

Generic Clearance for CDC/ATSDR

Formative Needs Assessment for Regional Worker Health Monitoring in a Rural Oil and Gas Basin: A Pilot

0920-1154

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Attachments

- Att 1 Authorizing Legislation: 42 USC CHAPTER 6A, SUBCHAPTER II, Part A: Research and Investigations
- Att 2 Authorizing Legislation: 29 USC 669: Research and related activities
- Att 3 Interview Guide: Motor Safety Priorities
- Att 4 Interview Guide: In-Vehicle Monitoring Systems Questionnaire
- Att 5 Draft Questionnaire on In-Vehicle Monitoring Systems Implementation
- Att 6 Interview Guide: Information System

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

For this project NIOSH researchers will conduct formative research to build upon existing tools and methodologies that are used to prevent motor vehicle injuries and deaths among workers in the oil and gas extraction (OGE) industry. The goal of this project is to understand the interests, attributes, and needs of occupational safety and health (OSH) professionals supporting motor vehicle safety among OGE workers in the Permian Basin region of Texas and New Mexico. The formative research and development activities will inform the design of information systems and information products that are tailored to the needs of professionals in the Permian Basin in order to ensure information systems and products are acceptable to the target population and feasible before any further investment in information system development. This project will also seek to improve the relationships between OSH professionals, companies, and state and federal agencies.

Background

Workers in the OGE industry are at increased risk for a wide range of adverse occupational health and safety outcomes, including fatal motor vehicle injuries. In 2022 the fatal workplace injury rate in the OGE industry was more than five times higher than the U.S. average. Motor vehicle crashes (MVCs) are the leading cause of work-related fatality in OGE. Existing occupational health surveillance systems are insufficient to capture comprehensive, detailed work-related motor vehicle safety data at the national, state, regional, or county-levels. The need for better motor vehicle safety data in OGE has been identified through multiple efforts, including the National Occupational Research Agenda (NORA); the NIOSH Strategic Plan; an Ambassador Alliance Agreement between NIOSH, the Occupational Safety and Health Administration (OSHA), and the National Service, Transmission, Exploration, & Production Safety (STEPS) Network; a report by the National Academies of Sciences, Engineering, and Medicine titled “A Smarter National Surveillance System for Occupational Safety and Health in the 21st Century”; as well as testimony from OSH professionals in the industry.

NIOSH conducts surveillance and prevention research projects as part of its response to OSH issues. Many of these projects provide the basis for the recommendations and guidelines that NIOSH provides. To reduce the burden of work-related motor vehicle crashes, NIOSH invests in public health surveillance research to inform priorities and track worker injury patterns over time. An integrated research effort is needed to identify and fill gaps in knowledge, surveillance, and prevention programs among OSH professionals in OGE.

Short-term qualitative interviews and respondent questionnaires have previously proven invaluable in the development of scientifically valid and population-appropriate methods, interventions, and instruments. In this project, these tools will be used to inform various aspects of surveillance system design. The activities will include conducting interviews to understand the motor vehicle priorities and practices of OSH professionals in OGE, vis a vis the information systems they use; characterizing the capabilities and limitations of existing information systems;

determining the utility and acceptability of different data collection methods; assessing motor vehicle safety programs in OGE; and developing data sharing agreements. This data collection activity benefits the Federal Government by providing NIOSH with data to determine how to best manage and improve the safety of OGE workers at risk of a motor vehicle crash injury.

Data collection for this project is authorized under 42 U.S.C. 241, Chapter 6a - Public Health Service; Subchapter II - General Powers and Duties Part A - Research and Investigations (**Attachment 1**), as well as 29 U.S.C. 669, Section 20 (**Attachment 2**).

The information collection activities are limited to formative work that will result in the design of new or improved tools, concept development and/or product development and testing. The types of information collection activities included in this package are:

- 1) Semi-structured qualitative interviews will use volunteer respondents for exploratory and formative research to develop and/or improve upon existing surveillance methods, materials, and information system design. Interviews will be carried out with individuals, on the telephone, or via the internet (i.e. internet interviews). Results of qualitative interviews will be used to develop and/or improve upon population-appropriate methods, interventions, messages, information systems, and data collection materials for current and future projects.
- 2) Pilot tests of questionnaires with volunteer respondents to assess the design and use of draft materials. The purpose of this pilot testing is to develop new methods that address the rapid evolution of technology, interventions, and data management practices and use those methods to enhance NIOSH's projects and reduce burden of future data collections.

The information collected to facilitate interviews and pilot tests may contain personally identifiable information (PII) such as name, email address, etc. The collection of PII will only be to facilitate the administration of interviews and pilot tests. PII will not otherwise be used for formative research purposes and will be kept in a separate location and accessible only to the project-specific research staff. This information will be destroyed when the client's contribution to the project has ended. The information collected for this project will be maintained or stored locally under strict access controls limited to the local project leader/manager or his/her designate. Under no circumstances will an individual be identified using a combination of variables such as gender, race, birth date, and/or other descriptors.

This project may involve Respondent Driven Sampling (RDS) and/or purposive sampling and will include personal information that the local implementers will need to provide continuity of service, follow-up of referrals, and other outreach activities.

This package includes items of information to be collected and copies of the data collection instruments.

2. Purpose and Use of Information Collection

This project aims to improve OSH professionals' access to motor vehicle safety information in a rural oil and gas basin. NIOSH researchers will engage OSH professionals in enhancing or designing de novo an information system that prioritizes four domains. Data will be (1) available in a timely manner, to support decision-making among OSH professionals in the OGE industry. The approach will be (2) regional, to accommodate the ways in which the OGE industry is organized. The approach will be (3) user centered. OSH professionals will be the primary users of the pilot system. They will be engaged throughout the project to ensure the pilot system meets their needs. Finally, the approach will (4) prioritize system efficiency to increase the likelihood of future system sustainability. This pilot monitoring system will focus on a high-priority outcome among OGE workers, motor vehicle crash (MVC) injuries, in the Permian Basin region of west Texas and southeast New Mexico.

CDC/NIOSH requires the ability to process and/or integrate information into on-going national programs, such as the Oil and Gas Extraction Program, in a timely manner. Formative research is an integral part of the operations research and surveillance activities at CDC because they are dependent upon the consumers, health department staff, as well as other public and private partners to obtain the data needed to monitor changes in injury epidemiology and design more efficient interventions.

None of the proposed activities intend to produce results that can be generalized beyond the scope of this study. The objective of this request is to enable NIOSH to improve the quality of the data collection systems for a subset of our community of end users and respond to the needs of the affected persons and the community in a timely manner. The improved timeliness of the data collection activities and the data themselves will improve data quality, increase the efficiency of data collection, and decrease burden to the public.

Data collection for this formative research will involve semi-structured qualitative interviews to understand users' priorities, methods, interventions, and needs. Separate interview guides have been developed for one-hour interviews with OSH professionals (Attachment 3) and data management professionals (Attachment 6). Semi-structured qualitative interviews incorporate pilot testing of a draft questionnaire specifically designed to understand in-vehicle monitoring systems (IVMS) implementation in OGE. IVMS are common in OGE and provide a rich source of data that could be used to address a wide range of OSH professionals' motor vehicle safety priorities. A questionnaire has been drafted addressing different dimensions of IVMS implementation (Attachment 5). During a one-hour interview, individuals will be asked to complete the questionnaire and then be interviewed about the questionnaire with the remaining time (Attachment 4). The draft questionnaire will be completed solely for the purpose of evaluating the questionnaire itself; data from questionnaire responses will not be collected or used. CDC/NIOSH will conduct qualitative interviews with individual volunteer respondents using standardized methods. Results of qualitative interviews will be used with other information to develop the most appropriate and successful surveillance methods and data collection instruments for current and future projects.

Field experience with prototype data collection instruments is crucial for the development and/or improvement of methods, interventions, and instruments that may improve surveillance and

other research projects. Qualitative interviews and questionnaire pilot testing with members of the target population will provide input on project methods, interventions, and instruments will assure success in future information system development. The combined methods are especially relevant for projects like this one intending to reach vulnerable populations, such as rural end users and small companies, and explore novel areas of research.

General Methodological Research

CDC and NIOSH regularly evaluate and refine surveillance and research methods, especially in response to advances in current methodologies or changes in the motor vehicle injury epidemic. In order to meet this need CDC/NIOSH may conduct research on the development of new methods. In addition to examining issues related to questionnaire design and administration, it is increasingly important for CDC/NIOSH to evaluate the benefits and risks of novel data sources and methods for surveillance and research, as well as any legal, social, cultural, technical, or linguistic factors that relate to novel methods. Conducting formative research with OSH professionals who use novel safety and health technologies that generate data can help examine how the data are used and perceived by OSH professionals in practice, and how professionals' behaviors and attitudes relate to potential secondary uses of the data that are generated. Users of safety and health technologies make numerous implementation decisions that could impact the effectiveness of the technologies for safety, as well as interpretation of data. For example, users of IVMS decide threshold values for alerts to OSH professionals (e.g., what constitutes a speeding event); which vehicles and which drivers require IVMS; whether IVMS data are used punitively or strictly for coaching purposes; who has access to PII within the IVMS platform; and so on. Research about these decisions is underdeveloped and could have a significant effect on CDC/NIOSH's ability to use these novel technologies for research and surveillance in the future.

Field testing, also referred to as pilot testing, of new materials may be used to evaluate data collection instruments for use in future efforts before significant investments in novel surveillance systems are developed. The results of this formative research will be applied to future proposals and decisions how to use novel data sources for public health goals. The objective of the pilot test will be to evaluate the feasibility of the 'new' strategies in NIOSH-funded projects. Information from pilot testing can be used to improve the existing instruments, interviewer training materials, or methodologies that would reduce the public burden.

3. Use of Improved Information Technology and Burden Reduction

This project requires direct interaction between respondents and project staff, especially in the case of qualitative interviewing. Interviews will be recorded to assist in the transcription, review, and interpretation of findings. Improved information technology will be used wherever possible.

4. Efforts to Identify Duplication and Use of Similar Information

A literature review was conducted to identify whether regional surveillance of motor vehicle fatalities or injuries among oil and gas workers yielded one result – authored by colleagues at NIOSH. Initial outreach and relationship building in the Permian Basin has identified two relevant activities. Texas A&M University's Transportation Institute conducted a study in partnership with

the Permian Road Safety Coalition (PRSC) to characterize motor vehicle crash patterns in the Permian Basin. However, this study was a single point-in-time study and there are no current plans to duplicate. The PRSC would also periodically share with its members the number of motor vehicle crash deaths in Permian Basin counties, using a state database of crashes. The counts shared by PRSC did not include crash characteristics and the state database they have used does not systematically capture information on the work-relatedness of the crashes, or the crashes' connections to oil and gas activity. The proposed system will be informed by these earlier efforts, but will not be duplicative. Representatives of PRSC and Texas A&M University are partners on this project.

5. Impact on Small Businesses or Other Small Entities

This surveillance research activity may involve data collection from small businesses (e.g. small oil and gas companies) or small governmental entities (e.g., small rural health departments). Small businesses in the oil and gas extraction industry experience the highest rates of motor vehicle fatalities and are therefore an important group to reach. If project staff do collect data with representatives of small businesses, these businesses will be approached in the same manner as the individuals we normally recruit: we will ask the organization to identify the appropriate staff members with whom to conduct the activities. The methods used to minimize burden on small businesses or other small entities will include, but not be limited to:

- We will rely on voluntary participation in project planning and data collection. There will be no requirements or coercion for small businesses to participate and it will be made clear that even if initiated, project participation can cease at any time without retribution or consequences.
- We will recruit participants using existing meetings and information channels (e.g., websites, listservs) to reduce the burden of recruitment to an absolute minimum.
- We are focused on recruiting professionals involved in fleet safety and we will ask for their participation during normal business hours. Participation in this project, as with other OSH activities, can reasonably be considered relevant to their job duties.
- We will limit the amount of time a given individual is asked to participate in data collection to a maximum of one questionnaire and one hour-long interview.

6. Consequences of Collecting the Information Less Frequently

This project will be time limited. Data collection activities will not recur. No single data collection activity will take longer than 1 year to complete from inception of information collection to the first report of findings. There are no legal obstacles to reducing the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A Federal Register notice was published for the generic information collection on July 22, 2022, Vol. 87, No.140, pp. 438360. No public comments were received.

The project's methods and data collection forms were developed in partnership with external partners in the oil and gas extraction industry, as well as subject matter experts at CDC and NIOSH over the initial project year (FY24). External partners included the leadership of two local nSTEPS chapters, both of which are based in the Permian Basin region. The presidents and vice presidents of the Permian Basin STEPS Network and the Southeast New Mexico STEPS network, as well as members of their executive committees met monthly with the Principal Investigator (Dr. Scott) and provided feedback on the methodology, as well as the specific priorities outlined in Attachment 3. For example, Dr. Scott had originally proposed collecting data with questionnaires of STEPS chapter members. External partners proposed the current approach as a more desirable alternative. The number of external partners providing input on the project has never exceeded 9 individuals, and Dr. Scott did not collect data from them systematically to ensure compliance with the Paperwork Reduction Act. Internal partners advising on the project have included subject matter experts from the National Institute for Occupational Safety and Health, as well as the CDC National Center for Injury Prevention and Control. Dr. Scott worked closely with Dr. Jennifer Bell, a NIOSH subject matter expert on the use of IVMS in the oil and gas extraction industry, to develop Attachments 4 and 5.

9. Explanation of Any Payment or Gift to Respondents

Incentives will not be necessary. Individuals will be asked to voluntarily participate during work hours. Data will be collected virtually. Travel reimbursements will not be necessary. The Permian Basin is largely rural. Concerns regarding saturation and competition from other research activities are low.

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

Primary data collected in the proposed project will be qualitative in nature and saved as audio files, transcripts, and transcript summaries. Researchers will use ODIT-recommended software to ensure data access, security, privacy, and confidentiality throughout the entire project, and follow ODIT guidance for data archiving and long-term preservation. The audio recordings of the interviews will be transcribed using ODIT-approved software (e.g., MS Office). Files will be managed on an ODIT-approved platform (i.e., a MUST drive). Interview guides have been designed to limit the inadvertent collection of personally identifiable information (PII) and, if volunteered during the interviews, PII will be scrubbed from the interview transcripts before analysis. Local project staff will verify that any individually identifiable information that has been collected during the course of their activities has been removed from information transmitted to or shared with CDC. Researchers will delete the audio recordings once transcripts have been produced and validated. Secondary data for quantitative analyses will, likewise, be managed on an ODIT-approved platform (i.e., an encrypted MUST drive) in accordance with CDC/NIOSH data use policies.

This project has received a non-human subjects research determination (STARS Project ID: 0900f3eb821be791; *HSC: Does NOT Require HRPO Review*. Completed 8/23/23). Participation in the formative research is strictly voluntary.

Persons participating in the project will be informed that their data will be maintained in a secure manner, and that the data will only be used for purposes stated in project materials. Although the identities of respondents may be known to local project personnel who conduct interviews and interact with respondents, data collected regarding sensitive topics will not be stored or accessed in a Privacy Act system of records, and the respondents' identifying information will not be submitted to CDC. Only authorized project staff will be allowed to have access to study information (whether identifiable or not) and all information will be kept in a secure electronic location, a locked cabinet and/or locked office with limited access.

Information might be collected electronically or on paper (depending on the individual information collection request). Electronic means include handheld devices, computer-assisted self-interview (CASI), audio computer-assisted self-interview (ACASI), computer-assisted telephone interview (CATI), web-based surveys, or other point of service collection devices.

Electronic data collection and data management systems used for these activities will comply with the current encryption security standards from National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). Each individual request under this generic clearance will provide adequate descriptions of information systems that will be used in their study.

All individually identifiable information collected will be unlinked or stripped from the data. Web-based methods for questionnaire delivery will use approved software platforms commonly used by CDC/NIOSH (e.g., REDCap). There will be no websites or internet content directed at children under the age of 13. Individual collection requests submitted under this generic approval will describe any web-based material involved.

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

IRB Approval

IRB approval is not required. This project has received a non-human subjects research determination (STARS Project ID: 0900f3eb821be791; *HSC: Does NOT Require HRPO Review*. Completed 8/23/23). Participation in the formative research is strictly voluntary.

Sensitive Questions

This project's data collection activities will not involve sexual attitudes and practices, use of illegal substances or other matters that are commonly considered private. Respondents' race and ethnicity data and diagnoses of medical conditions that may affect employability or insurability will not be collected in this information request. Under no circumstances will a participant's social security number be obtained for this formative research activity.

A.12. Estimates of Annualized Burden Hours and Costs

We anticipate approximately 75 qualitative interviews.

Exhibit A.12.A Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
Occupational Safety and Health Professionals	MVC_Priorities Interview	30	1	1	30
	IVMS_Interview	15	1	1	15
Data Professionals	Data_Interview	30	1	1	30
Total					75

A.12.B Estimated Annualized Costs

This project is being supported through the National Institute for Occupational Safety and Health (NIOSH) National Occupational Research Agenda (NORA) Intramural Research Competition. The project is scheduled for 10/1/2023 through 9/30/2027. The annualized cost to the respondent is segmented accordingly in Exhibit A.12.B.

The United States Department of Labor, Bureau of Labor Statistics, May 2023, data were used to estimate the hourly wage rate for Occupational Safety and Health Specialists (Standard Occupation Code 19-5011; <https://www.bls.gov/oes/current/oes195011.htm>) and Database Administrators (Standard Occupation Code 15-1242; <https://www.bls.gov/oes/current/oes151242.htm>).

Exhibit A.12.B. Annualized Cost to Respondents

Type of respondents	Form Name	No. of Respondents	Avg. Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
OSH Specialists	MVC_Priorities Interview	30	1	30	\$41.14	\$1,234
OSH Specialists	IVMS_Interview	15	1	15	\$41.14	\$617
Database Admins	Data_Interview	30	1	30	\$50.39	\$1,512

Total						\$3,363
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A.13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

CDC/NIOSH does not anticipate providing start up or other related costs to private entities.

A.14. Annualized Costs to the Government

Actual annualized costs to the government will vary depending on the specific needs of the individual information collection activity. Generally, each development activity will involve participation of at least one CDC project officer (GS-12, 13 or 14 levels) who will be responsible for the project design, obtaining IRB approvals, providing project oversight, and analysis and dissemination of the results. The CDC project officer will provide remote and onsite technical assistance to the local areas implementing the data collection. Travel may be required to provide this technical assistance. In some cases, a CDC data manager's (typically a contractor equivalent to GS-9) time may also be required. An estimated average cost per individual activity is listed below, but detailed costs will be submitted with each individual collection request.

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government		
	CDC Project Officer (GS-13, 0.25 FTE)	\$33,533
	CDC Data Manager (Epidemiologist II, 0.1 FTE)	\$8,000
	CDC Travel (0 trips)	\$0
	Subtotal, Direct costs	\$41,533
Cooperative Agreement or Contract	Cooperative Agreements, Task orders, or Contracts for implementation or information management	\$20,000
	TOTAL COST TO THE GOVERNMENT	\$61,533

A.15. Explanation for Program Changes or Adjustments

This is the initial submission for the formative research project described above and so does not have a previous OMB approval.

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

Individual data collections under this generic approval will be time-limited and generally conducted only once, except in the cases of individual interviews conducted during pilot testing of

interventions where respondents may have to be approached several times on the same or similar topic under evaluation. No single data collection activity will take longer than 1 year to complete from inception of information collection to the first report of findings.

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.

REFERENCE

Office of Management and Budget, Statistical Policy Directive No. 2: Standards and Guidelines for Statistical Surveys; Addendum: Standards and Guidelines for Cognitive Interviews. Published in the Federal Register, October 12, 2016, vol. 81, no. 197, pp. 70586.