Department of Veterans Affairs

RESEARCH CONSENT FORM

Medical Consent

Participant Name: _____ **Date:**_____

Title of Study: Immersive Virtual Reality to Improve Outcomes in Patients with Stroke: A Pilot Study

Principal Investigator: Johanna Tran, MD **VA Facility:** Tampa- 673

Informed Consent to Participate in Research

University of South Florida, the IRB of record for the James A. Haley Veterans' Hospital

Information to Consider Before Taking Part in this Research Study

IRB Study #1075

Doctors and researchers at James A. Haley Veterans' Hospital study diseases and other health problems people may have. Our goal is to try to find better ways to help treat these health problems. To do this, we need the help of people who are willing to take part in a research study.

STUDY OVERVIEW:

1. **WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?**
   We are asking you to choose whether or not to volunteer for a research study conducted by the Department of Veterans Affairs. It is being funded by VA Rehabilitation Research and Development (RR&D). The study will look at the use of a Virtual Reality intervention for individuals diagnosed with stroke who are currently participating in inpatient rehabilitation. This initial information is to give you key information to help you decide whether to participate. We have included detailed information after this information. Ask the research team questions. Taking part in this study is completely voluntary.

2. **WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?**

   By doing this study, we hope to learn if using a Virtual Reality (VR) headset in your spare time while in bed will help you relax, improve hand and arm movement, improve vision, and/or help with pain after a stroke. Your participation in this research will be two 30 minute sessions, 5 days a week for about 4 weeks.

   This research study is expected to take approximately two years.

3. **WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?**
   It is possible that this treatment will help improve your mood, arm and hand function, vision, and decrease pain. For a complete description of benefits, refer to the Detailed Consent Section.

4. **WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?**
   VR, in general, is well tolerated and risks are expected to be small and, if present, mild in severity. The therapeutic risks may include "cybersickness" (e.g. dizziness, feeling sick to your stomach), emotional adverse effects (e.g. fear, anxiety) and discomfort or inconvenience related to the VR equipment (e.g. headset discomfort). For a complete description of risks, refer to the Detailed Section of the Consent and/or Appendix.

5. DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

6. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Johanna Tran, MD of the James A. Haley Veterans' Hospital. This person is called the Principal Investigator. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: email Johanna.Tran@va.gov or phone 813-972-2000 ext. 5421.

After you read this form, you can:

- Take your time to think about the information that has been provided to you.
- Have a friend or family member go over the form with you.
- Talk it over with another health care provider.

It's up to you. If you choose to be in the study, then you can sign the form. If you do not want to take part in this study, you should not sign the form.

DETAILED RESEARCH CONSENT SECTION

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of the study is to determine if VR is helpful for patients with stroke.

With this research we hope to learn if Veterans like using VR headsets and games and if VR helps them get better.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About fifteen people will take part in this study at James A. Haley Veterans' Hospital**.**

HOW LONG WILL I BE IN THE STUDY?

Participation in the study will be about 4 weeks while you are on the acute inpatient rehabilitation unit. The VR session will consist of two 30-minute sessions, 5 days a week for 4 weeks.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

You will keep seeing your regular doctor. Your regular doctor will give you the same kind of treatment you would get anyway, whether or not you take part in the study. Your participation is voluntary. You do not have to participate and may stop your participation at any time. We do not know if there will be any benefit from your participation. There is no cost to participate. We will not pay you for the time you volunteer while being in this study.

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WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

Week 1: We will collect some information about you, including your age, sex, race, etc. and we will ask you to complete some questionnaires about your pain level and things you can and cannot do.

Week 2-4: We will show you how to use of the VR headset and games. You will then practice with the VR headset and games for two one-half hour sessions per day, Monday through Friday. We will be there to help you as needed. You will use the VR headset and games when you are not scheduled for other therapies and appointments, while you are reclining or seated in bed with both bed rails raised. We will start with an easy relaxation games, then you can begin choosing your own games. Once you are comfortable using the headset, we will set you up then return 30 minutes later to remove the headset.

Week 4 We will ask you some of the same questions that we did during week one, about your pain level and things you can and cannot do.

All procedures will be performed in the rehabilitation center under medical supervision. While participating in this research study, do not take part in any other research project without approval from the investigators. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

It is possible that you will experience "cybersickness" (e.g. dizziness, feeling sick to your stomach) or discomfort from the headset. We will select games that do not cause anxiety. Most people do not experience side effects, especially with the newer equipment.

These side effects usually are not serious and will go away when you stop using the VR headset. If you have any of these problems, tell the study doctor at your next visit. If these side effects bother or worry you, or if you have other problems, call your study doctor at 813-972-2000 ext. 5421.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect. It is important for you to tell us when you experience a side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

You will not receive any payment for participation in this study because you are an inpatient. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled.

If a participant is deemed at high risk for harm/suicide,
The study personnel will do the following:
- Stay with patient until they can be 'handed off' to appropriate medical staff. Since the patient is an inpatient, this will involve calling the patient's primary treatment team and/or escorting the patient to such providers.
All study personnel who work directly with research participants will be given the names and phone numbers of the patient's medical care team. After the patient has been 'handed off' to the appropriate staff, the PI, Dr. Tran, will be alerted.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no known direct benefits, but the VR treatment might improve your arm and hand function, your vision, and decrease your pain.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

We will store all data safely on VA computers behind password protected firewalls in secure password protected folders. Only a few people in the study will have access to your data. We will remove your identifying information and use an ID as soon as possible. By law, anyone who looks at your records must keep them completely confidential. The only people who will be allowed to see these records are:

• The research team, including the Principal Investigators and the program manager.
• Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.) These include:

- The University of South Florida Institutional Review Board (IRB) and the staff that work for the IRB. Other individuals who work for USF that provide other kinds of oversight may also need to look at your records.
- The Department of Health and Human Services (DHHS).
- Department of Veterans Affairs

We may present the data at meetings and publish in journals. If we publish or present the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential. We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are.

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The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize pictures and/ or videos, to be made of you by the study team at James A. Haley Veterans' Hospital while you are participating in this study. Your study team will have access to the photographs and/or videos. All research related video tapes or photographs will be held in accordance with the VA records control schedule (RCS) 10-1. The said picture, video, or voice recording is intended for the following purposes: Videos and or photographs may be used for quality control, and education/ dissemination purposes only.

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being filmed, photographed or recorded, and may rescind your consent for up to a reasonable time before the picture, video or voice recording is used.

CERTIFICATE OF CONFIDENTIALITY:
We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.
DISCLOSURE: The VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Giving your permission by providing your authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

We will include information about your study participation in your medical record.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other

information including your name, address, date of birth, and information from your medical records.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Institutional Review Board, Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability Organization (GAO).

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Principal Investigator of the study at this facility.

Principal Investigator: Johanna Tran, MD
James A. Haley Veterans' Hospital
13000 Bruce B. Downs Blvd., Mail Code 117
Tampa, FL 33612-4745

You can also ask a member of the research team to give you a form to revoke the authorization. The study team will contact the Release of Information Office. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dr. Johanna Tran and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

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 Website will include a summary of the results. You can search this Web site at any time.

WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?
You are participating in a research project approved by a Research and Development Committee and conducted under the supervision of one or more VA employees. Every

reasonable safety measure will be used to protect your well-being. If you are injured because of your participation as a research subject in this research study, the VA medical facility will provide you with necessary medical treatment.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. You have the alternative to choose not to participate in this research study. You should only take part in this study if you want to volunteer and should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time.

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You can decide after signing this informed consent document that you no longer want to take part in this study. If you decide you want to stop taking part in the study, tell the study staff as soon as you can.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

Even if you want to stay in the study, there may be reasons we will need to take you out of it. You may be taken out of this study if:

- We find out it is not safe for you to stay in the study. For example, your health may worsen.
- You are not coming for your study visits when scheduled.
- Study inclusion/exclusion criteria are not met.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions, complaints, and/or concerns about the research or related matters, Please contact the primary investigator, Dr. Johanna Tran at 813-972-2000 ext. 5421.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the USF IRB at (813) 974-5638 or contact the USF IRB by email at RSCH-IRB@usf.edu if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

If you would like to contact someone independent of the research study, or cannot reach the research staff, you may contact the James A. Haley Veterans' Hospital Research Compliance Officer at 813-903-4274.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Clinically relevant research results will be disclosed to subjects upon request after the study is completed.

FUTURE USE OF DATA AND RE-CONTACT

DISCLOSURE:

The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you. Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

• Non-VA Institutional Review Board (IRB): USF

• Study Sponsor/Funding Source: VA Rehabilatation Research and Development

• Compliance and Safety Monitors: Research Compliance Office RCO

• Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO): The Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, our local Research and Development Committee, may look at any portion of your record.

Access to your Individually Identifiable Health Information created or obtained during this research: You will not have access to your research related health records.

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The study coordinator has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

Signature of Person Obtaining Informed Consent/Research Authorization		
_____ Name	_____ Signature	_____ Date