Consent for Research Participation

Title: IMPRINT Randomized Evaluation
Investigator/Researcher(s): Contact PIs:
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Sponsors: The New England Consortium and Charles River Analytics

KEY INFORMATION FOR YOU TO CONSIDER:

We (the researchers) are asking if you would like to be in a research study. Some key information is provided in the boxes below to help you decide if you want to participate or not. Read the entire form and ask questions before you decide. The researchers will go over this form with you and you can ask any questions.

What is the purpose of this research?	This main purpose of this study is to learn whether virtual reality activities can improve HAZMAT training.
What will happen to you during the study?	You are being asked to be in this research study because you have enrolled in the 40-hour HAZWOPER training at The New England Consortium, or because you are serving as a trainer in this program. As a trainee enrolled in this study, you will complete several of the standard activities in Virtual Reality using a Virtual Reality headset instead of completing worksheets or reviewing 2D photographic images. As a trainer, you will be using the IMPRINT VR modules to deliver training content and provide feedback on their usability and effectiveness as a teaching tool. Virtual reality activities will last between 1 and 5 minutes. As a trainee you will be asked to complete all standard training and receive standard training assessments. There will be no differences in the content of this training and standard training. The only difference will be the method used to deliver the content. .

How long will you be in the research?	As a trainee you will be in this study for the duration of the 40-hour course. As a trainer, your involvement will span 60 to 90 minutes, during which you will use and evaluate the IMPRINT VR modules.
Could being in this research harm you?	You should understand the risks of this research study before you decide to participate. If you participate in this study, you might experience some risks and discomforts that might include the following: • Boredom • Dizziness • Nausea There is a slight chance of injury through falling when walking or moving through the room during the tasks performed. There are additional risks when using virtual reality equipment or engaging in a virtual environment. These risks are infrequent, but may include motion sickness, disorientation, and dizziness. The experimenter will explain how you can take breaks during the experiment to prevent or relieve these potential risks, and you will be allowed to stop a task, and if necessary, exit the virtual environment by removing the virtual reality goggles at any time if you begin to feel discomfort or other undesirable sensations. This research is no more than minimal risk. The level of risk is expected to about the same as risks of daily life or a working with protective equipment used throughout training. This study may involve risks to the subject which are currently unforeseeable.
Will being in this study help you in any way?	No benefits are promised. Some benefits might include an improved training experience and improved retention of training concepts.
Are there any costs to participate?	It does not cost anything to be in the study.
How do researchers protect your information?	Researchers keep your personal information confidential and stored securely. Only the researchers approved to be on this study may see your information.

ADDITIONAL DETAILED INFORMATION:

How many people will participate in this research study?

The researchers hope to enroll up to 300 trainees and a max of 15 trainers.

Who can you talk to about the research?

Contact the researcher listed on the first page if you have questions, concerns, complaints, or get hurt.

Pearl Institutional Review Board (IRB) oversees this research. You may call (317) 899-9341 to speak to the IRB for any reason, such as:

- You have questions about your rights.
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get more information.
- You want to provide your input about this research.

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

Are there any conflicts of interests reported for this study?

Dr. Turcotte and Dr. Cross are receiving funding from National Institute of Environmental Health Sciences Worker Training Program to complete this research. The outcome of this research study could be of interest to Charles River Analytics. This investigator does not participate in the recruitment, enrollment, or obtaining of informed consent for this research. The IRB oversees the conflict of interest policies. In accordance with these policies, the IRB has determined that Dr. Turcotte's and Dr. Cross's interests create no significant risk to the welfare of participants in this study or to the integrity of the research. If you want more information about this, please contact the IRB.

What other choices do you have besides taking part in this research?

You may choose not to participate in this research study.

There are other choices such as completing the training course with the standard materials and not participating in the Virtual Reality Activities.

You do not have to agree to participate in this research study to receive HAZWOPER Certification from The New England Consortium.

How do researchers protect your information?

The researchers will keep information about you in a secure location with limited access. If the results of this study are made public, information that identifies you will not be used.

There is a section at the end of this consent form that asks for your permission to use or share your information for future research. Your information will only be used or shared if it is coded or your identifiers are removed and if you agree. If you agree to this today, we will not ask for your permission in the future. This is optional. You do not need to agree to participate in any future research in order to be in the current study.

Is this research covered by a Certificate of Confidentiality?

This research is covered by a CoC from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal FDA. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The CoC does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What information about this study is available to the public?

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Can your participation end early?

Your participation in the research study may end for any of the following reasons:

- If you are pregnant
- If the research becomes harmful
- Whenever it is determined that it is not in your best interest to continue
- If you do not follow the instructions or adhere to the research requirements given to you by the study staff

Are there consequences of early withdrawal from the research?

No, you will be able to complete the course with the standard materials and will still receive your certificate given adequate performance within the course.

What additional information should I know?

The researchers will inform you of any significant new information that may affect you in a timely manner. Such information may help you decide if you want to stay in the study. The researchers will share any new information with you if it affects your ability to stay in the study.

Performance within the course will be measured as a group to evaluate the impact of the intervention and no identifiable information on your particular performance will be maintained by the study.

There is no compensation or medical treatments are available if injury occurs. Risks are minimal. The level of risk is expected to about the same as risks of daily life or a working with protective equipment used throughout training.

Will you receive anything for being in the research?

Trainees will have the opportunity to be entered into a $50 gift card raffle with the completion of the post course survey.

You will NOT receive any type of rights for discoveries, patents or products developed from this research.

May the researchers share your coded information for future research?

- The researchers approved for this current study will code your materials and have access to the key to the code.
- The researchers doing future research with coded materials do not have access to the key to the code and cannot identify you.
- The following materials may be used in the future research: group training responses, assessments
- Future research may include: The development of additional Virtual Reality Activities and training materials.
- You will not be able to get individual research results about you because the researchers who receive your materials will not have your identifiers.
- Future research will only take place under one or more of the following conditions:
    - it is authorized by you within this consent or a future consent,
    - it is reviewed and approved by an IRB, which is responsible for protecting your rights and welfare, or
    - your data is stripped of all identifiers (including any codes linked to you).

Please initial the ONE option that you choose below:	
_____ *(initials)*	YES. *You still have the right to withdraw this authorization later.*
_____ *(initials)*	NO.

May the researchers contact you after your participation in this research is over to invite you to consider other research studies?

- Your decision will not affect your participation in the current study.

• The study team may contact you to see if you are interested in other studies.

Please initial the ONE option that you choose below:	
_____ *(initials)*	YES.
_____ *(initials)*	NO.

SIGNATURES:

You have read this document and were told of the risks and benefits and a member of the research team answered questions to your satisfaction. A member of the research team will answer any future questions. You voluntarily agree to join the study and know that you can withdraw from the study at any time without penalty. You do not waive any legal rights by signing this form.

You will receive a signed copy of this document.

_____ **Print the Name of the Adult Research Participant** (18 years of age or older)	_____ **Signature of the Adult Research Participant**	_____ **Date Signed**