The Ohio State University Consent to Participate in Research

Study Title:	Evaluation of triage decision makers responding to a mass casualty incident (MCI) using Virtual Reality (VR)
Researcher(s):	Nicholas Kman, MD
Sponsor:	DARPA

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. If you decide to participate, you will be asked to sign this form and will receive a copy of the form.

Financial Interest:
The Ohio State University could benefit financially from the sale of the VR platform being tested. In addition, two researchers helping to perform this study, Drs. Nicholas Kman and Douglas Danforth, could benefit financially from the sale of the VR platform being tested. A conflict of interest committee at The Ohio State University has reviewed this information and determined the financial interests present no additional significant risk to the study's participants. Any questions about this information can be answered by Dr. Hussam Salhi at 614-293-8305.

Purpose:
Using a VR system, to evaluate individuals to triage and treat human victims in the wake of a mass casualty incident and evaluate their willingness to delegate triage decisions to other triage decision makers.

Procedures/Tasks:
Your part in the study will be to complete a list of research activities, which last up to 2 hours in total. The research activities include a pre-survey, a training session, an experiment, and a follow-up interview. The pre-survey includes questions regarding your demographic information. The training session includes an introduction of the MCI-VR platform, a system for evaluating triage decisions in virtual reality. After the training, you will participate in an experiment, in which you will make multiple diagnoses and triage decisions about virtual patients. You will also review and evaluate decisions made by other decision-makers. After the experiment, a follow-up interview and survey will be conducted regarding how you perceive and trust the other decision-makers.

We are asking individuals with professional interest in *search and rescue operations* or *disaster medicine*, to participate in this project. Individuals from a variety of organizations will be invited to participate. These individuals include medical students and residency trainees, faculty and practicing emergency medicine physicians, emergency medical services personnel such as licensed emergency medical technicians and paramedics, military first responders, and other groups approved by the Ohio State University Institutional Review Board.

If you agree to participate, a digital record from your encounter with the virtual reality training system will be generated and stored within the computerized platform. These digital records (data) are being used for research and development (calibration) of the scoring system that will eventually be used to assess individual's performance of triage and treatment of the mass casualty incident scene.

Numerous performance variables such as 1) time to treat a victim in distress or 2) time to complete triage and treatment of all the victims in the scene are being studied for how well they characterize an individual's performance during the mass-casualty encounter. The variables that result from your encounter will be time stamped (time and date) within the MCI-VR platform giving us the ability to link your performance data to your name and level of training from the time stamped registration forms.

Performance data stored in the MCI-VR system will be used for the following purposes.

1) Development of a norm-referencing database of performance data that individuals can use for interpreting their own performance scores (i.e. A database containing measures of performance variables that have been identified as important for characterizing the performance of an individual will be used to calculate means, standard deviations, and score distributions for an entire class of performers. These descriptive statistics can be used by an individual to see how their performance compared to others in their class.)

2) Research into which variables that best characterize a first responder's performance.

3) Improving the MCI-VR system.

Data gathered from the MCIVR Post Encounter Questionnaire will also be time-stamped so that we are able to link the feedback provided by participants to the version of the system that was being used at the time of their encounter. This data will be entered and stored in a separate Excel Spreadsheet for analysis, but will never be linked to the registration spreadsheet.

Performance data from the norm-referencing database and from the MCIVR post-encounter questionnaire spreadsheet will eventually be used for scholarly (research) presentations or publications. However, this data will be presented in aggregate format without any information that might personally identify and individual participant.

All data generated during the research and development of the MCI-VR Training and Assessment Platform will be stored and maintained on secured, password protected medical center computer networks or computer networks in the MCI-VR development laboratory. The three timestamped datasets (performance data in the MCI-VR system, registration dataset and post-encounter dataset) will be stored in separate locations as a further security measure to prevent the unauthorized linking of the performance and evaluation data to the participant's name until that point in time in which names are removed from the registration dataset altogether.

All data containing identifiable information (eg. user name) will be stored on the computers in the PI lab or the password protected encrypted laptop that will be used for mobile testing. Only the PI and Co-PI, will have access to identifiable data. The PI will generate a non-identifiable user ID for each participant and the names and IDs will be stored on a password protected spreadsheet on the PI's computer with a backup stored on Box or OneDrive. Electronic originals of all documents (consent forms, surveys, research data, etc.) will be maintained on the PI's computer in his locked office. De-identified copies for shared data analysis by the research team will be stored on Box or OneDrive. All hard copies of documents will be scanned into digital format the subsequently destroyed. All data, including videos will be archived for a minimum of five years after the final project closeout (this is based on the longest required retention period under the various applicable federal regulations), with original primary data retained wherever possible. We will work to make sure that no one sees your survey responses 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. Learners will be advised that their de-identified data may be used or shared with other researchers without their additional informed consent.

Military First Responder Participants:
For the research involving DoD-affiliated personnel, Dr. Kman will receive command or component approval to execute the research. Military and civilian supervisors, officers, and others in the chain of command are prohibited from influencing their subordinates to participate in research. Further, Military and civilian supervisors, officers, and others in the chain of command will not be present at any research participant recruitment sessions or during the consent process for DoD-affiliated personnel. Excluded supervisors or those in the chain of command may participate in separate human subjects research recruitment sessions.

Duration:
After providing your consent to participate, the time estimated to complete the entire MCI-VR encounter is about 90 minutes. Should you request a post-encounter feedback session, this will take an additional 30 minutes.

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:

- Some individuals suffer from a condition known as cybersickness after using immersive virtual reality equipment. This condition is similar to motion sickness. The researchers will be observing you during your MCI-VR encounter in an effort to mitigate cybersickness and associated problems before they become serious. Some individuals may also experience discomfort from witnessing the recreation of blast injuries on virtual patients in the VR setting.

- The data collected during this research will be stored in a secure location. All reporting of this information will be done without names in an aggregate form so that no individual subjects are identifiable.

- It is unlikely that you will directly benefit from your participation in this portion of the research, however repeat participation in the future will likely provide you with the competency of an effective first responder to a mass casualty incident.

- We anticipate that our summarization and evaluation of the performance of the MCI-VR system will contribute to improvements in the system to effectively train and assess first responders to effectively triage and treat a mass casualty scene.

- You may find some of the imagery disturbing or emotionally distressing. If that occurs, please remove the headset and inform us. The Stress, Trauma and Resilience (STAR) Program at the Ohio State Department of Psychiatry and Behavioral Health offers programs and services for trauma responders. If anyone expresses a need for support, please contact STAR:

  To receive training or support for your group contact:
  STAR Professional Support Services (PSS)
  The Ohio State University Wexner Medical Center
  1670 Upham Drive
  614-293-7827 (STAR)
  Hours: Mon. - Fri., 8 am – 5 pm

Confidentiality:

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. Identifiers might be removed from the data and non-identifiable data could be used for future research studies or distributed to other investigators for future research studies or published as part of a publicly available open-access research record without additional informed consent from you. 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;
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.
- The U.S. Department of Defense is providing support for the research. The U.S. Department of Defense personnel responsible for the protection of human subjects will have access to research records.

Future Research:
Your de-identified information may be used or shared with other researchers without your additional informed consent.

Incentives:
There are no incentives for participating in this study. Reimbursement for parking will not be provided.

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 signing this form, 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 research participants.

Contacts and Questions:
For questions, concerns, or complaints about the study you may contact Nicholas Kman, MD at 614-293-8305.

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.