

Instrument B
Informed Consent Form



Consent to be in a Research Study
Improving Safety of Human-Robot Interactions

Key Information Summary: Consent is being sought for research and participation is voluntary. The purpose is to investigate interactions between humans and robots that operate in close cooperation in a shared workspace. The expected duration of the study is 6 hours. You will be asked to complete a series of tasks in a virtual reality (VR) simulator. You will wear a pair of light-weight glasses and hold a controller to perform tasks that involve picking up and placing virtual objects, while interacting with virtual robots. Motion capture marker clusters will be strapped to different body segments to track your motion. The risks involve developing simulator sickness (e.g. nausea), skin irritation/discomfort from motion capture marker straps, 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.

1	Who is conducting the study?	NIOSH is conducting the study. NIOSH is a federal agency that studies worker safety and health and is part of the Centers for Disease Control and Prevention (CDC).
2	What is the purpose?	The purpose of this study is to investigate interactions between humans and robots that are designed to work safely in close proximity to humans at work stations. Specifically, the research will evaluate the effects of different characteristics of robots on human actions and safety.
3	What will I do?	You will be asked to complete a series of tasks in a virtual reality (VR) simulator. You will be asked to move and behave naturally, as you would in a real environment. You will wear a pair of light-weight glasses and hold a controller to perform tasks that involve picking up and placing virtual objects. After completing a pick-and-place task at one task position, you will be asked to move to the next task position. The study has two parts, in two different VR environments: (1) a warehouse with a mobile robot, and (2) an assembly line with a collaborative robot. Before beginning each part, you will have a 10 minute practice session to help you get familiar with the simulator environment and using the controller. During the practices, 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 practices, you will complete the actual tasks.

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		<p><i>Performance data:</i> Your movement will be recorded during the tasks by the cameras installed in the VR simulator that track motion capture markers that will be strapped to multiple body segments.</p> <p><i>Questions:</i> Prior to the experiment, you will complete a questionnaire consisting of 22 questions asking about your experience and opinion about robots. During the experiment, 15 questions will be displayed on a screen, asking your feelings and physical conditions. You will provide responses by ticking a number for each question. These questions will be repeated multiple times during the test.</p>
4	When, where, for how long will I be needed?	<p>You can choose to do the study in one longer visit or in two shorter visits. If you choose to do the study in one visit, your visit will take approximately 5-6 hours, including: 15-30 minutes for orientation, up to 4.5 hours for the actual test, and 5-10 minutes for post-study debriefing. If you choose to do the study in two visits, each visit will take up to 3 hours.</p>
5	Are there any risks?	<p>You may feel simulator sickness during and/or after the study. Symptoms of simulator sickness include: 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. You will not continue the study after experiencing any symptoms unless that the symptoms disappear, and you desire to continue. The symptoms are likely to be temporary and expected to disappear after a rest.</p> <p>To help to avoid simulator sickness, before you participate in the study you will be asked some questions that will help to understand if you might be susceptible. If you have suffered simulator sickness in the past, you should not participate in this study.</p> <p>You may experience skin irritation from the attachment/removal of motion capture markers. You will be encouraged to report any feelings of discomfort throughout the experiment.</p>
6	Is my participation voluntary?	<p>The study is voluntary. You may choose to be in the study or not. You may choose not to answer any or all questions. You may drop out 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>

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7	What if I am injured or harmed at a NIOSH research facility or at another location where the NIOSH research project is being conducted?	<p>NIOSH will summon emergency medical aid by calling 911. If NIOSH finds your injury was a direct result of participation in the study and if appropriate documentation is provided, NIOSH may provide short-term medical treatment that it deems necessary to treat the immediate medical needs arising from the injury. In general, no long-term medical care or financial compensation of research-related injuries will be provided by NIOSH, the CDC, or the Federal Government. However, 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. § 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.</p>
8	Will I be reimbursed or paid?	<p>You will be paid at a rate of \$30 per hour 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.</p>
9	Are there other benefits?	<p>There are no direct benefits to you for participating in this research. Your participation in this study may contribute to research in robotic safety and advance the field of workplace safety.</p>
10	What alternative procedures might benefit me?	<p>No alternative procedures are available to collect the information needed for this study.</p>
11	Will my personal information be kept private?	<p>Personal information collected for the study is limited to your birth date, gender, and general employee history and type. Each participant will be assigned a study number for identification. Name and other identifiable information will be collected in order to pay reimbursement. 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.</p> <p>NIOSH is authorized to collect your personal information and will protect it to the extent allowed by law.</p>

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		<p>Your information will not be used or distributed for future research studies even if identifiers are removed.</p> <p>This research is covered by a Certificate of Confidentiality from the Centers for Disease Control and Prevention. The researchers with this Certificate may not disclose or use information or documents that may identify you in federal, state, local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.</p> <p>The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is need for auditing or program evaluation by the CDC which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the research to release it.</p>
<p>12</p>	<p>Will I or anyone else receive study results?</p>	<p>Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. 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. 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, by the end of 2022.</p>
<p>13</p>	<p>Who can I talk to if I have more questions?</p>	<p>For questions about the research study, contact the principal investigator, Dr. Justin Haney at poe5@cdc.gov or 304-285-6179.</p> <p>For questions about your rights, your privacy, or harm to you, contact the Chair of the NIOSH Institutional Review Board at 513-533-8591.</p>

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14	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> <hr/> <p>NIOSH representative signature Date</p>
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Public reporting burden of this collection of information is estimated to average 10 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 Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX).