

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

0920-1381

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: Formative Respirator and Protective Clothing Laboratory Testing

PURPOSE AND USE OF COLLECTION:

NIOSH has a continuing need to a more comprehensive understanding of the impacts of wearing respirators and protective clothing on workers to inform relevant performance standards and associated test methods towards the goal of adequately protecting workers across a variety of industries via PPE as well as reducing the burden of wearing the PPE on the workers themselves. Further supporting this need for respiratory protection research advancement as an important subset of PPE, a 2007 assessment conducted by the National Academies of Sciences, Engineering, and Medicine (NASEM), the committee recommended that NIOSH continue to engage in research that enhances the understanding of respirator use in the U.S. to inform accurate decision making in this area. Towards this goal, barriers to use which often include the physiological and perceptual burden on the workers using respirators must be systematically examined to ultimately inform the associated performance standard adjustments and ensure proper protection while reducing user burden. These types of research activities are directly what is being proposed in this package.

In addition, an ever-changing United States workforce, workplace safety environment with new and evolving hazards, and continual development of new respirator and protective clothing technologies necessitate the constant revision of PPE implementation and performance standards to ensure both sustained protection and usability. For example, in 2017 the healthcare and social assistance industry sector employed more U.S. workers than the manufacturing sector. This is in stark contrast to 2000, where there were 7 million more workers in the manufacturing sector and 2.4 million more in the retail sector than in healthcare. These major shifts in the U.S. economy and associated increases in PPE demand and use represent the potential for a drastic change in how respirators and other PPE are used and managed in the workplace. Second a changing workplace safety environment must be considered. For example, novel infectious disease outbreaks such as the Ebola outbreak in 2014 and the COVID-19 pandemic in 2020 require sometimes drastic changes to the design and protection of PPE or the way workers wear PPE during work. Specifically, wear durations and frequency of respirator and PPE wear among healthcare and social assistance workers increased drastically during COVID-19 pandemic requiring a novel consideration of the burden of PPE on workers. Lastly, PPE-related technological advancements such as the introduction of novel sensors, improved design and construction, manufacturing advancements, and the introduction of nanotechnologies to name a few require continual re-consideration of the associated performance standards. These new technologies, designs, construction approaches, and use cases must be tested in an efficient manner to understand the direct impact on workers and necessary revisions to performance standards or test methods to accommodate the changing market.

This package will allow for the federal government to maintain a relevant and considerate scientific understanding of federal regulations and voluntary consensus standards that govern the performance; test method; or use, design, or construction of respirators and protective clothing allowing for robust PPE protection to the United States workforce while ensuring low burden and high usability in a consistently changing PPE environment. To achieve this goal, this package requests recurring information collection from human subjects which will directly examine the interaction between human subjects and PPE under varying boundary conditions. The types of data collection may include measurements of physiological, perceptual, and biomechanical responses to wearing PPE as well as examining PPE fit across various body shapes and sizes to ensure adequate protection and low user burden across a variety of use scenarios. The objective of this request specifically is to enable NIOSH to engage in these types of information collection activities in a time- and resource-efficient fashion, catalyzing improved worker health and safety experiencing novel workplace safety and protection scenarios. 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 information collected for a project will be maintained or stored locally under strict access controls limited to the local project leader/manager or his/her designate. In some cases, personally identifiable information (PII) will need to be collected primarily for the purpose of facilitating payment. If it is, PII will be kept in a separate location and accessible only to the project-specific research staff. This information will be destroyed when the participant's contribution to the project has ended. Under no circumstances will an individual be identified using a combination of variables such as sex, race, birth date, and/or other descriptors.

DESCRIPTION OF RESPONDENTS:

The respondent universe for the proposed data collection will be recruited from the general population but their demographic characteristics are expected to be reflective of the United States' workforce and from industries that rely heavily on PPE to protect workers (e.g., healthcare and social assistance, public safety and emergency response, and agriculture). Because the United States' worker population in some cases includes children down to the age of 8 years in certain industries such as agriculture, it is expected that studies included in this data collection may also include children. Because respondents will be recruited via a variety of different avenues (email, flyers, advertisements, etc.), it is expected that the respondent pool will vary in sex, age, races/ethnicities, persons residing in rural and/or urban locations, and/or in specific regions or health jurisdictions. Additionally, pregnant women may also be a focus of these data collection efforts as pregnant women are regular users of PPE which must be considered due to specific needs related to changes in body shape and size.

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: Jonisha Pollard

To assist review, please answer the following questions:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? ☒ Yes ☐ 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? ☒ Yes ☐ No

To incentivize participation, human subjects who participate in the research activities outlined in this generic will be compensated for their time. Incentives will not exceed \$40 per hour for participation in data collection unless compelling evidence is provided that recruitment is very difficult for a particular study or subgroup. These incentives will be provided to the subject.

BURDEN HOURS

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Members of the general public ¹	Informed Consent	970	1	30/60	485
	Health Screening Questionnaire: standardized form w/ decision logic allowing some questions to be omitted	970	6	1	5,820
	Demographics Questionnaire: standardized form w/ decision logic allowing some questions to be omitted, W-9 Tax Form, etc.	970	1	30/60	485
	Job-related Data: occupational Tasks, postures used, duration of exposure, etc.	970	1	15/60	243

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
	Physiological Measurements: chest-worn heart rate monitor strap, COSMED Kb5, SQ2020-1F8 temperature logger, TOSCA 500 pulse oximeter, koken breathing waveform recording mask, etc.	200	6	1.5	1,800
	Biological Measurements: cortisol (stress) levels, pregnancy tests, hydration status, lipids, inflammatory markers, heat shock proteins, etc.	100	6	15/60	150
	Anthropometric Measurements: calipers/digital measuring of facial and body dimensions	750	1	15/60	188
	Respirator Fit Measurements: filter cassettes with air pumps, fit-testing equipment, QLFT/sodium saccharin solution etc.	225	100	15/60	5,625
	Self-Perception Data: level of exertion, perceived comfort level, heat sensation, fatigue, etc.	500	6	15/60	750
	Biomechanics Measurements: force plate, stopwatch, accelerometers, etc.	30	3	30/60	45
Total					15,591
¹ Members of the general public may include anyone representative of the larger working population within the United States including adults and children between the ages of 8 and 65 years.					

FEDERAL COST: The estimated annual cost to the Federal government is \$774,091

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 ☒ 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 in the cases of individual studies where subjects may be asked to attend several separate data collection sessions. No single data collection activity is expected to take longer than 3 years to complete from inception of information collection to the first report of findings.

Potential respondents will be identified through targeted or generalized recruitment efforts towards members of the general public via emails, flyers, and advertisements. After an individual has self-identified themselves as being interested in participation, screening questions may be used to determine eligibility. All recruitment materials will indicate the voluntary nature of the study.

We anticipate that studies under this generic clearance will use mixed methods for data collection which may include randomized controlled trials, randomized cross-over trials, within subjects repeated measures trials, and observational methods. Studies may also include brief structured surveys that include closed-ended questions for collecting information on age, race/ethnicity, sex, medical history, and occupational history. The subjects' physical body shape may be measured to understand the fit of various types of PPE. Physical assessments of subject physiological, biological, biomechanical, and perceptual responses to a given stimulus or environment may also be measured via electronic devices or validated questionnaires. Lastly measures of respirator specific fit may be measured using electronic devices and standardized procedures. Individual project submissions will outline the methodologies and measurements used for each study associated with this generic.

Regardless of methods used, all studies 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.

Data collection will be supported and monitored by CDC/NIOSH researchers at all times to ensure human subject safety and compliance with approved methodologies. Questionnaires may be interviewer administered or self-administered. Data collection will generally be computer assisted. Implementers may also collect data with pencil and paper for some studies in certain situations. Data collected will be kept on secure computer servers with access restrictions and/or in locked cabinets

in secure locations. All personal identifiable information (PII) required to conduct the study, such as contact information or social security numbers, will be maintained separately from the data collected, either on a server with access restricted to authorized personnel only, or if on paper, in separate locked cabinets from the data or recordings/transcripts.

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

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.