crash tells police she fell asleep at the wheel (Reported on February 14, 2017). <http://www.wkbw.com/news/one-person-dead-in-dunkirk-crash>. WKBW Buffalo. Buffalo, NY. Last Updated: Accessed December 6, 2017.

recovery between shifts.<sup>4</sup> Odds of injury, medical error, and safety-compromising behaviors among fatigued EMS personnel are twice that of personnel who do not report fatigue.<sup>5</sup> A recent review of the published evidence shows that education and training tailored to the EMS personnel may reduce fatigue and improve safety on the roadways.<sup>6</sup> The purpose of this information collection is to measure the extent to which education and training in sleep health and fatigue will benefit EMS personnel. The study's two primary outcomes of interest include: [1] sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI); and [2] fatigue as measured by the Chalder Fatigue Questionnaire (CFQ).

### ***b. Statute authorizing the collection of information***

**Title 23, United States Code, Section 403** gives the Secretary authorization to use funds appropriated to conduct research and development activities, including demonstration projects and the collection and analysis of highway and motor vehicle safety data and related information needed to carry out this section, with respect to all aspects of highway and traffic safety systems and conditions relating to - vehicle, highway, driver, passenger, motorcyclist, bicyclist, and pedestrian characteristics; accident causation and investigations; emergency medical services, including the transportation of the injured; and human behavioral factors and their effect on highway and traffic safety, including driver education and impaired driving. [See 23 U.S.C. 403(b)(1)(A)(i), 23 U.S.C. 403(b)(1)(A)(ii), 23 U.S.C. 403(b)(1)(A)(iv), 23 U.S.C. 403(b)(1)(B)(i), 23 U.S.C. 403(b)(1)(B)(ii)].

### **A.2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.**

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Staff. Third ambulance crash in 30 days due to drowsy driving in Maine (Reported on August 4, 2017). <http://www.wcsh6.com/news/local/third-ambulance-crash-in-30-days-due-to-drowsy-driving-in-maine/461925181>. WCSH. Portland, ME. Last Updated: Accessed December 6, 2017.

Staff. Sleepy driver leads to second ambulance crash in one week, police say (Reported on July 14, 2017). <http://www.wmtw.com/article/sleepy-driver-leads-to-second-ambulance-crash-in-one-week/10307571>. WMTW. Bowdoinham, ME. Last Updated: Accessed December 6, 2017.

Staff. Ambulance driver falls asleep at the wheel, crashes rig (Reported on July 12, 2017). <http://www.wmtw.com/article/ambulance-driver-falls-asleep-at-the-wheel-crashes-rig/10297755> WMTW. Masardis, ME. Last Updated: Accessed December 6, 2017.

Hoffer J. The Investigators look at private ambulance drivers' qualifications after deadly crash (Reported on March 19, 2017). <http://abc7ny.com/news/the-investigators-look-at-private-ambulance-drivers-qualifications-after-deadly-crash/564956/>. ABC7NY WABC-TV. Last Updated: Accessed December 6, 2017.

Mallory B. Ambulance Crash Sends Several To Hospital (Reported on March 5, 2013). <http://www.keloland.com/news/article/news/ambulance-crash-sends-several-to-hospital>. KELO Media Group, Nexstar Broadcasting, Inc. Sioux, SD. Last Updated: Accessed December 6, 2017.

<sup>4</sup> Patterson PD, Weaver MD, Hostler D. EMS Provider Wellness. In: Cone DC, Brice JH, Delbridge TR, Myers JB, editors. Emergency Medical Services: Clinical Practice and Systems Oversight. Second Edition. Chichester, West Sussex; Hoboken: John Wiley & Sons Inc., 2015 pp. 211-216. ISBN: 978-1-118-86530-9. Patterson PD, Buysse DJ, Weaver MD, Callaway CW, Yealy DM. Recovery between Work Shifts among Emergency Medical Services Clinicians. *Prehosp Emerg Care*. 2015 Jul-Sep;19(3):365-75. doi: 10.3109/10903127.2014.995847. Epub 2015 Feb 6. PubMed PMID: 25658148.

<sup>5</sup> Patterson PD, Weaver MD, Frank RC, Warner CW, Martin-Gill C, Guyette FX, Fairbanks RJ, Hubble MW, Songer TJ, Callaway CW, Kelsey SF, Hostler D. Association between poor sleep, fatigue, and safety outcomes in emergency medical services providers. *Prehosp Emerg Care*. 2012 Jan-Mar;16(1):86-97. doi: 10.3109/10903127.2011.616261. Epub 2011 Oct 24. PubMed PMID: 22023164.

<sup>6</sup> Barger LK, Runyon MS, Renn ML, Moore CG, Weiss PM, Conde JP, Flickinger KL, Divecha AA, Coppler PJ, Sequeira DJ, Lang ES, Higgins JS, Patterson PD. Effect of Fatigue Training on Safety, Fatigue, and Sleep in Emergency Medical Services Personnel and Other Shift Workers: A Systematic Review and Meta-Analysis. *Prehosp Emerg Care*. 2018 Feb 15;22(sup1):58-68. doi: 10.1080/10903127.2017.1362087. Epub 2018 Jan 11. PubMed PMID: 29324059.

The National Association of State Emergency Medical Services Officials (NASEMSO) will conduct this study under a contract with NHTSA. The study protocol will be designed and led by subcontractors (the research team) at the University of Pittsburgh. Members of the research team will coordinate recruitment and enrollment of EMS organizations and individual EMS personnel. Recruitment will be limited to EMS organizations and affiliated personnel located in the United States, including Alaska and Hawaii. The research team will use webinars, conference calls, and a website to advertise the research study to those that may be interested. Participation in this research study will be voluntary. Participation is scheduled for 6 months. Remuneration is available to individual EMS personnel that participate.

The purpose of this study is to provide NHTSA with information about the effectiveness of education and training tailored to EMS personnel on the topics of sleep health and fatigue. Data collected from this study will be used to assist NHTSA in its ongoing responsibilities associated with Emergency Medical Services, safety, transportation, and fatigue mitigation. The data collected will: a) inform how NHTSA creates and disseminates education and training materials on the topics of sleep and fatigue for EMS and other shift workers in safety sensitive occupations and transportation; b) inform how NHTSA uses resources to address fatigue and fatigue mitigation in transportation; c) inform stakeholders and shape their program activities related to EMS and safety; d) help determine what are effective countermeasures to fatigue in occupations that deploy personnel in shifts and involve transportation. NHTSA will disseminate study findings to state offices of EMS, as well as share the information with state and local highway safety organizations. All findings will be presented in aggregate and be void of any participant information to protect the privacy of individuals and organizations that participated in the study.

**A.3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical or other technological collection techniques or other information technology. Also describe any consideration of using information technology to reduce burden.**

Data collection will involve use of surveys accessible on a password protected, secure study-specific website maintained by the University of Pittsburgh. Participants will complete these surveys at baseline, at 12-weeks post baseline, and again at 24 weeks post baseline. Data collection will also involve use of a mobile-phone text-messaging platform, utilized in previous research with EMS clinicians,<sup>7</sup> to capture detailed information from individual participants about shift schedules, and indicators of fatigue and sleep.

**A.4. Describe efforts to identify duplication. Show specifically why any similar information, already available cannot be used or modified for use for the purposes described in Item 2 above.**

NHTSA has not conducted a similar study of sleep health and/or fatigue education or training for EMS clinician shift workers. Findings from a recent systematic review show no similar studies that have addressed the aims and research questions germane to this proposal.<sup>6</sup> There are no existing sources for the desired information. This information request, which involves direct investigation with EMS clinicians, is necessary for NHTSA to evaluate the effectiveness of sleep health and fatigue education and training tailored to EMS clinicians shift workers.

**A.5. If the collection of information involves small businesses or other small entities, describe the methods used to minimize burden.**

The collection of information does not involve small businesses.

**A.6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

Under the current contract, data collection is scheduled to begin May of 2019. The proposed project is informed by the recent findings of a systematic review and meta-analysis that showed education and training on sleep health and fatigue has a positive impact on sleep related outcomes among shift workers.<sup>6</sup> Despite the positive findings, there is no model sleep health and

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<sup>7</sup>Patterson PD, Moore CG, Guyette FX, Doman JM, Sequeira D, Werman HA, Swanson D, Hostler D, Lynch J, Russo L, Hines L, Swecker K, Runyon MS, Buysse DJ. Fatigue mitigation with SleepTrackTXT2 in air medical emergency care systems: study protocol for a randomized controlled trial. *Trials*. 2017 Jun 5;18(1):254. doi: 10.1186/s13063-017-1999-z. PubMed PMID: 28583143; PubMed Central PMCID: PMC5460424. Patterson PD, Buysse DJ, Weaver MD, Doman JM, Moore CG, Suffoletto BP, McManigle KL, Callaway CW, Yealy DM. Real-time fatigue reduction in emergency care clinicians: The SleepTrackTXT randomized trial. *Am J Ind Med*. 2015 Oct;58(10):1098-113. doi: 10.1002/ajim.22503. Epub 2015 Aug 25. PubMed PMID: 26305869; PubMed Central PMCID: PMC4573891. Patterson PD, Moore CG, Weaver MD, Buysse DJ, Suffoletto BP, Callaway CW, Yealy DM. Mobile phone text messaging intervention to improve alertness and reduce sleepiness and fatigue during shiftwork among emergency medicine clinicians: study protocol for the SleepTrackTXT pilot randomized controlled trial. *Trials*. 2014 Jun 21;15:244. doi: 10.1186/1745-6215-15-244. PubMed PMID: 24952387; PubMed Central PMCID: PMC4080698.

education program for EMS shift workers and no concerted effort to evaluate the impact of education and training on safety in this worker group. A focused effort that targets EMS shift workers and is tailored to their unique work environment is needed. A study that evaluates the impact of these materials will guide NHTSA's future work with diverse shift worker groups and safety sensitive occupations and industries where fatigue is a threat.

**A.7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the guidelines set forth in 5 CFR 1320.6.**

No special circumstances require the collection to be conducted in a manner inconsistent with the guidelines in 5 CFR 1320.6.

**A.8. Provide a citation for the FEDERAL REGISTER document soliciting comments on extending the collection of information, a summary of all public comments responding to the notice, and a description of the agency's actions in response to the comments. Describe efforts to consult with persons outside the agency to obtain their views.**

The Federal Register published the 60-day Notice, which notified the public of NHTSA's intent to conduct this information collection and provided a 60-day comment period, on **DATE (CITATION)**. **[The notice did not receive any comments. OR SUMMARIZE COMMENTS RECEIVED.]**

The Federal Register published the 30-day Notice, which announced that this information collection request will be forwarded to OMB, on **DATE [CITATION]**.

**A.9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.**

Those that qualify for the study and choose to participate will receive remuneration worth approximately \$20 U.S. dollars, which will be delivered directly to the participant at the end of the study. As seen in Table 1, past research shows that when working with the EMS population, there is not a strong relationship between incentives and response rates. For example, studies 4 and 5 both delivered response rates in the high eighties for responding to text-message queries, like those being proposed for the current data collection, but differed in their incentive amounts (i.e., \$40+ and \$100), suggesting that the incentive amount did not play a major role in response propensity. Therefore, we selected a modest remuneration of \$20 to keep project costs lower because past research does not suggest that increasing the amount would deliver higher response rates.

Table 1. Incentives and Response Rates in Past Research

Study Number	Study Content	Incentive	Response Rate	Citation
1	170 survey items	Coffee mug and challenge coin of \$15 - \$20 value	45% participation rate	Patterson PD, et al. Emergency healthcare worker sleep, fatigue, and alertness behavior survey (SFAB): development and content validation of a survey tool. <i>Accid Anal Prev.</i> 2014 Dec;73:399-411. doi: 10.1016/j.aap.2014.09.028. Epub 2014 Oct 15. PubMed PMID: 25449415; PubMed Central PMCID: PMC4254576.
2	45 survey items on sleep health and fatigue	\$5 gift card	Not calculated, but participation perceived as moderate	Patterson PD, et al. Sleep quality and fatigue among prehospital providers. <i>Prehosp Emerg Care.</i> 2010 Apr-Jun;14(2):187-93. doi: 10.3109/10903120903524971. PubMed PMID: 20199233; PubMed Central PMCID: PMC2895322.
3	90 survey items on sleep health and fatigue	\$100 gift card to the EMS agency with highest response rate	The mean agency response rate was 35.6% (range 4.9% to 78.1%)	Patterson PD, et al. Association between poor sleep, fatigue, and safety outcomes in emergency medical services providers. <i>Prehosp Emerg Care.</i> 2012 Jan-Mar;16(1):86-97. doi: 10.3109/10903127.2011.616261. Epub 2011 Oct 24. PubMed PMID: 22023164; PubMed Central PMCID: PMC3228875.
4	Text-message assessments for 90 days	Coffee mug, \$40 gift card, computer drawing	89% response rate at individual person-level to all text-message assessments. 85% of individuals that started the study provided complete follow-up data.	Patterson PD, et al. Real-time fatigue reduction in emergency care clinicians: The SleepTrackTXT randomized trial. <i>Am J Ind Med.</i> 2015 Oct;58(10):1098-113. doi: 10.1002/ajim.22503. Epub 2015 Aug 25. PubMed PMID: 26305869; PubMed Central PMCID: PMC4573891.
5	Text-message assessments for 120 days	\$100 total in gift cards distributed monthly over the time-period of the study	Preliminary findings (data not yet published). 88.6% response rate at individual person-level to all text-message assessments. 52% of individuals that started the study provided complete follow-up data.	Patterson PD, Moore CG, Guyette FX, Doman JM, Sequeira D, Werman HA, Swanson D, Hostler D, Lynch J, Russo L, Hines L, Swecker K, Runyon MS, Buysse DJ. Fatigue mitigation with SleepTrackTXT2 in air medical emergency care systems: study protocol for a randomized controlled trial. <i>Trials.</i> 2017 Jun 5;18(1):254. doi: 10.1186/s13063-017-1999-z. PubMed PMID: 28583143; PubMed Central PMCID: PMC5460424.

#### **A.10. Describe any assurance of confidentiality provided to respondents**

Those that choose to participate in this study will be asked to complete an online eligibility screening form (Form 1461); which does not collect sensitive personal information. All data collected for purposes of this study will be kept confidential on computer servers maintained by the study team's institution and accessed only by the study team as approved by the institution's Institutional Review Board (IRB). NHTSA will not have direct contact with the participants. Eligible individuals will then watch a video-based consent procedure (Form 1462). This procedure has been used previously in studies that used similarly designed data collection technology.<sup>8</sup> The study team chose this method over a traditional paper-based method because:

- It was well received by EMS personnel in previous studies using the same technologies for data collection;<sup>9</sup>
- It is easily distributed on a secure website; and
- The video-based consent procedure reduces the time commitment burden on the study team and participant.

The video will be maintained on a password protected study-specific website (see Form 1462 for slides of the video consent). The consent video states that no individual results and no personal information will be published and that no personal results will be shared with their employer or any other authority. The consent documentation reports that all published results will highlight aggregate statistics that cannot be used to identify a particular individual or individual's data. After completing the video consent procedure, and accepting the terms and conditions of the study, individuals will provide their contact information (i.e., cellular phone number) and create a unique username and login. Next, the participants will answer baseline survey questions (Form 1463) and begin participation in the intervention or wait-list control group.

Once enrolled, and the baseline survey is complete, participants randomized to the intervention group will receive education/training materials. Next, all participants in the study (in both the intervention and wait-list control group) will be queried for seven straight days every third week for the duration of the 24-week study period. See Form 1464 for information about the daily queries. At week 12, all participants will complete the follow-up survey (Form 1465). At the same time, the group of participants randomized to the wait-list control group will crossover to the intervention group. The group that crosses over will then receive the education/training materials, and continue to receive the daily queries shown in Form 1464. At week 24, all participants will complete the follow-up survey (Form 1465) and conclude participation in the study. All data from these forms (1462, 1463, 1464, and 1465) will be collected electronically with the study's designated and secure website. The study's investigators

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<sup>8</sup>Patterson PD, et al. Fatigue mitigation with SleepTrackTXT2 in air medical emergency care systems: study protocol for a randomized controlled trial. *Trials*. 2017 Jun 5;18(1):254. doi: 10.1186/s13063-017-1999-z. PubMed PMID: 28583143; PubMed Central PMCID: PMC5460424.  
Patterson PD, et al. Real-time fatigue reduction in emergency care clinicians: The SleepTrackTXT randomized trial. *Am J Ind Med*. 2015 Oct;58(10):1098-113. doi: 10.1002/ajim.22503. Epub 2015 Aug 25. PubMed PMID: 26305869; PubMed Central PMCID: PMC4573891.

<sup>9</sup>Patterson PD, et al. Mobile phone text messaging intervention to improve alertness and reduce sleepiness and fatigue during shiftwork among emergency medicine clinicians: study protocol for the SleepTrackTXT pilot randomized controlled trial. *Trials*. 2014 Jun 21;15:244. doi: 10.1186/1745-6215-15-244. PubMed PMID: 24952387; PubMed Central PMCID: PMC4080698.

will use a series of procedures for protecting study data and participant confidentiality. These procedures will be outlined in the informed consent video and presented to each individual before he/she agrees to participate. Data will be maintained on University computer servers with access limited to investigators and computer / data management personnel. All information will be examined in aggregate and the findings will be reported with aggregate statistics.

**A.11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private.**

For purposes of the study, we will request the participant’s cellular/mobile phone number, email, and the contact information of a friend/relative. Information pertaining to a friend/relative is solicited for use if communication with the participant is lost and the study team is unable to regain that communication with the email or cellular/mobile phone number provided. Participants will be asked questions about their perceived fatigue and indicators of sleep health (e.g., self-rated sleep quality). These questions are not considered sensitive. However, if a participant expresses feelings of being uncomfortable answering a question or questions; he/she will be reminded that his/her participation is completely voluntary and may choose to not answer one or more questions. The participant will also be reminded that he/she can choose to withdraw from the study at any time for any reason. Appendix A provides justification for all survey items.

**A.12. Provide estimates of the hour burden of the collection of information on the respondents.**

The total estimated burden for this research study is estimated to be 10,141 hours. The following table summarizes the calculation of this estimated burden.

Table 3. Calculation of Burden Hour

	Respondents	Responses per respondent	Minutes per respondent	Estimated burden hours (rounded)
<b>Form 1460</b> Agency level screening form	200	1	5	17 hours
<b>Form 1461</b> Individual level screening form	3,000	1	5	250 hours
<b>Form 1462</b> Consent video process	1,500	1	10	250 hours
<b>Form 1463</b> Baseline survey process (signing up, and completing the demographics, sleep/fatigue survey items, and entering shift schedule on study website). In addition, this includes completing 10, 10-minute training	1,200	1	145	2,900 hours



sessions across the study period. <i>Note: 300 or 20% do not consent or do not complete baseline.</i>				
<b>Form 1464</b> Responding to text-message queries over study period. <i>Note: We estimate 1,200 respondents with 0% dropout to provide a conservative over-estimate of burden.</i>	1,200	56 (daily for eight weeks)	5	5,600 hours
<b>Form 1465</b> Follow-up survey at 12 weeks and 24 weeks (sleep/fatigue items). <i>Note: We estimate 1,200 respondents with 0% dropout to provide a conservative over-estimate of burden.</i>	1,200	2	25	1,000 hours
<b>Form 1466</b> Paper-based sleep diary for sub-set of participants (estimated 3 minutes per day for 7 days straight, for 8 weeks over study period = 168 minutes)	30	56 (daily for eight weeks)	3	84 hours
<b>Form 1467</b> PVT measurements taken at start and end of one shift during the seven-day periods when the participant completes the sleep diary.	30	16 (twice daily for eight weeks)	5	40 hours
<b>Total estimated burden hours</b>				10,141 hours

We will use a convenience sampling approach to identify EMS organizations (agencies) that may be interested, eligible, and willing to participate in this study. We will distribute the agency flyer (Appendix B) nationwide on popular EMS email listservs, electronic discussion boards, EMS news sites, and other popular EMS forums viewed by EMS leaders and administrators in the United States, inclusive of Alaska and Hawaii. We estimate that representatives of approximately 200 EMS agencies will contact our study team and complete the agency screening form (Form 1460). We believe that 30 total EMS agencies will be eligible and agree to participate in the study.

Eligibility criteria includes:

- Agency provides EMS service [including 911 response and transport] in the United States (Alaska and Hawaii included);
- Agency provides ground-based EMS services 24 hours a day;
- Agency employs between 50 and 300 EMS paid full-time and part-time clinicians/personnel; and
- Agency does not restrict use of personal cellular or mobile phones during shift work.

We will distribute a flyer to recruit EMS personnel working at the 30 participating agencies (Appendix C). We estimate that 3,000 total individual EMS personnel affiliated with 30 EMS agencies will complete the individual screening form (Form 1461) and be eligible to participate. We estimate that half (n=1,500) will watch/review the consent procedure (Form 1462) and agree to participate in the study. We believe that 1,200 total individuals that completed the consent procedure will complete the baseline survey (Form 1463). We anticipate a minimal dropout rate or attrition rate and provide a conservative estimate of burden for the total burden associated with completing Forms 1464 and 1465.

Both the agency and individual participant screening forms require approximately 5 minutes to complete. The total burden for the agency and individual level screening forms is 17 hours and 250 hours, respectively. The consent video requires approximately 10 minutes to complete. The total burden for the consent video is estimated at 250 hours. We estimate the total burden for completing the baseline survey process is 2,900 hours, including 900 hours for the survey and 2,000 hours for completing the training modules. Participants are asked to respond to intra-shift or inter-shift messages (Form 1464) for 7 straight days for 8 total weeks over the study period. The estimated total burden for this component of the study is 5,600 hours. Participants will be asked to complete follow-up survey at 12 weeks and 24 weeks (Form 1465). The estimated total burden for this component is 1,000 hours.

A sub-set of 30 participants, located at an EMS agency proximal to the University of Pittsburgh, will be asked to complete a paper-based sleep diary to inform interpretation of sleep data collected from wearing a wrist actigraph device for 7 days straight, for 8 total weeks during the study period (Form 1466). Completion of the sleep diary is estimated to take 3 minutes per day. The total burden for this component of the study is estimated at 84 hours. The same sub-set of 30 participants will be asked to complete psychomotor vigilance testing (PVT) measurements at the start and end of at least 1 shift during the same 7-day period when completing the sleep diary (Form 1467). This measurement will be repeated for at least 1 shift for each of the 8 total weeks of the study period when participants complete the sleep diary. The estimated total burden for this component is 40 hours.

The opportunity costs to respondents for participation in all study activities can be calculated based on the median hourly wage provided by the Bureau of Labor Statistics for EMTs and Paramedics (<https://www.bls.gov/oes/2016/may/oes292041.htm>). The estimated total cost to respondents is \$159,315 (10,141 hours X \$15.71/hour).

**A.13. Provide an estimate of the total annual cost to the respondents or record keepers resulting from the collection of information.**

There are no recordkeeping costs to the respondents, and there is no preparation of information required or expected of respondents. Participants do not incur either (a) capital and start-up costs, or (b) operation, maintenance, and purchase costs because of participating in the study.

**A.14. Provide estimates of the annualized cost to the Federal Government.**

The estimated contract cost to the government for this one-time information collection is \$669,282.88, which is an annual amount of \$159,353, divided across a 4.2 year or 50-month contract period.

**A.15. Explain the reasons for any program changes or adjustments in Items 13 or 14 of the OMB 83-I.**

This is a new information collection. As such, it requires a program change to add the estimated 10,141 hours for the new information collection to NHTSA's existing burden.

**A.16. For collection of information whose results will be published, outline plans for tabulation and publication.**

The current plan is for the contractor to produce a draft technical report in **2020** with publication of a final technical report in **2021**. The technical report will provide aggregate statistics and tables as well as the results of statistical analysis, but it will not include any personal information. These plans are based upon data collection starting in **May of 2019**. Delays in approval of this ICR could delay publication of the final technical report and could result in contract modifications and additional costs to the government.

**A.17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.**

NHTSA will display the expiration date for OMB approval.

**A.18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions" of the OMB Form 83-I.**

No exceptions to the certification are made.