**Request for Approval under the “Administration for Strategic Preparedness and Response—Office of Strategy, Policy, Planning, and Requirements Generic Clearance for the National Strategy for a Resilient Public Health Supply Chain”**

**OMB Control Number:** 0990-0488

**Expiration Date:** March 31, 2026

1. **TITLE OF INFORMATION COLLECTION:** Advancing Equitable PPE Protection for Women Working in Hazardous Environments
2. PURPOSE:

This research initiative serves as a crucial endeavor in advancing the resilience and effectiveness of the nation's public health supply chain, particularly concerning the provision of personal protective equipment (PPE) for female workers across pivotal sectors such as Healthcare, Emergency Medical Services (EMS), Firefighting, Construction, and Mining. Building upon insights gleaned from NIOSH's 2021 Federal Register Notice (FRN) entitled “Needs and Challenges in Personal Protective Equipment (PPE) Use for Underserved User Populations” and prior research highlighting challenges in equitable PPE protection, this project aims to delve deeper into these issues, particularly emphasizing the needs of female workers who play essential roles in critical infrastructure during health emergencies. By gathering firsthand insights into the challenges and barriers encountered by these frontline workers, this project aims to contribute to enhancing understanding and informing strategic decision-making processes aimed at improving PPE use, accessibility, availability, acceptability, and knowledge.

Furthermore, this work aligns with the goals of Action 23 – PPE Standardization for the Cross-Department Public Health Supply Chain Resiliency Work Groups (where Administration for Strategic Preparedness and Response (ASPR) is the agency with overarching coordination responsibility across all Actions). Specifically, the information collected in this study will be used by NIOSH and standards development organizations (e.g., National Fire Protection Association, NFPA), to inform the development of new test methods, performance criteria, or PPE selection guidance for essential female workers who serve as PPE consumers (e.g., firefighters, EMS, healthcare personnel, select construction workers, energy sector/mining workers) and who may additionally perform crucial functions needed to maintain or expand supply capabilities for the nation (e.g., manufacturing supply/mining workers). The enhanced test methods, performance, criterial, or selection guidance will ensure that PPE may be produced to meet the needs of these essential female workers. The Action 23 Work Group will work with its membership from the Manufacturing Sector (e.g., PPE manufactures and distributors) to address challenges to making this PPE available on the marketplace during periods of routine and surge demands. The Action 23 Work Group will then work with the Action 11 Work Group for End-to-End Supply Chain Visibility to ensure products meeting the needs of female workers are tracked for visibility.

As the lead Agency on Action 23 – PPE Standardization for the Cross-Department Public Health Supply Chain Resiliency Work Groups (where ASPR is the agency with overarching coordination responsibility across all Actions), NIOSH coordinated this project with relevant contributing agencies including ASPR, the Food and Drug Administration, National Institute for Standards and Technology, the Environmental Protection Agency and the Occupational Safety and Health Administration. By coordinating through this Work Group, NIOSH ensured that the work described within this genIC request was not duplicative of other government agencies with relevant authorities.

The insights derived from this initiative will inform the development of plans, policies, and strategies aimed at addressing critical gaps and challenges within the public health supply chain ecosystem. By exploring a wide range of topics, including stakeholder engagement, innovation, regulations, policy, standards, and stockpiling strategies, this research endeavor aims to facilitate informed decision-making and foster collaboration across sectors.

Moreover, by providing a platform for the voices of these workers to be heard, this research initiative promotes a collaborative and inclusive approach to enhancing public health emergency preparedness. These insights will not only guide immediate actions to strengthen PPE provisions but also lay the foundation for long-term strategies aimed at fostering a more resilient and equitable public health infrastructure. And the data collected through this initiative will offer valuable insights into stakeholder perceptions, experiences, and expectations, enabling ongoing, collaborative, and actionable communication among relevant stakeholders. This fosters alignment with the evolving needs and priorities of the public health community.

Ultimately, this research initiative underscores a collective commitment to enhancing the nation's preparedness and resilience in the face of public health emergencies, with a particular focus on strengthening the public health supply chain to safeguard the health and well-being of frontline workers and communities by addressing critical gaps and challenges in PPE access and protection.

1. DESCRIPTION OF RESPONDENTS

This project employs focus group methodology to gather data from two essential participant groups, crucial for understanding PPE dynamics in critical sectors, particularly during emergencies:

**Frontline Female Workers**: These individuals represent frontline workers across pivotal sectors such as healthcare, EMS, firefighting, construction, and mining. They play indispensable roles in ensuring operational continuity and public safety during emergencies. For instance, healthcare workers and EMS personnel are at the forefront of public health response, providing vital medical care and emergency services during crises. Protecting their well-being is paramount to sustaining healthcare services and containing outbreaks. Firefighters often face hazardous conditions which can pose significant health risks. Their protection is essential not only for their safety but also for maintaining firefighting capabilities during emergencies. Construction workers contribute to critical infrastructure projects essential for community resilience. However, they may be exposed to various risks, such as hazardous materials or environmental pollutants such as wildfire smoke. Ensuring their safety is crucial for maintaining essential infrastructure, especially during emergencies. Mining operations are vital for resource extraction, supporting manufacturing and industrial base expansion. During emergencies, increased production may be necessary to bolster supply chain management. Protecting mining workers is essential for sustaining production levels and ensuring resource availability during crises.

**Management/Administrative Personnel**: This group includes individuals overseeing employees and managing PPE procurement and distribution in the sectors mentioned above. They are responsible for maintaining adequate PPE supplies to safeguard worker health and safety. Participants may hold titles such as procurement specialist, purchasing manager, industrial hygienist, or health and safety manager. Both male and female personnel are eligible participants, reflecting the diversity of roles in PPE management.

Respondents are anticipated to represent diverse demographics, including individuals over 40, racial/ethnic minorities, pregnant women, and those serving low socioeconomic communities. Their varied backgrounds enrich the understanding of PPE challenges and requirements across different contexts and populations. Moreover, protecting these frontline workers not only ensures their safety and well-being but also strengthens the resilience of the public health supply chain during health emergencies, safeguarding critical services and infrastructure essential for community health and safety.

1. TYPE OF COLLECTION: (Check one box. If you are requesting approval of other instruments under the generic, you must complete a form for each instrument.)

|  |  |
| --- | --- |
| [ ]  Informed consent | [ ]  Supply chain questionnaires |
| [ ]  Demographics standardized questionnaire  | [ ]  Knowledge-based questionnaires |
| [ ]  Cognitive questionnaire  | [x]  **Interviews and focus groups** |
| [ ]  Formative interview and focus groups | [ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  Town hall and public meetings |  |

1. CERTIFICATION: Please read the certification carefully. If you incorrectly certify, OMB will return the generic as improperly submitted or it will be disapproved.

I certify the following to be true:

1. Information gathered may not directly inform influential public policy decisions as defined by OMB. Information may also inform the development of ASPR’s and the National Strategy interagency team’s future intramural and extramural research projects, which could in turn inform influential public policy decisions;[[1]](#footnote-3)
2. Information collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the broader population;
3. The collections are voluntary;
4. The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the federal government;
5. The collections do not raise issues of concern to other federal agencies; and
6. Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future.

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To assist review, please provide answers to the following question:

1. PERSONALLY IDENTIFIABLE INFORMATION (PII): Provide answers to the questions. Note: Agencies should only collect PII to the extent necessary, and they should only retain PII for the period of time that is necessary to achieve a specific objective.
2. Is personally identifiable information (PII) collected? [ ]  Yes [x]  No *(determination made by ODIT on May 20, 2024)*
3. If Yes, will any information that is collected be included in records that are subject to the Privacy Act of 1974? [ ]  Yes [x]  No
4. If Yes, has an up-to-date System of Records Notice (SORN) been published? [ ]  Yes [ ]  No
5. GIFTS OR PAYMENT: If you answer yes to the question, please describe the incentive and provide a justification for the amount.
6. Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ]  Yes [x]  No
7. BURDEN HOURS: Identify who you expect the respondents to be in terms of the following categories:
8. Individuals or households
9. Private sector
10. State, local, or tribal governments; or
11. Federal government

 Provide the burden hours for the information collection in the table below.

* Only one type of respondent can be selected per row.
* **No. of Respondents:** Provide an estimate of the number of respondents
* **Participation Time:** Provide an estimate of the amount of time required for a respondent to participate (e.g., fill out a survey or participate in a focus group)
* Multiply the number of respondents and the participation time to calculate the number of burden hours. Examples are provided in table.

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Focus Group Respondent** | **No. of Respondents** | **Participation Time (in hours)** | **Burden** |
| Private Sector: Frontline female healthcare workers | 100 | 1 | 100 |
| Private Sector: Frontline female EMS professionals  | 100 | 1 | 100 |
| Private Sector: Frontline female firefighters | 100 | 1 | 100 |
| Private Sector: Frontline female construction workers | 100 | 1 | 100 |
| Private Sector: Frontline female mining workers | 100 | 1 | 100 |
| Private Sector: PPE Management/Administrative stakeholders representing healthcare setting | 40 | 1 | 40 |
| Private Sector: PPE Management/Administrative stakeholders representing EMS setting | 40 | 1 | 40 |
| Private Sector: PPE Management/Administrative stakeholders representing public safety setting | 40 | 1 | 40 |
| Private Sector: PPE Management/Administrative stakeholders representing construction setting | 40 | 1 | 40 |
| Private Sector: PPE Management/Administrative stakeholders representing mining setting | 40 | 1 | 40 |
| **Totals** |  |  | 700 |

1. RESPONDENT COST: If applicable, provide an estimate of the cost to respondents or recordkeepers resulting from the collection of information. The cost estimate should be split into two components:
	1. a total capital and start-up cost component (annualized over its expected useful life)
		1. Not Applicable
	2. a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information.
		1. Burden cost estimate to respondents is shown below
		2. There is no other cost or expectations placed on respondents other than participation

Estimated Annualized Burden Costs

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Respondent | Annualized Burden Hours | Averaged Hourly Wage Rate | Total Respondent Costs |
| Organizational manager | 200 | $74.18 | $9,436.00 |
| Frontline worker | 500 | $26.88 | $13,440.00 |
|  |  |  | $22,876.00 |

The value assigned for the hourly wage rate is based on the average U.S. hourly wage rate for several sector positions available in the following information: Bureau of Labor Statistics, U.S. Department of Labor, *May 2020 National Industry-Specific Occupational Employment and Wage Estimates NAICS 29-0000, 31-0000, 33,0000 -Healthcare practitioners and technical occupations, healthcare support occupations, and protective service occupations*, on the Internet at [**https://www.bls.gov/oes/current/oes\_stru.htm#29-0000**](https://www.bls.gov/oes/current/oes_stru.htm#29-0000)(visited *June 22, 2023*).

The estimated cost to the respondents is: $22,876.00

1. FEDERAL COST: Provide an estimate of the cost to the Federal government. This can include a quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information.

The estimated cost to the Federal government is: $150,000

1. PLANS FOR TABULATION AND PUBLICATION: For collections of information whose results will be published, outline plans for tabulation and publication. Provide the time schedule for the project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

| Key Activities | Target Dates |
| --- | --- |
| Recruitment of frontline workers and supervisors/managers | Begin December 2023 and will be ongoing |
| Focus groups with frontline female healthcare workers | January - May 2024 |
| Focus groups with frontline female firefighters | January - May 2024 |
| Focus groups with frontline female construction workers | January - May 2024 |
| Focus groups with frontline female mining workers | January - May 2024 |
| Focus groups with frontline female EMTs (EMTs include positions such as ambulance driver, paramedic, EMS professional, pre-hospital registered nurse) | January - May 2024 |
| Focus group with managers of healthcare organizations | June 2024 |
| Focus group with managers of EMS organizations | July 2024 |
| Focus group with managers of firefighting | August 2024 |
| Focus group with managers of construction  | September 2024 |
| Focus group with managers of mining  | September 2024 |
| Data organization and cleaning | October 2024 |
| Qualitative data analysis | November 2024 – January 2025 |
| Write up reports | February – April 2025 |
| Disseminating study findings | April-September 2025 |

1. **STATISTICAL METHODS:** If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

**The selection of your targeted respondents**: Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe? [ ]  Yes [x]  No

If the answer is yes, please provide a description of both below (or attach the sampling plan). If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them.

Researchers will utilize both a convenience and purposive sampling strategy. Initially, a convenience method is being used based on existing relationships with organizations who have expressed an interest in NIOSH’s research activities on equitable PPE protections. Specifically, NIOSH hosted an Equitable PPE Protections workshop in November 2022, where a list of interested organizations and individuals who requested to be contacted with follow-up opportunities will be used. In addition to this list, NIOSH has extensive healthcare, construction, mining, and public safety organizational contacts across the United States that will be leveraged. First, leaders of organizations will be contacted through a recruitment/informational document describing the project (attached in complementary materials). Upon organizational consent, frontline workers will be given the opportunity to participate. These individuals will be recruited directly via e-mail or phone about (1) their willingness to participate as a leadership representative of their organization or (2) their willingness to participate as a frontline female worker. All recruitment materials are provided as attachments to this request.

**Administration of the Instrument:** Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g., for surveys) or facilitators (e.g., for focus groups) used.

1. How will you collect the information? (Check all that apply)

[ ]  Web-based or other forms of social media

[x]  Telephone

[x]  In-person

[ ]  Mail

[ ]  Other (Explain)

1. Will interviewers or facilitators be used? [x]  Yes [ ]  No

**Please make sure that all instruments, instructions, and scripts are submitted with the request**

List of attachments:

* Blanket Supporting Statement A
* Blanket Supporting Statement B
* Participant recruitment script
* Project information for organizational recruitment
* Electronic consent scripts/instructions
* Informed consent
* Focus Group guide

1. As defined in OMB and agency Information Quality Guidelines, “influential” means that “an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.” [↑](#footnote-ref-3)