UNIVERSITY of MARYLAND BALTIMORE

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title: Adjunct Virtual Reality Pain Management in Acute Brain Injury

Study No.: HP-00090603

Principal Investigator: Nicholas Morris, MD
410-328-4515

Sponsor: University of Maryland Baltimore Institute for Clinical & Translational Research

CONCISE SUMMARY:
The study that we are asking you to participate in is being conducted by Nicholas Morris, MD at the University of Maryland Medical Center (UMMC) and The Shock Trauma Center. Participation in this study is entirely voluntary. As you read this form, seeing the word "you" or "your" refers to the participant consenting for this study. If, at any point in time during this study you wish to remove yourself – you can do so without penalty. It is important to understand why this research is being done. This form will explain the details of the study and will help you decide if you want to participate.

Being in a research study is not part of your routine medical care. The purpose of this study is to determine if virtual reality can reduce pain in patients with traumatic injury, including but not limited to traumatic brain injury. You will be one of ~60 participants in the study. While enrolled in the study, you will be randomly assigned to two virtual reality-based immersive experiences and one experience presented on a tablet computer. Your experience using virtual reality-based experiences and experience on a tablet computer will be recorded by answering questions in a questionnaire. The length of time you would be enrolled in the study is between one and three days.

There is no cost to you to be enrolled into the study, nor does the study pay you for your participation. You are still responsible for your medical expenses as a part of your standard of care here at The University of Maryland Medical Center and The Shock Trauma Center. A potential benefit from participating in the study could be a reduction in pain and anxiety. Potential risks could range from loss of confidentiality to breach of privacy. Although these risks are possible, research staff and study doctors work very hard to make sure that this does not happen. Some of the questions in the questionnaire or your experience during the virtual reality experience could make you uncomfortable. There is the possibility that other unknown risks could present during the study. Again, study doctors and study team members will be present throughout the study timeline. If at any point you have any questions or concerns, the study team encourages you to bring them up to your study team, study doctor, nurse, doctor, or other clinical staff. Dr. Nicholas Morris and his research team will conduct research activities as the University of Maryland Medical Center and The Shock Trauma Center.

PURPOSE OF STUDY

The purpose of this research study is to determine if virtual reality can be used to reduce pain in participants with traumatic injury. Previous studies suggest that virtual reality may reduce pain. We will compare virtual reality-based immersive experiences to similar experiences presented on a tablet computer. As this is a pilot study, 60 participants will be enrolled at the University of Maryland Medical Center and The Shock Trauma Center.

Before and after each session, participants will answer simple questions via questionnaire to evaluate their pain and nausea. Participants' heart rate, blood pressure, respiratory rate, pupil size, and hand sweating (a marker of emotional stress) will be recorded before and after each session to monitor response. Pain will be assessed every 2 hours by nurses using the Numeric Rating Scale with additional assessment directly before and after each study session. Opioid usage will also be reviewed and documented during your time in the study. All patients will have orders for pain medication written by the clinical team. If pain is inadequately controlled, additional analgesic orders will be placed by the clinical team in communication with the research team. Should pain ratings be increased after study sessions, the nurses will notify both the clinical and research teams for assessment.

PROCEDURES

Your Medical records will be reviewed by the study staff to see if you meet all inclusion criteria, and none of the exclusion criteria. If you choose to consent into the study, you will be asked to answer a few questionnaires.

1. Questionnaire / Psychological Testing (~20 minutes) - After you consent to participate, you will be asked to complete several questionnaires to evaluate your current symptoms, your prior experience with virtual reality, and personality that may influence your experience. The questionnaires take roughly 1-10 minutes on average to complete individually. The research team will assist you if you have any questions about these questionnaires.

After you have answered the questionnaires, members of the research team will come and set up the virtual reality system or a tablet-based system in your room.

2. Interventional Session (~20 minutes x 3) - After the questionnaires, you will receive further instructions on how to use the virtual reality or tablet-based system. You will experience three sessions aimed at reducing your pain. One session will be a virtual reality-based immersive experience. Another session will be the same as the virtual reality-based experience but presented on a tablet computer instead of the virtual reality headset. In the third session, you will wear the virtual reality headset but no content will be displayed. There will be an interval of at least four hours between each session. The order of these three sessions will be randomly assigned. This is sort of like flipping a coin, neither the study doctor nor study team will choose what environment you get first – it will be chosen by chance. Your ratings of pain and nausea will be recorded both before and after each experience. We will also record data regarding your heart rate, blood pressure, pupillary size, and how much your hands are sweating before and after each session. You will receive further instructions with each experience. The time it takes to complete 3 sessions should be between 1-3 days. At the completion of your 3 sessions, you will be given the opportunity to experience more sessions if you would like.

In order to conduct analyses on the information derived from your sample, your information may be shared with other researchers from the University of Maryland. The investigator will abide by the federal privacy rules that are in place to safeguard your privacy and confidentiality. Your name and personally identifiable information will never be shared.

After you finish with your experiences in virtual reality, research staff members will ask you a few more questions to see how you felt about the experience. This will also be done when using a tablet, as well.

3. Questionnaire (~15 minutes) - You will then be asked to complete a questionnaire regarding your reaction to both the virtual immersive experiences and the similar experiences presented on tablet computers. The experimenter will assist you if you have any questions about this questionnaire.

The information collected as part of the research, even if identifiers are removed, will not be distributed for future research studies.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you are in this research study, you are expected to follow the instructions of the research staff and report serious or unusual side effects to the study or clinical staff.

POTENTIAL RISKS/DISCOMFORTS:

1. Loss of Confidentiality: There is always a risk for a loss of confidentiality when participating in a research study. However, every step to ensure the confidentiality and anonymity of your results and identity will be taken. Steps will include using only an assigned code number for your personally identifiable information, including your contact information and name, on any documentation from this study. Moreover, electronic data will be password-protected and all paper copies of data will be stored in a locked cabinet. You will not be given the results of your questionnaires.

2. Breach of Privacy: There is a minimal risk for a breach of privacy. However, to minimize this, you will be accommodated in a secured room to be screened and to give you a private space to read the consent and HIPAA forms, and complete the questionnaires. Only designated research personnel will have access to the rooms where you will be participating in research activities. We will make every effort to minimize you interacting with those who are not a part of this research study while you are participating.

3. Risks Associated with Psychological Questionnaires: You may experience some discomfort while answering questions on the psychological questionnaires. However, you are not required to answer any questions that make you feel uncomfortable.

4. Risks Associated with the immersive virtual reality. Immersion in virtual reality may cause of a sense of being in a closed environment and rarely nausea. These effects are only transitory but if you experience any discomfort, the virtual reality headset can be removed quickly. Per the manufacturer, there is a 1 in 4000 risk of severe dizziness, seizures, eye or muscle twitching or blackouts triggered by light flashes or patterns, and this may occur while they are watching TV, playing video games or experiencing virtual reality, even if they have never had a seizure or blackout before or have no history of seizures or epilepsy. Patients with traumatic brain injury are at an increased risk of having seizures, but these seizures are not known to be brought on by light flashes or patterns associated with virtual reality or computer screens. Should one of these complications occur, the virtual reality headset will be removed quickly and appropriate treatment will be administered if the complication persists. In

addition, your participation in the study will be discontinued if you experience one of these severe complications.

5. Unknown Risks: There may be unknown risks or discomforts involved with participating in this study that are not yet known. Research study staff will update you in a timely manner if any information that may affect your health, welfare, and decision to remain in the study surfaces.

POTENTIAL BENEFITS

Participants will potentially experience reduction in pain from the both the virtual reality-based immersive experiences and the similar experiences offered on a tablet computer that are offered as part of the study. There is no guarantee of benefit from either type of experience or to study participation.

ALTERNATIVES TO PARTICIPATION

Your alternative is to not take part. If you choose not to take part, your healthcare at the University of Maryland Medical Center / Shock Trauma Center will not be affected in any way.

COSTS TO PARTICIPANTS

There will be no additional cost to you for doing this study. All study-related treatments, procedures, and tests will be provided to you at no cost. You, your insurance company, and/or other third-party payer will be billed for medications and medical care that are not part of the research study in the normal manner.

PAYMENT TO PARTICIPANTS

You will not be paid to participate in this study.

CONFIDENTIALITY AND ACCESS TO RECORDS

Only Dr. Nicholas Morris and his trained and designated research personnel will have access to confidential information. All confidential information that includes personally identifiable information will be coded with a code number. The principal investigator will be the only individual with access to the key of the assigned code numbers. All confidential information will be locked in a cabinet in a secured location at the University of Maryland Shock Trauma Center. Your personally identifiable information will not be used for this study's analyses but it will be kept on file if federal agencies, the sponsor, or the the Intuitional Review Board (IRB) are mandated to review any information. The monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and date. By signing this document you are authorizing this access.

All study records will be considered confidential, and all participants' names and personally identifiable information will not be used in reports or publications. Efforts will be made to limit access to your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Those designated from the University of Maryland will be allowed examine certain research records of this study; however, anyone inspecting this information will do their best to keep this personal information confidential. Your personal information will not be released unless mandated by law.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law

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.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research study. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Dr. Nicholas Morris at (410) 328-4515. There are no adverse consequences (physical, social, economic, legal, or psychological) for deciding to withdraw from this research study. If you withdraw from this study, already collected data may not be removed from the study database.

If you wish to withdraw from this study at any time, a written withdrawal request is required and should be sent to Dr. Nicholas Morris at *Nicholas.Morris@som.umaryland.edu* or University of Maryland Shock Trauma Center, 22 S. Greene St., G7K18, Baltimore, MD, 21201. You will be informed of any findings in this study that may affect your willingness to continue participating. If you are an employee or student, your employment status or academic standing at UMB will not be affected by your participation or non-participation in this study.

CAN I BE REMOVED FROM THE RESEARCH?

The investigator, Dr. Nicholas Morris, can remove you from the research study without your approval. Possible reasons for removal include incomplete data, abnormal pain sensitivity responses, and non-compliance with completing tasks. The entire study can be stopped at any time by the university, investigator, sponsor, Institutional Review Board (IRB), or the facility where the study is conducted.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research the rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

Participating in research may result in an injury, as explained above. If you suffer an injury directly related to your participation in this project, UMB and/or one of its affiliated institutions or health care groups will help you obtain medical treatment for the specific injury and provide referrals to other health care facilities, as appropriate. UMB and/or its affiliated institutions or health care groups will not provide you with financial compensation or reimbursement for the cost of care provided to treat a research-related

injury or for other expenses arising from a research-related injury. The institution or group providing medical treatment will charge your insurance carrier, you, or any other party responsible for your treatment costs. If you incur uninsured medical costs, they are your responsibility. The study staff can give you more information about this if you have a study injury.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____

If you would like to be contacted for future research studies, please sign your name below:

_____

Participant's Signature

Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Name of Study Participant:_____
_____

Date of Birth: _____ **Medical Record Number:** _____

NAME OF THIS RESEARCH STUDY: *Adjunct Virtual Reality Pain Management in Acute Brain Injury*

UMB IRB APPROVAL NUMBER: *HP-00090603*

RESEARCHER'S NAME: *NICHOLAS MORRIS, MD*

RESEARCHER'S CONTACT INFORMATION:

Department of Neurology
University of Maryland School of Medicine (UMSOM)
22 S Greene St, G7K18
Baltimore, MD 21201
410-328-4515

This research study will use health information that identifies you/your child. If you/your child agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- *Demographic information (i.e. age, name, gender, date and time of study)*
- *History of Pain Medication and Medications received while in hospital*
- *Research tests*

Federal laws require this researcher to protect the privacy of this health information. He/she will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- Dr. *Nicholas Morris* and his research team.
- The sponsor of the study, or its agents, such as data repositories or contract research organizations
- Organization that will coordinate health care billing or compliance such as offices within UMSOM; the University of Maryland, Baltimore (UMB); University Physicians, Inc. (UPI) and the faculty practices of the UMB; University of Maryland Medical System (UMMS)

THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.
To revoke this Authorization, send a letter to this researcher stating your decision. He/she will stop collecting health information about you/your child. This researcher might not allow you/your child to continue in this study. He/she can use or share health information already gathered.

ADDITIONAL INFORMATION:

- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you/your child receive at:
    - University Physicians, Inc. (UPI)
    - University of Maryland Medical System (UMMS)
    - Veteran Affairs Maryland Health Care System (VAMHCS)

  It will not cause any loss of benefits to which you/your child are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, UPI, UMMS or VAMHCS to give it to them.
- This researcher will take reasonable steps to protect your/your child's health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, UPI, UMMS or VAMHCS.
- Except for certain special cases, you/your child have the right to a copy of your/your child's health information created during this research study. You may have to wait until the study ends. Ask this research how to get a copy of this information from him/her.

My signature indicates that I authorize the use and sharing of my/my child's protected health information for the purposes described above. I also permit my doctors and other health care providers to share my/my child's protected health information with this researcher for the purposes described above.

Signature: _____Date: _____

Name (printed) _____

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your/your child's rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.