Request for genIC Approval
CDC/ATSDR Formative Research and Tool Development

0920-1154

CIO: The Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), National Personal Protective Technology Laboratory (NPPTL)

PROJECT TITLE: Assessing Respirator Perceptions, Experiences, and Maintenance

PURPOSE AND USE OF COLLECTION:

The Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), National Personal Protective Technology Laboratory (NPPTL) seeks approval from the Office of Management and Budget (OMB) to conduct research around the perceptions, experiences, and maintenance of respiratory protection from both an individual user and organizational standpoint.

NIOSH NPPTL has a need to collect data to evaluate the use of approved respiratory protective devices under 42 CFR 84 CFR to pinpoint areas where improvements in respirators and complementary RPPs are necessary. The combination of major shifts in the U.S. economy and an increase in alternative or non-traditional work arrangements represents the potential for a drastic change in how respirators are used and managed in the workplace. Additionally, to fulfill recommendations made by the National Academies of Sciences, Engineering, and Medicine, an integrated research effort is needed to fill in the gaps around respirator use and maintenance as well as organizational programs that reduce barriers surrounding these topics. Such research activities occur across NPPTL projects to understand barriers to respirator use and integration as well as the development of programs and best practices in the workplace.

A primary goal of this generic package is to identify patterns in respiratory protection use, as well as health and safety programs including practices and directives that are missing in RPPs. This includes workplaces whose use of an RPP framework both is and is not under OSHA for enforcement purposes. In other words, it can include workers in nontraditional work arrangements such as contractors. None of the studies proposed under the auspices of this generic IC intend to produce results that can be generalized beyond the scope of each study. The types of information collection activities included in this generic package include qualitative interviewing or focus groups for exploratory and formative research purposes, perception and knowledge-based surveys, qualitative fit testing, and physiological monitoring while wearing a respirator.

The objective of this request is to enable NIOSH to engage in information collection activities that are focused on assessment and will result in the development of interventions, new or improved respirator designs and adoption of respiratory protection/best practices, and concept development and/or product development and testing and decrease burden to the public. Outcomes will inform new content for improved respirator training, management, and use.

DESCRIPTION OF RESPONDENTS:

Respondents include persons in the general population or from specific subpopulations that are reflective of the full spectrum of the U.S. workforce, from industries that rely heavily on respiratory protection to protect workers (e.g., healthcare and social assistance and public safety and emergency response) to those who more seldomly wear respiratory protection. Expected respondent job roles include industrial hygienists, occupational health professionals, infection control professionals, physicians, nurse practitioners, nurses, infection preventionists, fire department chiefs, battalion chiefs, sheriffs, shift supervisors, firefighters, police officers, paramedics, and those who might choose to wear a respirator at their place of employment. Respondents may also include those who work at smaller businesses that employ fewer than 10 people and therefore, are not held to the same RPP requirements. Because respondents will be recruited from a variety of different workforces and occupations, it is expected that the respondent pool will vary in gender, age, races/ethnicities, persons residing in rural and/or urban locations, and/or in specific regions or health jurisdictions.

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. Information gathered will not be used to substantially inform influential policy decisions.
5. The study is not intended to produce results that can be generalized beyond its scope.

Name: Emily J. Haas

To assist review, please answer the following questions:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [ ] Yes [X] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [ ] No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [X] Yes [ ] No

In many cases incentives will not be necessary, but when they are, incentives will not exceed $40 per hour for such intensive interviews like focus groups and cognitive interviews unless compelling evidence shows that recruitment is very difficult for a particular subgroup.

BURDEN HOURS

Category of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response	Total Response Burden (Hours)
Individuals who wear respirators in any occupational setting or oversee/advise on respirator use	Informed consent	110,000	1	5/60	9,167
Individuals who wear respirators in any occupational setting or oversee/advise on respirator use	Demographics standardized survey with decision logic allowing some questions to be omitted	110,000	1	15/60	27,500
Individuals who wear respirators in any occupational setting or oversee/advise on respirator use	Qualitative fit testing survey measurements	675	20	15/60	3,375
Individuals who wear respirators in any occupational setting or oversee/advise on respirator use	Perceptions-based survey instrument	105,000	2	15/60	52,500
Individuals who wear respirators in any occupational	Knowledge-based survey instrument	105,000	2	30/60	105,000

setting or oversee/advise on respirator use					
Individuals who wear respirators in any occupational setting or oversee/advise on respirator use	Interview/Focus group	4,000	2	1	8,000
Individuals who wear respirators in any occupational setting or oversee/advise on respirator use	Physiological Monitoring: Heart rate, blood pressure, blood oxygen saturation, breathing rate, etc.	1,000	1	9	9,000
Total					214,542

FEDERAL COST: The estimated annual cost to the Federal government is $574,091

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

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?

Because this generic clearance covers a wide range of studies, each individual project submitted under this generic clearance will clearly define the specific data collection methods and procedures. Individual data collections will be time-limited and generally conducted only once, except when pilot testing of interventions occur, and respondents may have to be approached several times on the same respirator or similar type of respiratory protection under evaluation.

Information collection requests for each individual project associated with this generic clearance will clearly define the specific goals, respondent population and sampling method. Populations and sampling methods will vary from project to project. Sampling methodologies will include probability sampling methods such as simple or stratified random sampling, or multi-stage random sampling, or nonprobability methods such as respondent-driven sampling, purposive sampling, and convenience sampling.

Potential respondents will be identified through targeted recruitment efforts or purposive selection of key informants selected from the relevant study population. Screening questions may be used to determine eligibility. In some cases, an algorithm may be used to randomly select or ensure a diverse respondent pool. Recruitment methods, whether a convenience sample or randomly identification via an algorithm, will vary by individual project. All recruitment materials will indicate the voluntary nature of the study.

Regardless of methods, projects will comply with all federal regulations for consent based on the nature of the study. Any consent process will inform potential participants of the private and voluntary nature of the study and provide general information about the study, the topics to be covered in the study, potential risks, and the token of appreciation available for completing the study. Screening questions may be asked; the screener includes questions to assess eligibility.

Administration of the Instrument

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

    [X] Web-based or other forms of Social Media

    [X] Telephone

    [X] In-person

    [X] Mail

    [ ] Other, Explain

2. Will interviewers or facilitators be used? [X] Yes [ ] No

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

Instructions for completing genIC Request for Approval for CDC/ATSDR Formative Research and Tool Development

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TITLE OF INFORMATION COLLECTION: Provide the name of the collection that is requested.

PURPOSE and USE: Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

DESCRIPTION OF RESPONDENTS: Briefly describe the targeted group/groups for this collection.

CERTIFICATION: Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

Personally Identifiable Information: Provide answers to the questions.

Gifts or Payments: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

BURDEN HOURS:

Category of Respondents: Identify who you expect the respondents to be in terms of the following categories: (1) Individuals or Households; (2) Private Sector; (3) State, local, or tribal governments; or (4) Federal Government. Only one type of respondent can be selected.

Form: Provide the title of the information collection form.

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).

Burden in Minutes: Multiply the Number of responses and the participation time and divide by 60.

FEDERAL COST: Estimate the annual cost to the Federal government for this collection.

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.

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.