

**Direct Reading Methodologies, Sensors, and Robotics Technology Assessment
in Lab/Simulator-based Settings**

GENERIC Information Collection Request

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CDC/NIOSH

Supporting Statement B

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B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

Information collection requests for each individual project associated with this generic clearance will clearly define the specific goals, respondent population, and sampling method. Generally, 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 full spectrum of the U.S. workforce and from industries that rely heavily on direct reading methodologies, sensor and automation technologies, and robotics technologies to protect workers (e.g., public safety and emergency response, manufacturing, retail and trade, construction, mining, and oil and gas). Expected respondents include any worker who has experience with, is required to use, or willing to use and provide feedback on any sort of direct reading methodologies, sensor technologies, or robotics technology in the workplace – these could be wearable or non-wearable. Common job roles that wear, interact with, or oversee such technology include construction workers, manufacturing workers, oil gas and extraction workers, mineworkers, retail workers, manufacturing workers, fire chiefs/firefighters, maintenance workers, law enforcement officers, and any industrial hygiene or occupational safety and health professional who oversees the integration and use of new technologies in the workplace.

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 gender, 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 included in some data collection efforts as pregnant women are regular users of direct reading methodologies, sensors, and robotics at some stages during their pregnancy. Their inclusion may be helpful when researchers must consider specific needs related to changes in body shape and size.

Sampling methods for laboratory and virtual reality-based studies will depend on the methods of the individual studies and therefore, the populations will vary from project to project. Information collection requests for each individual project associated with this generic clearance will clearly define the specific goals, respondent population and sampling method. 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. 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 study aims.

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 as well as via professional industry/trade associations and C-suite leadership for industry sectors. 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. Some studies may include qualitative open-ended questions to ascertain feedback on the technology or implementation processes and uses being studied, and experiences or perceptions. Studies may also include brief structured surveys that include closed-ended questions for collecting information on age, race/ethnicity, sex and gender identity, medical history, occupational history, and the statuses of their organization's use of direct reading methodologies, sensors, and robotics technologies.

The subjects' physical body or face shape (i.e., anthropometrics) may be measured using electronic devices, applications, or other standardized procedures to identify and understand the fit of various types of wearable devices. 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.

Individual project submissions will outline the methodologies and measurements used for each study associated with this generic. Regardless of the data collection methods used, all aspects of information collection will be implemented by trained personnel. All studies will comply with 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. Data collection may be interviewer administered or self-administered. Generally, data collection will be computer assisted whether data is automatically captured and transferred from wearable devices or whether participants respond to share their perceptions and experiences via electronic surveys. 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. When applicable, NIOSH will work with collaborators identified for each

individual study. Examples include organizational point of contacts who volunteer to participate in studies, who will be explained the importance of the study for the organizations, their employees, and the occupational industry before the study period begins. Additionally, study sessions will be scheduled at times convenient for each participant 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. Individual projects will aim to improve recruitment materials beyond only flyers to maximize the sample.

It is important to maximize response rates during information collection. Data collection efforts have not involved so many different health entities and occupations in one effort, so it is difficult to determine workers' overall willingness to participate in each individual package. However, projects may use follow-up probes to encourage participation and for some data collection that can occur via e-survey software, respondents will be able to easily select their answers, facilitating rapid questionnaire completion. For convenience, if participants cannot complete an electronic survey at one sitting, they will be able to stop at any point and pick up where they left off at a later time – this includes the ability to take a survey QR code with them upon leaving the laboratory to finish answering questions later about their experiences, if desired.

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 for some studies, participants may be compensated for their time and will be informed of their compensation but also indicate that they can discontinue their participation at any time without any repercussion from the study whatsoever.

CDC NIOSH does not claim that the workers selected for each study are statistically representative of the entire population. It should not be assumed that the findings of individual projects are generalizable to other entities. Due to the diversity of direct reading methodologies, sensors, robotics technologies, and their varied used in different occupational settings, any individual project results are not meant to be generalizable. Rather they are meant to be case studies to help professionals, workplaces, standards organizations, and manufacturers make decisions about how to support the safe, effective use and advancement of direct reading methodologies, sensors, and robotics technologies in the workplace. Generalizability is not the goal; the goal is for results of individual projects to be utilized by experts in taking the results/lessons learned and adapt them for their specific environment.

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 and gender identity, medical history, and occupational history. The subjects' physical body shape may also be measured to understand the fit of various types of wearable devices/equipment/technologies. Assessments of participant physiological, biological, biomechanical, and perceptual responses to a given direct reading method, sensor, or robot within their environment may also be measured via electronic devices or validated questionnaires. Measures of wearable device 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, including survey items and interview questions, used will be thoroughly vetted for validation via literature reviews, manufacturer guidelines, consensus standards, 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.