

Attachment B: Informed Consent Form

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30333. ATTN: PRA (XXX).

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**Centers for Disease Control
and Prevention**
National Institute for Occupational
Safety and Health

Consent to be in a Research Study

Evaluation of Robot-to-Human Communication Designs

1

Key Information Summary

Consent is being sought for research, and your participation is voluntary. The purpose is to investigate effectiveness of how a robot communicates errors to human workers. The expected duration of the study is 4 hours. You will be asked to complete a series of tasks in a virtual reality (VR) simulator. You will wear a head-mounted display (HMD) VR device and hold two controllers to perform tasks that involve picking up and placing virtual objects, while interacting with virtual robots. The risks involve developing simulator sickness (e.g., nausea), discomfort from the HMD, bumping into objects or tripping, and possible breach of privacy. The study is designed to reduce each of these risks as described below. There are no direct benefits to you for participating in this research. You may stop participating in the study at any time. Your participation will help improve the safety of human-robot interaction in the workplace. We will recruit a total of 61 participants to complete the study.

There is a small risk you could get a respiratory infection (e.g., COVID-19, influenza) through an in-person interaction while participating in this study. To minimize your risk of exposure to viruses and maximize your protection against infection, NIOSH researchers follow COVID-19 and other relevant respiratory infectious disease guidance for CDC and NIOSH staff and workplaces.

Consent to be in a Research Study

Evaluation of Robot-to-Human Communication Designs

2	Who is conducting the study?	<p>NIOSH is conducting the study. The National Institute for Occupational Safety and Health (NIOSH) is a federal agency that studies worker safety and health. We are part of the Centers for Disease Control and Prevention (CDC).</p>
3	What is the purpose?	<p>The purpose of this study is to investigate robot-to-human safety communication designs. Specifically, the research will evaluate the effects of varying robot interface modalities and message types on safety communication effectiveness and user perception of a robot.</p>
4	What will I do?	<p>You will be asked to complete a series of tasks in a virtual reality (VR) environment. You will be asked to move and behave naturally, as you would in a real environment. We will track your task performance, in terms of accuracy and completion time, using the VR system.</p> <p>You will wear an HMD VR device and hold two controllers to perform tasks that involve picking up and placing virtual objects. We will measure your inter-pupillary distance using a ruler to properly adjust the HMD so that you can clearly see the VR environment. The study will take place in a virtual assembly line with a collaborative robot. Before beginning the task, you will have a 5-minute practice session that will help you get familiar with the simulator environment and using the controller. During the practice, you will be asked to walk and move around the environment and pick and place the virtual objects using a controller. After the completion of the practice, you will complete the actual tasks.</p> <p>Before beginning the VR study, you will complete a demographics survey (6 questions) the robot experience questionnaire asking about your experience with and attitudes towards robots (18 questions) and the virtual reality experience questionnaire asking about your experience with virtual reality tools (4 questions).</p> <p>During the VR study, you will also respond to the post-condition questionnaire consisting of a total of 12 questions asking your perception of the robot and the task. This post-condition questionnaire will be repeated after each of the 20 testing conditions. You will also complete a 14-item robot evaluation</p>

Consent to be in a Research Study

Evaluation of Robot-to-Human Communication Designs

		<p>questionnaire after each testing condition.</p> <p>Finally, you will rate your virtual reality simulator sickness symptoms on nine criteria before and after the VR study.</p>
5	When, where, for how long will I be needed?	<p>You will be asked to visit the NIOSH laboratory in Morgantown for this study. Your visit will take approximately 4 hours, including: 15-30 minutes for orientation, up to 3 hours for the actual test, 10-15 minutes for the post-study survey, and 5-10 minutes for post-study debriefing.</p>
6	Are there any risks from participating in the study?	<p>You may feel simulator sickness during and/or after the study. Symptoms of simulator sickness include: dizziness, hyperventilation (rapid breathing), nausea, vomiting, or fainting. If you feel the onset of any of these symptoms at any time during or after the study, please tell the investigators immediately. The study will be stopped, and you will be guided to a comfortable chair to rest until the symptoms disappear. The symptoms are likely to be temporary and expected to disappear after a short rest. You will not continue the study after experiencing any symptoms unless the symptoms disappear, and you desire to continue.</p> <p>Pregnant women have an increased risk of developing simulator sickness and will be provided extra opportunities for sitting, taking water breaks to maintain hydration, and will be asked to provide feedback on simulator sickness symptoms throughout the study. Motion sickness does not have negative health effects on a fetus (Cleveland Clinic).</p> <p>During the recruitment process, you will be asked some questions that will help to understand if you might be susceptible to simulator sickness. If you have suffered simulator sickness in the past, you should not participate in this study. Further, if you commonly experience some level of motion sickness (e.g., from traveling in cars or planes) then you may be at an increased risk of experiencing simulator sickness.</p> <p>You may experience minor discomfort while wearing the HMD headset that will be worn over the head.</p>

Consent to be in a Research Study

Evaluation of Robot-to-Human Communication Designs

		<p>There's a risk of tripping, falling, or colliding with physical objects while wearing the HMD headset. To minimize this risk, you will perform the study tasks away from physical objects in the middle of the robotics lab. Also, study team members will monitor you while you perform the study task and warn you if you near a physical object.</p> <p>There is a potential risk for a breach of confidentiality and for private/personal information exposure, which may cause you to experience psychological or social stress (see section 12 and 13). We will minimize this risk by assigning a code to your data collection forms.</p> <p>There is a very small risk you could get a respiratory infection (e.g., COVID-19, influenza) through an in-person interaction while participating in this study. To minimize your risk of exposure to viruses and maximize your protection against infection, NIOSH researchers follow COVID-19 and other relevant respiratory infectious disease guidance for CDC and NIOSH staff and workplaces.</p>
7	Are there other benefits?	<p>You will not receive any direct benefits from participating in this study. Your participation in this research will help researchers to better understand the effects of robot interfaces on communication effectiveness during human-robot collaboration which may help prevent traumatic injuries that involve robots in the workplace.</p>
8	Is my participation voluntary?	<p>Your participation in the study is voluntary. You may choose to be in the study or not. You may choose to answer any or all questions. You may decline to participate or drop out at any time, for any reason, without consequences to you. If you have completed your participation in the study but would still like to withdraw, you may do so prior to publication of the study by contacting the researcher using the contact information on this form.</p>
9	What if I am injured or harmed at a NIOSH	<p>NIOSH will summon emergency medical aid by calling 911 if needed. NIOSH will not provide payment for medical care or compensation. If you believe NIOSH has been negligent in conducting the research study and you believe you have suffered a harm as a result, you have the right to pursue a legal remedy under the Federal Tort Claims Act (28 U.S.C. §§ 2671-2680 and 28 U.S.C. §</p>

Consent to be in a Research Study

Evaluation of Robot-to-Human Communication Designs

	research facility or at another location where the NIOSH research project is being conducted?	1346(b)). To learn more about how to file a Federal Tort claim, call the General Law Division of the HHS Office of the General Counsel at (202) 619-2155 or go to https://www.hhs.gov/about/agencies/ogc/key-personnel/general-law-division/index.html .
10	Will I be reimbursed or paid?	<p>You will be paid at a rate of \$30 per hour by gift card for your time during the study. For periods of time less than one hour, you will receive partial pay of \$10 per 20 minutes, with periods less than 20 minutes rounded up. If you complete the study you will receive a total of \$120.</p> <p>By participating in this study, you acknowledge that it would not cause you to exceed \$599 in payment by CDC for participation in other research studies or service activities (e.g., project reviews).</p>
11	What alternative procedures might benefit me?	No alternative procedures are available to collect the information needed for this study.
12	Will my personal information be kept confidential?	Personal information collected for the study is limited to your age, gender, race/ethnicity, and a measurement of your inter-pupillary distance. Each participant will be assigned a study number for identification. We will record your name to reimburse you for your time during the study. This information will be stored separately and not connected to any data collected during the study. Identifying information will be destroyed after the project is completed.

Consent to be in a Research Study

Evaluation of Robot-to-Human Communication Designs

		<p>NIOSH is authorized to collect your personal information and will protect it to the extent allowed by law.</p>
13	Certificate of Confidentiality	<p>This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.</p> <p>There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.</p> <p>Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information.</p>
14	Will I or anyone else receive study results?	<p>The results of the study will be documented in a journal article or a NIOSH research report. No individual results or pictures of you will be shown.</p> <p>Copies can be provided to you upon publication if requested. If you would like a copy of the summary report, please contact Dr. Justin Haney, the project officer at poe5@cdc.gov or 304-285-6179.</p>
15	Will my personal	<p>We may remove your name and other identifiers from the information that we collect during the study and then use the information for future research studies without asking you for</p>

Consent to be in a Research Study

Evaluation of Robot-to-Human Communication Designs

	information or samples collected from me be used in other research?	additional consent. We also may remove identifiers from the information that we collect and then share it with other researchers without asking you for additional consent.
16	Is this a Clinical Trial?	No
17	Did you receive all necessary information?	You should have been given all the information that a reasonable person would want to have in order to make an informed decision about whether to participate in this study. You should also have been given the opportunity to discuss the study and have your questions answered. If you need more information, or still have questions, please ask the person who is reviewing the study with you or the study Principal Investigator (Dr. Justin Haney).
18	Who can I talk to if I have more questions?	For questions about the research study, contact the principal investigator, Dr. Justin Haney at poe5@cdc.gov or 304-285-6179. For questions about your rights, your privacy, or harm to you, contact the Chair of the NIOSH Institutional Review Board at 513-533-8591.
19	Your signature	<p>The study was explained to me. My questions were answered. I agree to be in the study.</p> <hr/> <p>Printed name of participant</p> <hr/> <p>Participant signature Date</p> <p>I have accurately described this study to the participant.</p>

Consent to be in a Research Study
Evaluation of Robot-to-Human Communication Designs

		<div></div> <div>NIOSH representative signature</div> <div></div> <div>Date</div>
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