Nurse Fatigue-Mitigation Education: Does it Change Nurse Sleep Behavior?

Supporting Statement- Section A

OMB No.

New

Request for Office of Management and Budget (OMB) Review and Approval for a Federally Sponsored Data Collection

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Table of Contents

List of Attachments

Attachment G: Determination from Chief Information Officer/Human Subjects Contact

Attachment H: Participant Information Sheet

Attachment I: Actigraphy watch training

Attachment J: Actigraphy watch fitting

- **Goals of the study:**
  This project is an evaluation of an established NIOSH product, "Training for Nurses on Shift Work and Long Work Hours." This two-part project is designed to 1) describe the cohort of nurses who have taken the training since its inception in 2015; and 2) assess the effectiveness of the training on nurse sleep health and wellbeing at 1-month, 3-month, and 6-month post-training.
- **Intended use of the resulting data:**
  With this evaluation project, NIOSH can 1) identify where future dissemination efforts should be tailored to increase training reach across the nursing population; and 2) determine whether the training needs to be enhanced to meet the greater needs of the current nursing population.
- **Methods to be used to collect:**
  There will be no data collection for study 1, as study goals will be obtained using CDC administrative data collected from nurses who have completed the online training since 2015.
  Study 2 data collection will be via online surveys, online open-ended questions, and research grade actigraphy watches
- **The subpopulation to be studied:**
  Study 1 Nurses who have taken the NIOSH Training for Nurses.
  Study 2 Registered Nurses (RNs) working night shifts will be recruited nationally to participate.
- **How data will be analyzed:**
  Study 1 will require quantitative analyses to describe the cohort of nurses (e.g. nursing specialty, worksite type) who have completed the training.
  Study 2 will require quantitative analyses to determine statistically significant change in sleep and wellbeing, post-training. Additionally, open-ended survey questions will be analyzed for themes related to RN perceptions of the training program presentation and style, sleep behavior strategies adopted post-training, and facilitators and barriers to improved sleep.

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH) seeks approval from the Office of Management and Budget (OMB) to conduct an evaluation study of an established NIOSH product targeting nurses working shift work. This is a new Information Collection Request (ICR), with approval requested for three years post-approval date. This evaluation project of NIOSH training will require collecting data from Registered Nurses (RNs) who work night shift. These data will be collected by NIOSH under Section 20(a) (1) of the Occupational Safety and Health Act (29 U.S.C.669) (Attachment A).

In 2018, 67% of RNs in the US worked in around-the-clock facilities,[1] requiring nonstandard work hours, including shift work (e.g. early mornings, over-nights, rotating between days and nights) and long work hours, to provide a critical public health service. These work organizational characteristics are primary factors contributing to sleep-related fatigue,[2] and decreased health and wellbeing for nurses.[3] Studies have found 36% of healthcare workers (including nurses) report sleeping less than the recommended 7-9 hours of sleep/24 hours,[4] with prevalence rates climbing to a little over 50% for those working night shift.[5]

Sleep disparity among shift workers, including RNs, is concerning as evidence is growing on the negative impact of insufficient sleep on worker health and safety.[6-9] Prospective studies have demonstrated

evidence of the increased risk of cardiovascular disease and subsequent death with insufficient sleep.[10] The International Agency for Research on Cancer[11] has classified night shifts as a probable carcinogen based on the scientific evidence linking exposure to light at night and cancer. Because of this growing knowledge, subject matter experts,[12] NIOSH,[13] and other stakeholders such as professional nursing organizations,[14, 15] have supported the implementation of sleep promoting and fatigue mitigation efforts within the healthcare industry. Included in this approach would be worker education regarding sleep health.[12, 15]

In 2015, NIOSH published the online training program titled, “Training for Nurses on Shift Work and Long Work Hours (Attachment C).” This online training provides information for nurses and nurse managers on the health and safety risks associated with nonstandard work hours. The training also provides strategies for improving sleep and reducing fatigue-related risks within the healthcare setting. Over 6,000 people have completed the training since publication. The training has been publicized on over 45 different webpages. To our knowledge, this training program is one of a kind, addressing a longstanding work hazard in a no-cost and easily accessible format. The NIOSH Training for Nurses program has become a cornerstone product of NIOSH’s sleep and fatigue resources to workers.

Evidence regarding worker sleep education training suggests this type of training can be effective at improving worker sleep.[16] Yet, recent research suggests some discrepancies exist on best methods for

delivery.[17] Considering the evidence, the time since NIOSH published the Training for Nurses, as well the changing landscape of the healthcare industry, an evaluation study of the training is warranted. Results of this evaluation project can provide evidence the training improves nurses' sleep and fatigue. Project results will identify: 1) if enhancements to the training are needed; and 2) evidence of the training's effectiveness at improving nurse sleep.

A.2 Purpose and Use of the Information Collection

The purpose of this project is to evaluate the effectiveness of the NIOSH online "Training for Nurses on Shift Work and Long Work Hours". NIOSH is committed to providing educational materials to employers and workers on workplace health and safety topics. Part of this commitment is regular evaluation of education products to determine if NIOSH-sponsored products are still successful at communicating and translating knowledge, impactful to worker health and safety. This evaluation is supported by NIOSH intramural NORA funding and will evaluate RN sleep health and wellbeing pre- and post-training.

NIOSH will collect data from participants during five distinct data collection periods: baseline (prior to training), immediately post-training, and at 1-, 3-, and 6-months post-training. Data collection periods will be for 7-days at the baseline and 1-, 3-, and 6-months post-training. Immediate post-training data collection will be a one-time survey with open-ended questions.

Survey data (Attachment D), open-ended questions (Attachment D), and sleep diary (Attachment E) data will be collected via REDCap, a secure, CDC approved data collection and management system.

Data collection instruments and timing of collection

Prior to online training: The baseline survey will ascertain information regarding demographics, known workplace characteristics which can contribute to fatigue (i.e., shift length, hours of work per week), and sleep health (i.e., sleep quality, daytime function) and wellbeing. Participants will be asked to complete this 23-minute survey 1 month prior to taking the NIOSH online training. In addition, participants will be asked to complete a daily 3-minute online sleep diary to ascertain sleep activity (i.e., time in bed, time awake) and to wear an actigraphy watch to record daily sleep time activity for one week.

Immediately after taking the online training: Participants will complete a 7-minute survey with open questions about intent to change behaviors for improving sleep health, and an opportunity to provide feedback on the training delivery and content.

Post-training at 1-, 3-, and 6-months: Participants will answer a 19-minute survey on sleep health and wellbeing, with three open ended questions about facilitators or barriers to adopting sleep behavior changes. Participants will also be asked to complete a sleep diary and wear an actigraphy watch for 7 days, similar to baseline data collection.

Data will be used to evaluate the NIOSH online training on improving RN sleep and wellbeing. Data specific to the training content and delivery, as well as behavior change intention, barriers, and facilitators can assist in identifying any enhancements that may be needed in the training.

A.3 Use of Improved Information Technology and Burden Reduction

Participants will complete the NIOSH Training for Nurses online. Surveys, open-ended questions, and sleep diary documentation will occur through CDC's online REDCap system. Actigraphy watches will passively record sleep health data. Use of specified technology to collect data can decrease participant burden during data collection, as well as decrease data processing burden on the NIOSH research team.

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

During the development and piloting testing of the online Training for Nurses, NIOSH collected data related to nurses' intended sleep behavior changes and knowledge gained following completion of the training, but no data were collected to measure whether behavior change occurred.

For this current project, NIOSH will be extending upon prior knowledge by ascertaining objective (i.e. actigraphy) and subjective (i.e. sleep diaries) measures of sleep activity 3-, 6-, and 9-months post-training. This additional data gathered over an extended period of

time will allow researchers to better understand if the effects of the training promote long-term behavioral changes.

In addition, a recent systematic scoping review conducted by NIOSH revealed that out of over 10,000 articles, only seven studies examined sleep training education for nurses. Information gathered from these studies would not be applicable to this current project because the content of their training materials (e.g. meditation strategies, cognitive behavioral therapy) differed substantively from content in the NIOSH online Training for Nurses. Our scoping review also determined there are no other free, online sleep training for nurses, and therefore, no other sources of data are available.

A.5 Impact on Small Businesses or Other Small Entities

This study does not include any small businesses or other small entities.

A.6 Consequences of Collecting the Information Less Frequently

Participants in this evaluation project will be responding to five data collection requests over a 7-month period: baseline (pre-training), immediately following the training, and post-training at 1-, 3-, and 6-months. Pre-training data collection will provide a baseline comparison for post-training to examine effective change in sleep and wellbeing. Immediate post-training data collection will measure RN behavioral intention, to examine whether behavioral intention is related to RN sleep post-training and to obtain

participants' opinions of the training content and delivery style. The multiple post-training measures will be compared to baseline measures, providing evidence of longer-term effectiveness of the training.

We are asking participants to provide data over several time periods (e.g., baseline, immediately post-training, and 3-, 6-, and 9-months post training). Prior studies report adoption of behavior change can differ between 18 to 254 days.[18] Therefore, gathering less data and at fewer intervals will not allow the research team to fully evaluate the impact of the training among shift working RNs.

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 May 14, 2021, vol. 86, No. 92, pp 26517. (Attachment B). CDC received four non-substantive public comments related to this notice and replied with a response (see Attachment F).

B. This study protocol and design was reviewed externally by three experts in Fall, 2020. Expert reviewers approved the evaluation methods. Reviewers provided minor suggestions for study improvement, which were incorporated in the study design. The contact information and titles at the time of consultations are listed below:

1. **Dr. Heather Duncan, MD:** Birmingham Women's and Children's NHS Foundation, heather.duncan5@nhs.net
2. **Rachel Shaw, PhD:** Life & Health Sciences Reader, Psychology Applied Health Research Group, Aston University, r.l.shaw@aston.ac.uk
3. **Lynda Robson, PhD:** Research scientist at the Institute for Work and Health, lrobson@iwh.on.ca

A.9 Explanation of Any Payment or Gift to Respondents

Participants will be provided a non-coercive token (e.g., $25 grocery gift card) at the completion of each actigraphy data collection period and return of actigraphy watch (sent back to study team via pre-paid postage). Additionally, after the end of the final data collection period, study participants will be given their own personal data report, documenting their sleep health, and wellbeing over the course of the study period, along with an additional $100 gift card as a non-coercive token of appreciation for completion of all 4 data collection periods.

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

Participant confidentiality and privacy are strictly held in trust by the participating investigators, their staff, the safety and oversight monitor(s), and DSI/SSTRB. This confidentiality is extended to the data being collected as part of this study. Data that could be used to

identify a specific study participant will be held in strict confidence within the study team.

Part 1, a descriptive study, will be using only data already collected by CDC as part of the Training and Continuing Education Online system. Study team members (Drs. Caruso, Hittle, or Wong) will obtain data from the CDC. All data will be de-identified by two study team members (Drs. Hittle and Wong) prior to use. Only aggregate statistics will be reported. Data will be stored within an encrypted folder on secure CDC servers accessible only by a password protected CDC laptop/computer, with folder access limited to only three study team members (Drs. Caruso, Hittle, and Wong).

Part 2, a field evaluation study, will collect potentially sensitive information through actigraphy and surveys. However, no personal identifying information will be included on the surveys or actigraphy data, only unique study identifiers will be used. A master key of study participants and their unique study identifiers will be kept on a government issued encrypted drive, in a locked filing cabinet, in a locked office within the 24/7 secured NIOSH premises. Only study team members will have access to the key and the key will be destroyed following dissemination of individualized reports each participant.

Survey data will be stored via CDC approved REDCap data management system. Participants will be emailed a personalized, encrypted link for accessing the survey via a mobile device or web-browser. REDCap is password protected and data will only be accessed by study team

members via a password protected CDC issued laptop. Data on REDCap can be securely exported to a CDC based statistical program. By default, REDCap sets data to exported de-identified of any participant personal identifiers.

It is CDC/NIOSH policy that the results of the activities that it funds should be made available to the public, if possible. These de-identified data will not be made available to the public since part 1 study data are CDC property and part 2 study data requires specialized software for analyzing. The management plan will be updated as needed throughout the project.

ISSO determined in conjunction with the CDC Privacy Office that Privacy Act is not applicable. The collection contains PII.

Research Electronic Data Capture (REDcap) and NIOSH Edge Computing Platform (NCEP) include the in-place technical, physical, or administrative controls (safeguards).

Research Electronic Data Capture (REDcap) and NIOSH Edge Computing Platform (NCEP) System Security Plan (SSP) defines 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.

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

Based on review by the Chief Information Officer/Human Subjects Contact, this study was determined to not require Human Research Protection Office review (Attachment G).

No sensitive questions are asked during this study, aside from questions of self-identifying race and ethnicity during the baseline survey (Attachment D). Race and ethnicity questions are asked in accordance with the Office of Management and Budget guidelines.

A.12 Estimates of Annualized Burden Hours and Costs

NIOSH estimates a total annual response burden of 341 hours for this information collection. This estimate was drawn from the literature, questions used in previous research surveys, and timed estimates from the research team completing the surveys. Data will be collected from each participant over a 7-month period. The annual burden for each RN is estimated at 6.8 hours annually. The U.S. Department of Labor lists the median hourly pay for RNs in 2020 at $36.22 (https://www.bls.gov/ooh/healthcare/registered-nurses.htm). Therefore, the total cost burden for 50 RNs to participate is estimated at $12,351.

Table A12.1 Estimated Annualized Time Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Registered Nurses	Baseline Survey	50	1	23/60	19
	Online Nurses Training	50	1	3.5	175
	Immediate Post-Training Survey	50	1	7/60	6
	Post-Training (1, 3, and 6-months) Survey	50	3	16/60	40
	Consensus Sleep Diary	50	4	21/60	70
	Actigraphy watch training	50	1	10/60	8
	Actigraphy watch fitting	50	4	7/60	23
Total					341

B. Annualized Cost to Respondents

Table A12.2 Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs
Registered Nurse	Baseline Survey	19	$36.22	$688.18
	Online Nurses Training	175	$36.22	$6338.50
	Immediate Post-Training Survey	6	$36.22	$217.32
	Post-Training	40	$36.22	$1448.80

	(1, 3, and 6-months) Survey			
	Consensus Sleep Diary	70	$36.22	$2535.40
	Actigraphy watch training	8	$36.22	$289.76
	Actigraphy watch fitting	23	$36.22	$833.06
Total				**$12,351.02**

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

There are no additional cost burdens to respondents or record keepers.

A.14 Annualized Cost to the Federal Government

The annualized cost to the government for this four-year project is approximately $69,000. The total cost for the entire four-year period is $276,000. Expenses include equipment, travel, tokens of appreciation, shipping, and staff (e.g., project officer, project manager, fee for service for specialized work).

Table A14.1. Estimated Annualized Cost to the Federal Government

	Annualized Cost
Equipment	$7,000
Travel	$8,000
Other (Tokens of Appreciation, shipping)	$4,000
Support staff	$50,000
Total	**$69,000**

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

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

Table A.16.1 gives a detailed timeline for this two-part evaluation study. Three years is being requested for data/information collection clearance.

Part 1: Data cleaning and analyses is anticipated to take one year, with an additional 6-9 months for dissemination of work. Data analyses includes descriptive statistics (e.g., means, standard deviations, medians, range) with a test of equality for proportions conducted to compare study population characteristics to the broader nursing workforce. A p-value ≤ 0.05 will indicate statistical significance.

Part 2: Participant recruitment will begin immediately following OMB approval and is anticipated to occur for 3-months. Data collection from each study participant is anticipated to take 7-months (baseline through 6-month follow-up). It is likely data collection will not be concurrent for all 50 part 2 study participants, therefore time from first participant beginning data collection to the 50th participant completing data collection may take up to 18-months. Data analyses will be ongoing, with completion estimated to be 27-months after OMB approval. Manuscripts are anticipated to be submitted 36-months after OMB approval.

To answer the research questions for part 2, three separate data analyses will be conducted.

Research question 1: Is sleep health and wellbeing significantly improved at 1-, 3-, and 6-months post-training, compared to baseline?

Analysis 1: Descriptive statistics will be reported for sleep health and wellbeing from each data collection period (baseline, 1-month, 3-months, and 6-months). Linear mixed model will be used to estimate the change in sleep health and wellbeing over time by calculating the mean differences in sleep health and wellbeing at 1-, 3-, and 6-months post-training (with baseline measures as a reference) and effect size estimates determined using 95% confidence interval. Statistical significance will be set at $p<0.05$. We will control for the effects of potential a priori confounders such as demographic data (i.e., age, sex/gender identity, race, ethnicity, children, chronotype), workplace characteristics (i.e., tenure, hours of work/week, shift length, multiple jobs), and seasonality (to account for seasonal changes in sleep patterns).

Research question 2: What nurse characteristics (i.e., demographics, work characteristics) are predictors of behavioral intention?

Analysis 2: Appropriate inferential parametric testing (i.e., t-test) will be used based on the level of the predictor variable data. Should the assumptions of parametric testing not be met, non-parametric testing (i.e., Mann-Whitney U test) will be used. Two-tailed analyses will be conducted with statistical significance set at $p<.05$. Nurse characteristics (measured at baseline) will be analyzed with behavioral intention measured at immediate post-training.

Research question 3: Is there a relationship between behavioral intention and sleep health?

Analysis 3: Correlation between behavioral intention immediately after training with sleep health at 1-, 3- and 6-months will be explored using Pearson's Correlation. Significance will be set at p=<.05 and Cohen's standard will be used to assess effect size.

In addition to the statistical analysis described above, five open-ended questions are included in the surveys. Answers to these questions will be analyzed for common themes using content analysis. Answers from three open-ended questions will help establish barriers and facilitators to change nurses may experience. Answers from other two questions will provide preference feedback on the training program,

Table A.16.1. Project Time Schedule

Activity		**Time Schedule**
Part 1	Data cleaning and analyses	12 months after OMB
	Manuscript development and publications	18-21 months after OMB
Part 2	Participant recruitment	3 months after OMB
	Data collection	21 months after OMB
	Data cleaning and analyses	27 months after OMB
	Manuscript development and publications	36 months after OMB

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

The display of the OMB expiration date is not inappropriate.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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