Generic Clearance for CDC/NIOSH/NPPTL

Formative Respirator and Protective Clothing Laboratory Testing

OMB Control Number: 0920-1381 Expiration Date: 01-31-2026

Supporting Statement B

Jonisha Pollard
Tel. 412.386.5220
Jni3@cdc.gov

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B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

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.

Sampling methods for laboratory bases evaluations will greatly depend on the methods of the individual studies and there for the populations will vary from project to project. These methods will be described in detail for each individual project. While convenience sampling is likely to be widely used due to the practical reality of recruitment for such studies, sampling strategies may also employ other methods such as stratified sampling by demographic characteristics (sex, age, race) pertinent to the particular study aims.

Information collection requests for each individual project associated with this generic clearance will clearly define the specific goals, respondent population, and sampling method.

2. Procedures for the Collection of Information

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.

3. Methods to Maximize Response Rates and Deal with No Response

To maximize participation, NIOSH will work to clearly define the expectations of each individual study up front to any potential subjects via both the recruitment materials and through an initial study visit or informed consent process. Additionally, study sessions will be scheduled at times convenient for each subject and be limited to only necessary time of active study participation with little down time. Any flyers or other recruitment materials to be used to encourage participation prior to commencing data collection will be included in applicable projects.

Participation in all research under this generic ICR is voluntary. 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 via check mailed to the subject’s home address by a contracting company of CDC/NIOSH. This practice is routine and common at CDC/NIOSH and has been done for many previous data collection efforts.

While some studies may require only one visit or study session, some may also require participants to attend multiple study data collection sessions. These sessions will be clearly explained to each potential subject prior to them volunteering to participate. Additionally participates will be compensated for all sessions that they participate in and will be informed that they can discontinue their participation at any time without any repercussion from the study whatsoever.

CDC/NIOSH does not claim that the subjects selected for each study are statistically representative of the entire PPE user population of interest. It should not be assumed that the findings of this demonstration study are generalizable to other entities.

4. Tests of Procedures or Methods to Be Undertaken

Depending on the purpose of the individual study covered under this Generic ICR, a variety of measurements may be conducted. Measurements and tests conducted in each individual study may include closed-ended questions for collecting information on age, race/ethnicity, sex, medical history, and occupational history. The subjects' physical body shape may also be measured to understand the fit of various types of PPE. 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.

Data collection methods to be used in each individual study will be confirmed to be valid to accurately inform the study outcomes. Specifically, all measurement instruments used will be thoroughly vetted for its validation and safety for the project specific use from the manufacturer or other prior research prior to its use during data collection during any individual project associated with this generic. Survey items and interview questions will be used from or created based on a thorough literature review of studies related to the individual project aims.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

This information collection request does not employ statistical methods. Individual studies covered under this generic ICR will provide statistical reviews and design if applicable.