Information Collection Request for Occupational Exposures to Surgical Smoke in Veterinary Personnel

Request for Office of Management and Budget Review and Approval for Federally Sponsored Data Collection

Section A

Project Officer:
Ethan Fechter-Leggett, DVM, MPVM
Research Epidemiologist
National Institute for Occupational Safety and Health
Field Studies Branch
1000 Frederick Lane, MS 2800
Morgantown, WV 26508
Phone: 304-285-6030
E-mail: iun8@cdc.gov
Fax: 304-285-5820

AUGUST 2024

Table of Contents

Attachments

- **Goals of the study:** The goal of this study is to characterize occupational exposure to surgical smoke (SS) and related respiratory health effects in U.S. clinical veterinary settings. Findings from this study will help to provide guidance on engineering controls to improve air quality in veterinary medicine/animal care (VM/AC) personnel's work environment by reducing exposure to SS.
- **Intended use of the resulting data:** These data will be used to examine (1) work-related factors that contribute to exposure to SS in clinical veterinary settings, (2) relationships between SS exposure in clinical veterinary settings and respiratory health, and (3) barriers and aids to implementing SS extraction systems that reduce occupational exposures to SS.
- **Methods to be used to collect data:** A baseline questionnaire conducted through telephone calls with trained interview staff will be used to collect data from respondents about demographics, work history, job tasks, exposures to respiratory hazards, use of personal protective equipment, workplace safety climate, and respiratory health and symptoms. A post-shift questionnaire conducted during two in-person site visits will be used to collect data from respondents on acute respiratory symptoms and job tasks during the work shift.
- **The subpopulation to be studied:** The respondent sample for the study will come from VM/AC personnel who are 18 years or older, speak English, and work at a collaborating clinical veterinary workplace.
- **How data will be analyzed:** Data will be summarized using descriptive statistical methods (including means, medians, standard deviations, percentages, and frequencies), inferential statistical methods (including univariable regression, multivariable regression, and structural equation modeling), and Bayesian modeling.

A. Justification

A1. 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 a study on surgical smoke (SS) and related respiratory health effects in U.S. clinical veterinary settings. This is a new Information Collection Request (ICR), with approval requested for three years post-approval date. Data will be collected by NIOSH under Section 20(a)(1) of the Occupational Safety and Health Act (29 U.S.C.669) (Att.1–Authorizing Legislation).

Surgical smoke produced during tissue cutting and cauterizing tissues and blood vessels generates hazardous gaseous compounds and aerosols. While there is a growing body of literature surrounding surgical smoke exposures generated during human surgeries, no research has been done characterizing surgical smoke generated from animal tissue in clinical veterinary settings. Surgical smoke exposure in human medicine literature has been reported to induce acute and chronic inflammatory changes in the respiratory tract, including those leading to upper respiratory tract irritation, rhinitis, asthma, and bronchiolitis and emphysematous changes consistent with chronic obstructive pulmonary disease, but similar studies among veterinary medicine/animal care (VM/AC) personnel are lacking. Additionally, surgical suites in veterinary clinics are often multiple bay suites or have less effective ventilation systems than human operating rooms, potentially leading to higher exposure levels. Given previous research has documented hazardous compounds are generated during electrocautery use, respiratory symptoms can be associated with surgical smoke exposure among human hospital workers, and a knowledge gap exists on these topics among VM/AC personnel, further evaluation of the potential occupational exposures to surgical smoke and respiratory health effects among VM/AC personnel is warranted.

There is also a lack of understanding about barriers and aids to the use of surgical smoke controls, such as surgical smoke evacuations systems that are designed to reduce occupational exposures to surgical smoke, in clinical veterinary settings. Although barriers and aids to the use of surgical smoke controls have been examined among physicians and nurses in human-healthcare settings, no research has examined barriers and aids to the use of surgical smoke evacuation systems among VM/AC personnel. This research would be the first to examine the associations between usage of surgical smoke controls and personal protective equipment, perceived risks of surgical smoke, and organizational safety climate in clinical veterinary settings. Having a better understanding of the relations between perceived risks of surgical smoke, safety climate, and risk-reduction behaviors (such as using surgical smoke evacuation systems) can help identify appropriate interventions to better inform workers of potential hazards and increase the use of controls and other safety-related behaviors in this industry.

Therefore, the overarching goal of this project is to characterize occupational exposure to surgical smoke and related respiratory health effects in U.S. clinical veterinary settings. This study will describe surgical smoke-related respiratory health effects in VM/AC personnel and barriers/aids to implementing surgical smoke evacuation systems among VM/AC personnel.

A2. Purpose and Use of the Information Collection

The data collected from this study will be used to examine (1) work-related factors that contribute to exposure to surgical smoke in clinical veterinary settings, (2) relationships between surgical smoke exposure in clinical veterinary settings and respiratory health, and (3) barriers and aids to implementing surgical smoke extraction systems that reduce occupational exposures to surgical smoke. These findings will ultimately be used to help develop guidance for engineering controls that improve air quality in VM/AC personnel's work environment, thereby reducing exposure to surgical smoke and the risk of respiratory diseases.

Descriptive statistics will be used to summarize means, medians, and standard deviations for continuous variables and percentages and frequencies for binary and categorical variables. Differences by subgroups will be tested using established, valid statistical techniques such as t-tests and Chi square tests (or the equivalent tests for paired data, when indicated); non-parametric tests will be used if normality tests indicate that is appropriate. Modeling such as univariable regression, multivariable regression, generalized linear modeling, and structural equation modeling will be used to examine relationships between risk or protective factors (predictor variables) and surgical smoke constituents and respiratory health outcomes (response variables), including examination of potential confounder or modifying factors (such as age, sex, smoking status, allergic status, and stress); then Bayesian methods, which can simultaneously account for repeated measures and left censoring, will be used for modeling and comparison analyses.

A3. Use of Improved Information Technology and Burden Reduction

Participating veterinary facilities will be provided an electronic study recruitment fact sheet (Att. 3–Study Recruitment Fact Sheet) to circulate electronically to eligible workers and post in employee work areas to generate awareness and interest in the project. The study recruitment fact sheet describes the objectives of the study and the study's requirements for participation, including screening requirements and anticipated time needed to complete study questionnaires. This study recruitment fact sheet will be distributed electronically accompanied by a recruitment email (Att. 4–Recruitment Email). The study recruitment fact sheet and the recruitment email will each contain a quick response (QR) code that, when scanned, brings the potential participant to a one-page expression of interest form (Att. 5–Expression of Interest Form) via Epi Info™ Secure Web Survey for the potential participant to complete to express interest in participating in the study. Epi Info™ Secure Web Survey is a web-based data collection tool for use at CDC and has a Moderate security level classification and approval; name, email address, and phone number are types of personal identifying information (PII) explicitly allowed to be collected via Epi Info™ Secure Web Survey. Workers who complete the expression of interest form will be offered a day/time to complete the informed consent (Att. 6–Informed Consent) and be enrolled into the study.

During the scheduled day/time with the participant, after the participant has provided consent, a NIOSH investigator will administer the baseline questionnaire (Att. 7–Baseline Questionnaire). The baseline questionnaire will be conducted virtually through a secure government platform such as Microsoft Teams, and the NIOSH investigator will enter collected data directly on a CDC network-connected, password-protected NIOSH computer via data collection software approved for use and collection of PII at CDC. Trained NIOSH investigators directly entering data collected for the baseline questionnaire is anticipated to substantially reduce the time required to collect questionnaire responses. Skip patterns will be applied in the baseline questionnaire where appropriate to avoid asking non-applicable questions.

NIOSH project staff will additionally make two site visits to each participating veterinary facility during the project for field work. Two site visits are required to meet the aims of the study: site visit #1 will be the "no intervention" condition, and site visit #2 will be the "intervention" condition where a surgical smoke evacuation system will be used. NIOSH project staff will administer the post-shift questionnaire (Att. 8–Post-shift Questionnaire) in person using the same procedures during all site visits at all participating facilities. The post-shift questionnaires will be conducted in a private location at the veterinary facility, away from management or supervisors. Participants will have the option to complete the post-shift questionnaire with a NIOSH interviewer who will enter data on a password-protected NIOSH computer via the NIOSH/Respiratory Health Division (RHD) eQuestionnaire Application, which is part of the NIOSH Modernization Platform (MPN) that has an authority to operate (ATO) and is approved to collect PII, or paper copy, whichever they prefer. While the vast majority (if not all) post-shift questionnaires are expected to be completed electronically, the expected time to complete the post-shift questionnaire electronically and via paper copy is the same. All post-shift questionnaires completed on a password-protected NIOSH computer will be stored on the computer, in the possession of NIOSH staff, during the site visit. Post-shift questionnaires completed on paper will be stored in a secure lock box, in the possession of NIOSH staff, during the site visit; data from the paper questionnaires will be double-entered into the NIOSH/RHD eQuestionnaire Application by two different study personnel, and then the paper questionnaires will be destroyed. All NIOSH investigators administering the post-shift questionnaire will be trained on the protocols required to successfully complete the data collection, including the use of the data collection software. Once study personnel have returned to secured CDC offices and connected to the secure CDC network, the post-shift questionnaire data will be stored on a MUST share which is listed in the NIOSH MPN and erased from the computer. Access to the MUST share is restricted to NIOSH staff involved in this research study. Skip patterns will be applied in the post-shift questionnaire where appropriate to avoid asking non-applicable questions.

A4. Efforts to Identify Duplication and Use of Similar Information

To our knowledge, there are no previous studies that have examined associations between surgical smoke exposure and respiratory health effects among VM/AC personnel. To our knowledge, there are also no previous studies that have examined barriers and aids to the use of surgical smoke evacuations systems among VM/AC personnel.

Content of the baseline questionnaire designed for this study is based on: (1) previous work at NIOSH that identified work- and respiratory health-related data that would be relevant to VM/AC personnel (i.e., tasks, procedures, and processes specific to the veterinary industry); (2) portions of the NIOSH Well-Being Questionnaire (WellBQ)[1] (pilot tested under OMB 0920-1234); and (3) the Surgical Smoke module of the NIOSH Survey of Healthcare Workers' Health and Safety Practices (OMB 0920-0860), which included questions on surgical smoke exposure and personal protective equipment used for respiratory protection.[2][3] Respiratory health-related questions included were drawn from standardized questionnaires: the European Community Respiratory Health Survey (ECRHS),[4][5] the American Thoracic Society (ATS) adult respiratory questionnaire (ATS-DLD-78),[6] and the CDC's National Health and Nutrition Examination Survey (NHANES) questionnaires.[7][8] Content of the post-shift questionnaire designed for this study is based on data collection instruments previously used in post-shift questionnaires used to evaluate occupational respiratory and eye concerns during NIOSH Health Hazard Evaluations in healthcare settings; these results are summarized in multiple publications.[9][10][11]

While the baseline and post-shift questionnaires were designed from previous data collection instruments, none of the previous data collection instruments have previously been deployed specifically among VM/AC personnel. Therefore, existing data are not able to meet the current needs to provide guidance on surgical smoke engineering controls to improve air quality in VM/AC personnel's work environment. This research would be the first to address these knowledge gaps in the veterinary industry and is necessary to develop risk mitigation strategies.

Letters of support from the three veterinary teaching hospitals, a national network of community veterinary clinics, and one professional veterinary organization (Att. 9–Letters of Support) indicate that our academic, industry, and professional organization partners consider the proposed research valuable and applicable to the occupational safety and health of VM/AC personnel. Our study team includes subject matter experts from across several disciplines, including veterinary medicine, industrial hygiene, exposure assessment and control, ventilation assessment, mechanical engineering, behavioral research, and biostatistics.

A5. Impact on Small Businesses or Other Small Entities

Three veterinary teaching hospitals and a national network of community veterinary clinics that were recruited during the project funding proposal stage have agreed to participate in this research, and these workplaces are of varying sizes. Some of these veterinary facilities may be small businesses. The duration of the questionnaire is not expected to impact the participating businesses. The number of questions on the questionnaires have been held to the minimum to meet study aims. They include only what are considered essential topics and the lengths of the questionnaires were kept as short as possible. Questionnaire questions that are not applicable to the respondent are skipped. Participation in the questionnaires is voluntary and conducted at a time convenient for the participant as well as the business, which would allow the worker time to complete the questionnaires.

Additionally, there may be benefits for participating facilities. Participating facilities will receive an aggregate report of their employee's questionnaire responses; all study results reported will be

in aggregate such that no individual responses will be identifiable or linked back to individual participants. The information provided back to participating facilities is valuable information that can be used to maintain or improve a healthy and safe workplace and reduce the impact of work-related respiratory exposures and illness.

A6. Consequences of Collecting the Information Less Frequently

This request includes data collection for (1) an expression of interest form to be completed one time by each participant, (2) a baseline questionnaire to be completed one time by each participant, and (3) a post-shift questionnaire to be completed a maximum of 10 times by each participant (once per workday over a five-day site visit, during each of two site visits) over the course of the study. All data collections are voluntary. Less frequent data collection for the expression of interest form would not allow potential participants to potentially enroll in the study. Less frequent data collection for the baseline and post-shift questionnaires would not allow the information to be captured necessary to perform the analyses to meet project aims. If this data collection does not take place, NIOSH would not capture the data needed to accurately improve our understanding of surgical smoke-related respiratory health effects in VM/AC personnel or the barriers/aids to implementing surgical smoke evacuation systems among VM/AC personnel; NIOSH also would not be able to provide guidance for engineering controls that improve air quality in VM/AC personnel's work environment to reduce exposure to surgical smoke and the risk of respiratory diseases. Additionally, this data collection will inform NIOSH's research agenda by aiding in prioritization of research activities and resources. There are no legal or technical obstacles to reduce the burden of the data collection.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A8. 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 November 03, 2023, vol. 88, No. 212, pp. 75595–96 (Att. 2–60-day FRN). CDC did not receive public comments related to this notice.

B. We consulted with several experts on the topic of veterinary medicine, industrial hygiene, exposure assessment and control, ventilation assessment, behavioral research, and biostatistics, within and external to CDC. Consultations on the type of information to be collected began in 2021 and have continued throughout the project planning and protocol development. There were no issues with data collection methods or frequency that were unable to be resolved through this consultation.

CDC programs consulted during project development, drafting of the data collection tools, and designing of methods:

- CDC/NIOSH Healthcare and Social Assistance Program. Contact person: Megan Casey, BSN, MPH, RN, Nurse Epidemiologist, 304-644-3274, ydg7@cdc.gov
- CDC/NIOSH Respiratory Health Program. Contact person: Paul Henneberger, MPH, ScD, Research Health Scientist, 304-285-6161, pkh0@cdc.gov
- CDC/NIOSH Exposure Assessment Program. Contact person: Matthew Dahm, PhD, MPH, REHS, Supervisory Environmental Health Specialist, 513-458-7136, iwa6@cdc.gov
- CDC/NIOSH Prevention Through Design Program. Contact person: Jonathan Bach, PE, CSP, CIH, Safety Engineer, 513-533-8317, yeh6@cdc.gov
- CDC/NIOSH Small Business Assistance Program. Contact person: Brenda Jacklitsch, PhD, MS, Research Health Scientist, 513-533-8369, gwe6@cdc.gov
- CDC/NIOSH Engineering Controls Program. Contact person: Duane Hammond, MS, PE, Mechanical Engineer, 513-841-4286, ahz0@cdc.gov

Non-CDC collaborators with the following affiliations were consulted during the development of the project, drafting of the data collection tools, and designing of methods:

- Cummings School of Veterinary Medicine at Tufts University
- The Ohio State University College of Veterinary Medicine
- University of Tennessee College of Veterinary Medicine
- BluePearl Specialty and Emergency Pet Hospitals
- West Virginia University

A9. Explanation of Any Payment or Gift to Respondents

This study does not provide a payment or gift to the respondents.

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

Privacy Act Review
System Security and Privacy Officer (SSPO) determined in conjunction with the CDC Privacy Office that the Privacy Act **is** applicable. The collection contains PII with demographic information in the survey.

List of data elements: Age (DOB), Race, Ethnicity, current health information, and Gender.

Methods used to collect data: Baseline questionnaire conducted through telephone calls with trained interview staff will be used to collect data from respondents about demographics, work history, job tasks, exposures to respiratory hazards, use of personal protective equipment, workplace safety climate, and respiratory health and symptoms.

- A post-shift questionnaire conducted during two in-person site visits will be used to collect data from respondents on acute respiratory symptoms and job tasks during the work shift.

Intended use of resulting data:
The study recruitment fact sheet and the recruitment email will each contain a QR code that, when scanned, brings the potential participant to a one-page expression of interest form (Att. 5–Expression of Interest Form) via Epi Info™ Secure Web Survey for the potential participant to complete to express interest in participating in the study.

How is it protected and stored?
Epi Info™ Secure Web Survey is a web-based data collection tool for use at CDC and has a Moderate security level classification and approval; name, email address, and phone number are types of PII explicitly allowed to be collected via Epi Info™ Secure Web Survey.

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 System Security and Privacy Officer (SSPO) (previously called 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.

Consent of Participants
To participate in the study, each participant will be required to review an informed consent document (Att. 6–Informed Consent). This document provides potential participants information about the study, their participation, risks and benefits of participation, and procedures for keeping personal information confidential. The consent document is written at a reading level that is expected to be understood by VM/AC personnel. The NIOSH Institutional Review Board (IRB) granted a waiver of documentation of informed consent; therefore, no PII will be collected on the informed consent document.

Data Access Control
Study participants will each be given a unique study identifier number (ID) that will be used to manage their data. After the participant provides informed consent, a NIOSH project investigator will assign this study ID. All questionnaires completed by the participant (baseline questionnaire and post-shift questionnaire(s)) will contain this study ID in order to link the same participant's contributions to the study without using PII. Date of birth is being collected to be used to verify the study ID and confirm consent for an individual who participates in components of the study at different points in time. The key linking a worker's name and their study ID will only be used to ensure the same study ID is used for each participant during subsequent data collections (e.g., post-shift questionnaire during site visits). The key linking participant names and study IDs will be electronically stored separately from questionnaire data in a file on the secure CDC network accessible only to NIOSH personnel. Only NIOSH project investigators with the need to know will have access to this link between participant names and study IDs.

The expression of interest form (Att. 5–Expression of Interest Form) data will be collected via Epi Info™ Secure Web Survey, which is a web-based data collection tool for use at CDC and has a Moderate security level classification and approval; name, email address, and phone number are types of personal identifying information (PII) explicitly allowed to be collected via Epi Info™ Secure Web Survey.

Baseline questionnaire (Att. 7–Baseline Questionnaire) data will be collected by a NIOSH investigator and entered directly on a CDC network-connected, password-protected NIOSH computer via data collection software approved for use and collection of PII at CDC.

Post-shift questionnaire (Att. 8–Post-shift Questionnaire) data will be collected by a NIOSH investigator on a password-protected NIOSH computer via the NIOSH/RHD eQuestionnaire Application, which is part of the NIOSH MPN that has an ATO and is approved to collect PII. Participants may opt to complete the post-shift questionnaire via paper copy if they prefer; post-shift questionnaires completed on paper will be stored in a secure lock box, in the possession of NIOSH staff, during the site visit, and data from the paper questionnaires will be double-entered into the RHD eQuestionnaire Application by two different study personnel and then the paper questionnaires will be destroyed. All post-shift questionnaires completed on a password-protected NIOSH computer will be stored on the computer, in the possession of NIOSH staff, during the site visit. All NIOSH investigators administering the post-shift questionnaire will be trained on the protocols required to successfully complete the data collection, including the use of the data collection software. Once study personnel have returned to secured CDC offices and connected to the secure CDC network, the post-shift questionnaire data will be stored on a MUST share which is listed in the NIOSH MPN and erased from the computer. Access to the MUST share is restricted to NIOSH staff involved in this research study. Digital copies of all questionnaire data will be stored in a restricted access computer folder that is backed-up daily on the CDC network.

CDC will treat data and gathered information in a secure manner and will not disclose, unless otherwise compelled by law.

Data for this study are collected under the system of record notice (SORN) CDC Privacy Act System Notice 09-20-0147 Occupational Health Epidemiological Studies and EEOICPA Program Records and will be maintained in accordance with the Federal Privacy Act of 1974.

Additionally, consistent with Section 301(d) of the Public Health Service Act, a Certificate of Confidentiality (CoC) applies to this research because this research is funded, conducted, or supported by CDC and the following is true:

1. The activity constitutes biomedical, behavioral, clinical, or other research; and
2. The research involves information about an individual for which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

Therefore, CDC and any of its collaborators, contractors, grantees, investigators or collaborating institutions that receive "identifiable, sensitive information" as defined by subsection 301(d) of the Public Health Service Act shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding "identifiable, sensitive information" that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose "identifiable, sensitive information" or provide ISI to any other person not connected with the research.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the Food, Drug and Cosmetic Act or required by state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

CDC and its collaborators conducting this research will establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the research is managed in compliance with subsection 301(d) of the Public Health Service Act. CDC will ensure the following:

1. that any investigator or institution not funded by CDC who receives a copy of identifiable, sensitive information protected by this Certificate, understands that it is also subject to the requirements of the Certificate; and
2. that any subrecipient that receives CDC funds to carry out part of this research involving a copy of identifiable, sensitive information protected by a Certificate understands that it is subject to subsection 301(d) of the PHS Act.

Therefore, all study staff will receive training on the importance of protecting the confidentiality of human research subjects and of personal information acquired, including the collection of biological specimens. All research subjects will be informed of the protections and the limits to protections provided by this Certificate through the informed consent process. All study staff who obtain consent from study subjects will be trained on how the Certificate protects the information collected and the limitations of the Certificate's protections.

Collaborating partners may assist in data collection during site visits at the collaborating veterinary facilities; however, CDC/NIOSH will own and maintain the data.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB) Approval
The project has been determined to be research involving human subjects. The NIOSH Institutional Review Board has reviewed and approved the proposed study (Att. 10–IRB Approval Letter).

Justification for Sensitive Questions
The proposed questionnaire contains questions that may be sensitive in nature, including race/ethnicity, gender, sex assigned at birth, and diagnoses of medical conditions. The potentially sensitive demographic questions on race/ethnicity, gender, and sex assigned at birth are essential to the usefulness of the research for accurately describing the demographics of the workforce population in the research study and to identify disparities among minority populations. The included race/ethnicity demographic question follows the most recent OMB standards.[12] The potential benefit of more detailed race/ethnicity data beyond the minimum categories does not justify the additional burden to participants because (1) according to the U.S. Bureau of Labor Statistics, approximately 86–90% of VM/AC personnel (potential participants) are White and more than 87% are not Hispanic or Latino,[13] and (2) the planned study sample size needed to achieve the project's primary objectives is not anticipated to be large enough to conduct meaningful analyses by more detailed race/ethnicity categories. Therefore, in keeping with the data collection principle of parsimony (collecting only necessary data), the included race/ethnicity question follows SPD-15 Figure 2.[12] Gender and sex assigned at birth data collections are also considered demographic questions and these data collections are supported by the Federal Evidence Agenda on LGBTQI+ Equity[14] and OMB Recommendations on the Best Practices for the Collection of Sexual Orientation and Gender Identity Data on Federal Statistical Surveys.[15] Additionally, the U.S. Department of Health and Human Services Sexual Orientation and Gender Identity (SOGI) Data Action Plan states if a data collection is capturing demographic data that is not solely related to program eligibility or compliance, SOGI data elements should be included in the data collection, unless there is a compelling legal reason not to collect these data.[16] Although some participants may feel demographic questions on race/ethnicity, gender, and sex assigned at birth are sensitive in nature, these data remain critical to understand differences among populations; participants may refuse to answer these demographic questions.

Social security numbers will not be collected.

All questionnaire response data will be treated in a secure manner and will not be disclosed, unless compelled under law. Aggregation of responses will ensure participants will not be identifiable.

A12. Estimates of Annualized Burden Hours and Costs

Estimates of Annualized Burden Hours
An estimated 150 VM/AC personnel are anticipated to complete the expression of interest form (Att. 5–Expression of Interest Form), informed consent (Att. 6–Informed Consent), baseline questionnaire (Att. 7–Baseline Questionnaire), and post-shift questionnaire (Att. 8–Post-shift

Questionnaire) during the data collection period, which is 3 years, for an annualized number of 50 respondents per year for each data collection.

The expression of interest form will be completed once per respondent. The duration of the expression of interest form is estimated to be 2–3 minutes, as determined by fewer than 10 pilot tests during form development that included time for reviewing instructions, gathering mock information, and completing the form. Based on these results, the estimated time range for actual respondents to complete the form is 2–3 minutes. For the purposes of estimating burden hours, the average time (rounded up) to complete the form is used.

The baseline questionnaire will be completed once per respondent. There is a screening question at the beginning of the baseline questionnaire so all respondents may not actually participate. The duration of the baseline questionnaire is estimated to be 20–35 minutes, as determined by fewer than 10 pilot tests during questionnaire development that included time for reviewing instructions, gathering mock information, and completing the questionnaire. Based on these results, the estimated time range for actual respondents to complete the baseline questionnaire is 20–35 minutes. For the purposes of estimating burden hours, the average time (rounded up) to complete the baseline questionnaire is used.

The post-shift questionnaire could be completed up to a maximum of ten times per respondent (once per workday over a five-day site visit, during each of two site visits). For the purposes of estimating burden hours, the upper limit of the number of times a respondent could complete the post-shift questionnaire (10 times) is used. The duration of the post-shift questionnaire is estimated to be 5–10 minutes, as determined by fewer than 10 pilot tests during questionnaire development that included time for reviewing instructions, gathering mock information, and completing the post-shift questionnaire. Based on these results, the estimated time range for actual respondents to complete the post-shift questionnaire is 5–10 minutes. For the purposes of estimating burden hours, the average time (rounded up) to complete the post-shift questionnaire is used.

Therefore, the approximate total estimated burden is an annualized 107 hours.

Table: A12.1. Estimated Annualized 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)**
VM/AC personnel	Expression of Interest Form	50	1	3/60	3
VM/AC personnel	Informed Consent	50	1	15/60	13
VM/AC personnel	Baseline Questionnaire	50	1	28/60	24
VM/AC personnel	Post-shift Questionnaire	50	10	8/60	67
Total					107

Estimates of Annualized Burden Costs
Based on the U.S. Department of Labor's Occupational Employment and Wage Statistics (May 2023), the updated annual average wage for Veterinarians is $136,300 (average hourly wage $65.53), for Veterinary Technologists and Technicians is $44,040 (average hourly wage $21.18), and for Veterinary Assistants and Laboratory Animal Caretakers is $37,310 (average hourly wage $17.94). The distribution of respondents among these three occupations (Veterinarians, Veterinary Technologists and Technicians, and Veterinary Assistants and Laboratory Animal Caretakers) is unknown and not possible to estimate. Therefore, the average of these three occupations' average hourly wages was calculated as: ($65.53 + $21.18 + $17.94) /3 = $34.88.

Table A12.2. Estimated Annualized Cost Burden to Respondents

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs
VM/AC personnel	Expression of Interest Form	3	$34.88	$105
	Informed Consent	13	$34.88	$454
	Baseline Questionnaire	24	$34.88	$838
	Post-shift Questionnaire	67	$34.88	$2,337
Total				$3,734

*Hourly wage rate is the average of hourly wage rates for Veterinarians, Veterinary Technologists and Technicians, and Veterinary Assistants and Laboratory Animal Caretakers average hourly wages found at May 2023 National Occupational Employment and Wage Estimates (bls.gov).

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to respondents or record keepers.

A14. Annualized Cost to the Federal Government

The estimated annualized cost to the government is $674,960 for the three years of the project. The breakdown by cost type is outlined in Table A14.1. The estimated costs will cover the following:

- Government personnel time (pro-rated using percentage of time dedicated to the project)

- Equipment and supplies for intervention component
- Contracts for staff and sample analytical service
- Travel for partner development, field post-shift questionnaire delivery, and dissemination of findings

Table A14.1 Annualized costs to the government incurred by this project

Item	Annualized Cost
NIOSH personnel	$534,982
Equipment and supplies for intervention component	$63,441
Contracts for staff and sample analysis	$46,566
Travel	$29,971
Total	$674,960

A15. Explanation for Program Changes or Adjustments

This is a new data collection.

A16. Plans for Tabulation and Publication and Project Time Schedule

We plan to publish study results in both peer reviewed and non-peer reviewed journals. Our projected timeline for the project is detailed in table A.16.1 below.

	Months after OMB approval											
Activity	**0–3**	**4–6**	**7–9**	**10–12**	**13–15**	**16–18**	**19–21**	**22–24**	**25–27**	**28–30**	**31–33**	**34–36**
Recruitment												
Data collection (Baseline Questionnaire)												
Site visit #1 and data collection (Post-shift Questionnaire)												
Site visit #2 and data collection (Post-shift Questionnaire)												
Data analyses												
Aggregate data reporting to participating facilities												

Prepare publications for journals												
Presentations at scientific meetings												

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of OMB expiration date is not inappropriate.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

1. NIOSH (2021). NIOSH worker well-being questionnaire (WellBQ). By Chari R, Chang CC, Sauter SL, Petrun Sayers EL, Huang W, Fisher GG. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2021-110 (revised 5/2021), https://doi.org/10.26616/NIOSHPUB2021110revised52021.
2. Steege AL, Boiano JM, Sweeney MH. NIOSH health and safety practices survey of healthcare workers: training and awareness of employer safety procedures. Am J Ind Med. 2014;57(6):640–652. https://doi.org/10.1002/ajim.22305.
3. Steege AL, Boiano JM, Sweeney MH. Secondhand smoke in the operating room? Precautionary practices lacking for surgical smoke. Am J Ind Med. 2016;59(11):1020–1031. https://doi.org/10.1002/ajim.22614.
4. Burney PG, Luczynska C, Chinn S, Jarvis D. The European community respiratory health survey. Eur Respir J. 1994;7(5):954-960, https://doi.org/10.1183/09031936.94.07050954.
5. ECRHS. Questionnaires and protocols. European Community Respiratory Health Survey, 2018. https://www.ecrhs.org/questionnaires-and-protocols.
6. Ferris BG. Epidemiology Standardization Project (American Thoracic Society). Am Rev Respir Dis. 1978;118(6 Pt 2), 1–120.
7. CDC. Third National Health and Nutrition Examination Survey, 1988–1994. Hyattsville, Maryland: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. https://wwwn.cdc.gov/nchs/nhanes/nhanes3/default.aspx.
8. CDC. Continuous National Health and Nutrition Examination Survey, 2007–2012. Hyattsville, Maryland: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. https://wwwn.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx

9. NIOSH (2023). Evaluation of exposure to a hydrogen peroxide, peracetic acid, and acetic acid containing cleaning and disinfection product and symptoms in hospital employees. By Blackley BH, Virji M, Harvey R, Cox-Ganser J, Nett R. Morgantown, WV: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, NIOSH HHE Report No. 2017-0114-3357. http://www.cdc.gov/niosh/hhe/reports/pdfs/2017-0114-3357.pdf.
10. Blackley BH, Nett RJ, Cox-Ganser JM, Harvey RR, Virji MA. Eye and airway symptoms in hospital staff exposed to a product containing hydrogen peroxide, peracetic acid, and acetic acid. Am J Ind Med. 2023;66(8):655–669. https://doi.org/10.1002/ajim.23488.
11. Hawley B, Casey M, Virji MA, Cummings KJ, Johnson A, Cox-Ganser J. Respiratory symptoms in hospital cleaning staff exposed to a product containing hydrogen peroxide, peracetic acid, and acetic acid. Ann Work Expo Health. 2017;62(1):28–40. https://doi.org/10.1093/annweh/wxx087.
12. Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, 89 Fed. Reg. 22182 (Mar. 29, 2024), https://www.govinfo.gov/content/pkg/FR-2024-03-29/pdf/2024-06469.pdf
13. Labor Force Statistics from the Current Population Survey. Table 11 – Employed persons by detailed occupation, sex, race, and Hispanic or Latino ethnicity. Bureau of Labor Statistics, U.S. Department of Labor. Updated January 26, 2024. Accessed October 25, 2024. https://www.bls.gov/cps/cpsaat11.htm
14. Subcommittee on Sexual Orientation, Gender Identity, and Variations in Sex Characteristics (SOGI) Data, Subcommittee on Equitable Data, National Science and Technology Council, Executive Office of the President of the United States (2023). Federal Evidence Agenda on LGBTQI+ Equity. https://www.whitehouse.gov/wp-content/uploads/2023/01/Federal-Evidence-Agenda-on-LGBTQI-Equity.pdf
15. Office of Management and Budget/Office of the Chief Statistician of the United States (2023). Recommendations on the best practices for the collection of sexual orientation and gender identity data on federal statistical surveys. https://www.whitehouse.gov/wp-content/uploads/2023/01/SOGI-Best-Practices.pdf
16. U.S. Department of Health & Human Services (2023). Sexual Orientation and Gender Identity (SOGI) Data Action Plan. https://www.hhs.gov/sites/default/files/hhs-sogi-data-action-plan.pdf