

Attachment F: Informed Consent Form

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 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

Identification of Risk Factors for Demolition Robot Operators **Study 1: Human, environment, and control-pad factors, and Study** **2: Human behavior and perceptions of safety and trust when the** **robot moves unexpectedly.**

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| 1 | Key Information Summary | <p>Your consent is being sought for you to participate in a research study and your participation is voluntary. You will be given a copy of this form for your records.</p> <p>The purpose of the study is to understand what factors may lead operators of demolition robots to stand in hazardous places near the robot, and to explore the perception of operator about the safety of the demolition robot.</p> <p>Study 1 will take approximately 2.5 hours (of which 60 minutes you will be inside the VR simulator) and Study 2 will take approximately 2 hours (of which 40 minutes you will be inside the VR simulator). However, if you are only participating in Study 2, it will take approximately 3 hours to complete the study.</p> <p>Both Study 1 and Study 2 will be conducted in the NIOSH's Virtual Reality Lab. This lab uses a CAVE-type surround screen virtual reality system, which consists of four large projected screens: front, left, right, and floor; and provides a semi-immersive virtual reality experience.</p> <p>You will be asked to complete a series of tasks while in a standing position; you may be required to move two or three steps in every</p> |
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Study 1: Human, environment, and control-pad factors, and Study 2: Human behavior and perceptions of safety and trust when the robot moves unexpectedly.

direction. There will not be any other human subjects participating in the studies concurrently with you. During the time you complete the tasks, you will be wearing virtual reality glasses. Motion capture markers will be strapped to different parts of your body. The markers on the VR 3D glasses, as well as the markers on your waist and hand, and the markers on the Logitech remote control will serve to collect your position and motion data.

Some people who use virtual reality equipment can have symptoms like those of motion sickness (general discomfort, nausea, fatigue, headache, eye strain, difficulty focusing, fullness of head, blurred vision, dizziness, and vertigo). When this happens with virtual reality equipment it can be called 'simulator sickness'.

The risks of participating in Study 1 and/or Study 2 involve developing simulator sickness symptoms. There is also a small risk that you could feel discomfort from wearing the VR goggles, and that you could develop psychological stress due to the awareness of safety failures.

Throughout the study we will ask you to fill different questionnaires, including a Virtual Reality Sickness questionnaire, a Construction/Demolition Robot Experience Questionnaire, a NASA Task Load Index questionnaire, a Human-Robot Trust questionnaire, and a Post-Test questionnaire.

We will make every effort to protect your privacy and you will not be individually identified in any scientific document for your participation in this study. You will be paid for your time. We will recruit up to 200 participants to complete both Study 1 and Study 2.

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

Consent to be in a Research Study

Identification of Risk Factors for Demolition Robot Operators

Study 1: Human, environment, and control-pad factors, and Study 2: Human behavior and perceptions of safety and trust when the robot moves unexpectedly.

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| | | workplaces. We will also clean the equipment including the VR glasses, the hand and waist markers' straps, and the remote control, after each participant to minimize contamination or germ transmission. |
| 2 | Who 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). |
| 3 | What is the purpose? | Both Study 1 and Study 2 involve research. The purpose of Study 1 is to explore how visibility of a demolition task, environment lighting, and remote control-pad design affect an operator in operating a demolition robot. The purpose of Study 2 is to assess the perception and physical responses of the operators of demolition robots to various unexpected motions of the robot/structure. |
| 4 | What will I do? | <p>For Study 1 you will be asked to operate a virtual demolition robot using a remote control to perform demolition work in the following scenarios:</p> <ul style="list-style-type: none">• You will operate the demolition robot to tear down the upper half of a wall.• You will operate the demolition robot to tear down the lower half of a wall.• You will operate the demolition robot to tear down a marked portion of the ground.• You will operate the demolition robot to tear down a marked portion of the structure from a position in which you will be facing the robot. <p>For Study 2 you will be asked to operate the virtual demolition robot to demolish a block wall. In this study, a block in the wall will be highlighted, and you will need to move the tip of the robot's arm to that block, and then activate the chip hammer to break off the face of the block. When this happens, a number will appear on</p> |

Consent to be in a Research Study

Identification of Risk Factors for Demolition Robot Operators

Study 1: Human, environment, and control-pad factors, and Study 2: Human behavior and perceptions of safety and trust when the robot moves unexpectedly.

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| | | <p>the highlighted block for approximately one second. You will need to read the number and then press a left button in the remote control if the number is odd, or a right button if the number is even.</p> <p>While completing the tasks for both Study 1 and Study 2, you will be asked to walk and move around the environment and select a place where you can perform your tasks comfortably.</p> <p>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 different parts of your body.</p> <p>Before the experiment, you will complete a questionnaire consisting of 4 questions asking about your experience in construction and your experience with demolition robots and video games. During the experiment, you will be asked to complete questionnaires to assess your task load and your trust level on the demolition robot. After completing the experiment, you will respond to a post-test questionnaire.</p> |
| 5 | When, where, for how long will I be needed? | <p>You will initially be screened to determine your eligibility to participate via phone. If you are eligible to participate in the study, you will be asked to visit the Virtual Reality Laboratory located at NIOSH's facilities in Morgantown, WV. Study 1 will take approximately 2.5 hours and Study 2 will take approximately 2 hours. However, if you are only participating in Study 2, it will take approximately 3 hours to complete the study.</p> |
| 6 | Are there any risks from participating in the study? | <p>You will be asked to operate a virtual demolition robot similar to a video game. You may feel simulator sickness during and/or after the study due to wearing the VR glasses. Symptoms of simulator sickness include general discomfort, nausea, fatigue, headache, eye strain, difficulty focusing, fullness of head, blurred vision, dizziness, and vertigo, or fainting. If you feel the onset of any of these symptoms at any time during or after the study, please be vocal</p> |

Consent to be in a Research Study

Identification of Risk Factors for Demolition Robot Operators

Study 1: Human, environment, and control-pad factors, and Study 2: Human behavior and perceptions of safety and trust when the robot moves unexpectedly.

and tell the investigators immediately. The study will be stopped, and you will be guided to a comfortable chair to rest until the symptoms disappear. If you feel like you want to vomit, there will be a lined trash can that you can use; also, the researcher can walk you to the nearest restroom if you need to use it. You will not continue the study after experiencing any symptoms unless the symptoms disappear, and you tell us you desire to continue. The symptoms are likely to be temporary and expected to disappear after a rest. However, if you experience the simulator sickness symptoms in more than two occasions, the test will be terminated to guarantee your safety and well-being.

To help avoid simulator sickness, before you participate in the study you will be asked some questions that will help us understand if you might be susceptible. If you have ever experienced motion sickness in the past (for example from being in a motor vehicle or plane) severe enough that you have had to stop your activity because you were sick, you could also be at increased risk of experiencing simulator sickness, and you should not participate in this study.

There are no tripping hazards like cables hanging from you or laying in the floor since all the equipment uses wireless technology; also, there are no mats or rugs on the floor that could cause you to trip and fall. A researcher will monitor you throughout the study from approximately 10 feet away from you, and if you get too close to the wall, the researcher will alert you, and if necessary, will intervene to prevent you from bumping against the wall.

You may also experience psychological stress due to the fact that you will be aware that there will be safety failures with the virtual demolition robot. If you feel that you are feeling stressed, then let the researcher immediately know about this situation. The researcher will immediately stop the test and reassure you that the safety failures related to the demolition robot will all be entirely simulated, and that the laboratory environment is completely safe. If you feel better and decide to continue the study, the test will

Consent to be in a Research Study

Identification of Risk Factors for Demolition Robot Operators

Study 1: Human, environment, and control-pad factors, and Study 2: Human behavior and perceptions of safety and trust when the robot moves unexpectedly.

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| | | <p>continue; otherwise, the test will be terminated, and you will receive payment for your participation up to that point.</p> <p>You will be asked to provide your name and birth date for payment purposes only; this is considered Personal Identifiable Information. There is a very low risk related to a potential breach of confidentiality of your Personal Identifiable Information; however, we will take all the precautions necessary to protect this information.</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. In addition, we will also clean the equipment including the VR glasses, the hand and waist markers' straps, and the remote control, after each participant to minimize contamination or germ transmission.</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 scientists identify the best practice procedure while operating demolition robots which may advance the field of workplace safety.</p> |
| 8 | Is my participation voluntary? | <p>Your participation in the study is voluntary. You may choose not to answer any or all questions. You may 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 our publication of the study by contacting the researcher using the contact information on this form.</p> <p>If you decide to drop out of any of the studies, at any time, a partial payment will be made to you at a rate of \$10 per 20 minutes, with periods less than 20 minutes rounded up. For example, if you</p> |

Consent to be in a Research Study

Identification of Risk Factors for Demolition Robot Operators

Study 1: Human, environment, and control-pad factors, and Study 2: Human behavior and perceptions of safety and trust when the robot moves unexpectedly.

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| | | decide to drop out after 25 minutes, you will receive \$20. |
| 9 | What if I am injured or harmed at a NIOSH research facility or at another location where the NIOSH research project is being conducted? | 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. § 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? | 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. For example, if it takes four and a half hours to complete the study, you will receive \$140. |
| 11 | What alternative procedures might benefit me? | No alternative procedures are available for this study. |
| 12 | Will my personal information be | 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 will be collected in order to pay reimbursement. This |

Consent to be in a Research Study

Identification of Risk Factors for Demolition Robot Operators

Study 1: Human, environment, and control-pad factors, and Study 2: Human behavior and perceptions of safety and trust when the robot moves unexpectedly.

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| | kept confidential? | <p>information will be stored separately and not connected to any data collected during the study. The 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. Monitors, auditors, the IRB, and/or the regulatory authorities will be granted direct access to the subject's study records for verification of study procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.</p> <p>Your information will not be used or distributed for future research studies even if identifiers are removed.</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> |

Consent to be in a Research Study

Identification of Risk Factors for Demolition Robot Operators

Study 1: Human, environment, and control-pad factors, and Study 2: Human behavior and perceptions of safety and trust when the robot moves unexpectedly.

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| | | 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. |
| 14 | Will I or anyone else receive study results? | <p>Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies, nor shared with any past or current employer or union. The results of the study will be documented in a journal article or a NIOSH research report. No individual results of yours will be shown.</p> <p>Copies of any published work using your data can be provided to you upon publication if requested. If you would like a copy of the summary report, please contact Dr. Hugo Camargo, the project officer, at (304)285-6123, or via email at HCamargo@cdc.gov.</p> |
| 15 | Will my personal information or samples collected from me be used in other research? | <p>De-identified data will be stored at the DSR research laboratory. The raw data will be entered and stored on a computer. Two levels of physical security are always maintained for the data libraries—controlled office access, and ID/password access to data storage devices. Data will be kept up to 5 years after the completion of the study.</p> <p>This study will comply with the CDC Data Management and Sharing Policy. Every attempt will be made to publish results in peer-reviewed journals. We will not use the information that we collect from you in future research studies or share your information with other researchers.</p> |
| 16 | Is this a Clinical Trial? | No, this study is not a clinical trial. |

| <p align="center">Consent to be in a Research Study</p> <p align="center">Identification of Risk Factors for Demolition Robot Operators</p> <p align="center">Study 1: Human, environment, and control-pad factors, and Study 2: Human behavior and perceptions of safety and trust when the robot moves unexpectedly.</p> | | |
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| 17 | Did you receive all necessary information? | <p>We believe you 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. We invite you to take this 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. Hugo Camargo).</p> |
| 18 | Who can I talk to if I have more questions? | <p>For questions about the research study, contact the principal investigator, Dr. Hugo Camargo at HCamargo@cdc.gov or (304)285-6123.</p> <p>For questions about your rights, your privacy, or harm to you, contact the Chair of the NIOSH Institutional Review Board (IRB) in the Human Research Protection Program at 513-533-8591.</p> |
| 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> <hr/> <p>NIOSH representative signature Date</p> |
| 20 | Do I wish to receive a copy | <p>If you wish to receive a copy of the final results of this study in the form of a journal article, please indicate below the physical address, or the email address where you want this document to be</p> |

Consent to be in a Research Study

Identification of Risk Factors for Demolition Robot Operators

Study 1: Human, environment, and control-pad factors, and Study 2: Human behavior and perceptions of safety and trust when the robot moves unexpectedly.

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| | of the results? | sented: _____ Address where final results are to be sent. |
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