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TITLE: Interactive Virtual Occupational Safety Training Designed for Home Healthcare Workers

NCT: 240315-036

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Sommerich, Carolyn

From: Buck-IRB <irbinfo@osu.edu>
Sent: Sunday, January 12, 2025 5:33 PM
To: Sommerich, Carolyn
Cc: Anderson, Sarah; Siva Sathya, TJ
Subject: Amendment #11 Approved for #2024B0193

THE OHIO STATE UNIVERSITY

Behavioral and Social Sciences Institutional Review Board

130C Mount Hall
1050 Carmack Road
Columbus, OH 43210-1002

orrp.osu.edu

01/12/2025

Study Number: 2024B0193
Study Title: Interactive Virtual Occupational Safety Training Designed with and for Ohio Home Healthcare Workers and Agencies

Type of Review: Amendment #11

Review Method: Expedited

Request to amend the research dated November 13, 2024 (add Aim 1-step 2, Aim 3-step 1, and Aim 3-step 2 Aim 1-step; add new recruitment materials, flers, informed consent materials, interview guides and stimuli; add 87 participants (n=143); update research protocol based upon requested changes)

Date of IRB Approval: 01/12/2025
Date of IRB Approval Expiration: 08/12/2025

Dear Carolyn Sommerich,

The Ohio State Behavioral and Social Sciences IRB **APPROVED** the above referenced research.

As Principal Investigator, you are responsible for ensuring that all individuals assisting in the conduct of the study are informed of their obligations for following the IRB-approved protocol and applicable regulations, laws, and policies, including the obligation to report any problems or potential noncompliance with the requirements or determinations of the IRB. Changes to the research (e.g., recruitment procedures, advertisements, enrollment numbers, etc.) or informed consent process must be approved by the IRB before implemented, except where necessary to eliminate apparent immediate hazards to subjects.

This approval is issued under The Ohio State University's OHRP Federalwide Assurance #00006378 and is valid until the expiration date listed above. ***Without further review, IRB approval will no longer be in effect on the expiration date.*** To continue the study, a continuing review application must be approved before the

expiration date to avoid a lapse in IRB approval and the need to stop all research activities. A final study report must be provided to the IRB once all research activities involving human subjects have ended.

Records relating to the research (including signed consent forms) must be retained and available for audit for at least 5 years after the study is closed. For more information, see university policies, Institutional Data and Research Data.

Human research protection program policies, procedures, and guidance can be found on the ORRP website.

Daniel Strunk, PhD, Chair
Ohio State Behavioral and Social Sciences IRB

The Ohio State University Consent to Participate in Research

Study Title:	Interactive Virtual Occupational Safety Training Designed with and for Ohio Home Healthcare Workers and Agencies – Aim 3b
Protocol Number:	204B0193
Researcher:	Sarah Anderson and Carolyn Sommerich
Sponsor:	Ohio Bureau of Workers Compensation

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

Purpose:
The overall goal for this research project is to develop an enhanced version of an existing software program that is designed to be an engaging and effective means of training home healthcare workers about hazards (objects and conditions) in client homes that pose a health and safety risk to home healthcare workers and how to address those hazards. The purpose of this particular part of the research project is to assess the usability and usefulness of the next generation of this training software program.

This research is being conducted by researchers at The Ohio State University, the University of Kansas Medical Center, and Virginia Commonwealth University.

Procedures/Tasks:
If you decide to participate in this study, you will first complete a brief demographics form. Next, you will complete a portion (one module) of the new version of the occupational safety training software program for home healthcare workers. After finishing the program module, you will inspect a physical simulated home setting for hazards that can be present in home healthcare client homes. After completing the inspection, you will participate in a brief interview to talk with OSU researchers about your experience using the program.

The session will be audio-recorded and video-recorded, so that information provided by participants can be preserved for analysis. At any point in the interview portion of the session, you may request that the recording be interrupted if you want to say something that you do not want recorded.

Duration:

This session is expected to take approximately about 1.5 - 2 hours.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits:

There is a remote risk of cybersickness, because you will be viewing a computer program during this study that is similar to a computer game. The term cybersickness is a motion sickness-like experience that can occur when viewing a computer game where movement occurs on the screen. As such, if you consent to participate in the study, you will be screened for risk of cybersickness by a member of the research team prior to being scheduled to participate in the study. If cybersickness is determined to be a risk for you, you will not be able to participate in the study.

In terms of benefits, it is possible that you may gain useful knowledge beyond what you currently know about home hazards. Otherwise, this study does not provide any direct benefits to you in the short term, but it may eventually lead to the development of an online training program that provides home healthcare workers with important information about their health and safety when working in client homes, to reduce their risk of work-related injury or illness.

Confidentiality:

We will work to make sure that no one sees your online responses to the questionnaire without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- University of Kansas Medical Center;
- Virginia Commonwealth University Institutional Review Board or Office of Responsible Research Practices;

- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information; and
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

Future Research:
Your de-identified information may be used or shared with other researchers without your additional informed consent.
'De-identified' means that the information you shared cannot be connected to you.

Incentives:
You will be provided with a $100 gift card the same day you participate in the session or the day after.

By law, payments to participants are considered taxable income.

Participant Rights:

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By agreeing to participate, you do not give up any personal legal rights you may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

Contacts and Questions:
For questions, concerns, or complaints about the study, or you feel you have been harmed as a result of study participation, you may contact Carolyn Sommerich, sommerich.1@osu.edu, 614-292-9965 and/or Savannah Meinen, savannah.meinen@osumc.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251 or hsconcerns@osu.edu.

Providing consent

I have read (or someone has read to me) this page and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by agreeing to participate.

To print or save a copy of this page, select the print button on your web browser.

Please click the "I AGREE" button below to proceed and participate in this study. If you do not wish to participate, please close out your browser window.

Thank you for agreeing to participate in this study.
Please provide your name so that we can document your consent to participate.

(After you type your name in the boxes below, please click the button in the lower right corner)

Your first name: _____
Your last name: _____