Participant Name: _____ Date: _____

Title of Study: Feasibility and Functional Outcomes of a Novel Mixed Reality based system to manage phantom pain for Patients with lower limb amputation.

Principal Investigator: Gargi Raval, Thiru Annaswamy VA Facility: Dallas VA Medical Center

Please read this form carefully. Take your time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it.

KEY INFORMATION

A. 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. The purpose of this research is to design and develop a home-based virtual mirror therapy program and evaluate its usefulness and effectiveness on lower limb amputee patients. 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.

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

By doing this pilot study, we hope to learn how best to manage phantom pain with the use of virtual reality systems, much like mirror box therapy. Your participation in this research will last about one month.

C. WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By volunteering in this study, you will help us develop a new type of therapy program for others experiencing phantom limb pain. We aim to take the information provided in this study into an even larger clinical trial. For a complete description of benefits, refer to the Detailed Consent.

D. WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

If you volunteer for this study, the major risk involved is increased baseline pain and swelling during rehabilitation. For a complete description of risks, refer to the Detailed Consent.

E. 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.

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

The person in charge of the study is Dr. Gargi Raval of the VANTHCS. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is (214) 857-4582.

DETAILED CONSENT

1. WHAT IS THE PURPOSE OF THE STUDY?

This study aims at research in managing phantom pain for patients with lower limb amputation. The research team has designed and developed a game-based exercise therapies that provides a visualization for phantom limb movement in real-time. The technology captures the 3D model of the patients and puts them in various virtual environments where they can interact with virtual objects. Such a virtual visualization creates a realistic illusion of the phantom limb movement as if they were interacting with surrounding objects with their phantom limb. The exercises developed are fun, realistic, engaging and motivating.

2. HOW LONG WILL I BE IN THE STUDY?

The approximate number of research subjects involved in this study is 10, with all subjects enrolled at the VA North Texas Health Care System. This research study is expected to take approximately two years. Your individual participation in the project will take one month.

3. WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Before any study-related tests or procedures are performed, you will be asked to read and sign this consent document. If you choose to participate in this study, the researchers will ask you questions about your health, including medical history. After this, you will be asked to complete questionnaires regarding your pain levels and how your pain affects your life.

Once enrolled, the study team will set up the program for you and explain how to use the system. After that, you will take the system home and perform the exercises for a 1-month period. Detailed descriptions of each visit can be found below:

Baseline Visit:

During an initial visit as an outpatient, following hospital discharge, you will undergo a basic, standard of care evaluation by a rehabilitation physician.

You will also complete the following assessments at various time points during the study:

a) Numerical Rating Scale (NRS)
This is a test that consists of measuring the intensity or the amount of pain that a patient feels, ranging across a continuum from none to an extreme amount. The numerical rating scale uses numbers from 0 (no pain) to 10 (worst possible pain) to rate pain.

b) Brief Pain Inventory (BPI)
The brief pain inventory rapidly assesses the severity of pain and the amount of interference the pain has on your ability to function in everyday life.

c) McGill Pain Questionnaire
This questionnaire is a pain survey to measure the intensity, amount and frequency of the phantom pain during patient's daily routine after the amputation. You will be asked to complete this questionnaire at the beginning of the study and again when you return for follow-up visits.

d) Patient Specific Functional Scale
In this questionnaire, we ask that you rate your ability to complete an activity at a level experienced prior to injury, on a scale of 0 to 10. 0 represents "unable to perform activity", and 10 represents "able to perform at prior level". This assessment is used to quantify activity limitation and measure functional outcome for patients with any orthopedic condition.

e) Phantom Limb Pain Diary
This 4-weeks diary will record your level of pain before and after exercise each day that you use the system.

f) Usability Survey
This survey is to collect feedback on your experience with the game-based exercise therapy.

g) Medication Use
You will be asked about your current and past medication use related to phantom limb pain.

Following your appointment with your physician, the research team will provide you a laptop, a camera and Oculus Rift and then instruct you on its use at home. You will then use the system and perform your personalized home exercises 2 times per day for one month. The coaching software will monitor you and record the number of repetitions, dates and times of exercises, as well as correctness of performing the exercises. This will serve as your digital diary. You will also be asked to keep a daily pain diary.

1 Week Visit:
At the end of the initial 1-week visit. You will visit the physician where you will be examined to verify your eligibility for continued participation in the study. You will also meet with the research team to review use of the Virtual Reality System. You will be asked to complete the Numerical

Rating Scale (NRS), Brief Pain Inventory (BPI), McGill pain questionnaire, and Patient-specific functional questionnaire.

1 Month Visit:

At the end of the 1-month period, the system (including camera and Oculus Rift) will ne returned or retrieved from your home. You will once again come for a visit and complete the Numerical Rating Scale (NRS), Brief Pain Inventory (BPI), McGill pain questionnaire, Patient-specific functional questionnaire, medication use and usability survey. You will return the daily phantom limb pain diary you completed before and after ach exercise at this visit. You will also have the option to fill out a questionnaire about your use of the rehabilitation system and give comments and suggestions for future use.

Schedule of events:

		Visits		
		Baseline Visit	**1-Week Visit**	**1-Month Visit**
Study Procedures	**Informed Consent**	X		
	Past Medical History/Medication Use	X		X
	Numerical Rating Scale	X	X	X
	Brief Pain Inventory	X	X	X
	McGill Pain Questionnaire	X	X	X
	Patient-Specific Functional Scale	X	X	X
	System Setup, Instructions, Review	X	X	
	MrMAPP Usability Survey			X
	Return Phantom Limb Pain 4-week daily diary			X
	Return System			X

4. WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

If you volunteer to take part in this research study, you will be expected to complete the questionnaires and complete all the assessments required for the study. You will be expected to complete the subsequent 1-week and 1-month study visits as well.

5. WHAT ARE MY RISKS?

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 below, you may experience a previously unknown risk or 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 healthcare providers if you have any questions about the risks of usual care.

Some people become uncomfortable at being asked questions about pain. If for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize pictures and/or voice recording(s) to be made of you by the study team while you are participating in this study. You also authorize disclosure of the picture and/or voice recording to Dr Prabhakaran/Dr Dakshit of the University of Texas Dallas, an academic affiliate related with VA in the performance of this study. The said picture, video, and/or voice recording is intended for the purpose of helping to establish intervention acceptability and feasibility. The images of the patients will be stored in the encrypted laptop and analyzed at UTD. Participants' videos will be destroyed at UTD after 5 years, however, a copy will be kept at the Dallas VA.

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.

Anticipated adverse events include those that might reasonably be expected to occur in association with Physical Therapy following a lower limb amputation along with the events that may occur as a result of your disease/amputation state.

The following is a list of anticipated adverse events and reactions that may occur: These may include, but may not be limited to the following:

Risks associated with Physical Therapy

- Increased baseline pain during rehabilitation
- Swelling

Risks associated with lower limb amputation

- Wounds
- Infection
- Falls

6. WHAT ARE POSSIBLE BENEFITS OF THIS STUDY?

The goal for the study is to determine whether game-based exercise therapies that provide a visualization for phantom limb movement in real-time can be helpful in treating phantom limb pain. There is no guarantee that you will personally benefit by participating in this study. This study will provide valuable information to doctors and therapists to determine the effectiveness of a home-based rehabilitation-coach system for treatment of phantom limb pain.

7. WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study at this time. Alternative treatments for patients with phantom limb pain would include a traditional physical therapy program.

8. HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

The study doctors keep your research records private in the same way as your other medical records. No one has access to your records except as required by law. You are, however, authorizing the Dallas VA Institutional Review Board (IRB), the Dallas VA Research Development Committee and the members of the Dallas VA Research Office to inspect your medical and research records. These committees, people, and offices at the Dallas VAMC are responsible for overseeing human studies.

If you chose to take part in the study, certain government agencies (such as the FDA or VA) may look at your research records. Your name as a subject in this study is private and will not be included in any report prepared as a result of this study.

Identifiers might be removed from the identifiable private information that is collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

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 such as medical history, drug or alcohol treatment, or mental health treatment.

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: our collaborators at the University of Texas Dallas, the Institutional Review Board, Food and Drug Administration (FDA), Office of Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (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 Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. 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 Gargi Raval 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.

9. WHAT ARE THE COSTS 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. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study. The costs related to your condition and the standard care for your condition not related to the study, will continue to be billed.

For your time and inconvenience related to your participation in this study, you will be compensated for the amount of $50 at the end of the study, when you return the equipment. This stipend will be disbursed via a mailed check only when you complete the study and return the equipment.

Your name and social security number must be disclosed to Dallas VA Research Corporation employees in order to process any payments to you. An Internal Revenue Service (IRS) Form 1099 will be generated, which will use your Social Security Number. This payment is considered taxable income. If you owe money to the government, this payment may be garnished to satisfy the debt.

10. WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

The VA has the obligation to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with federal law (38 CFR 17.85).

Emergency and ongoing medical treatment will be provided as needed. The DVARC answering service is available at 800-725-4436 to receive calls from patients after hours.

There are no plans to provide any other payments or other forms of compensation for a study related injury (for example, for lost wages or discomfort). By signing this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call during the day, Ms. Elonm Gbedey at 214-857-0304 and after-hours Dr. Gargi Raval at 214-8574582. By signing this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

11. DO I HAVE TO TAKE PART IN THE STUDY?

Taking in this study is voluntary and you may refuse to take part without penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw your consent and stop taking part at any time. Not taking part in the study will in no way affect the quality of care you receive now or in the future from the VA. This will also not affect your right to take part in other studies. The study doctors will answer any questions you may have about the study.

12. RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The study doctor can stop your participation at any time without your consent for the following reasons: if it appears to be medically harmful to you, if you fail to follow directions for participating in the study, if it is discovered that you do not meet the study requirements, if the study is canceled, or for administrative reasons.

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

If you have any questions about this study or have any bad effects of your treatment, you should call the study doctor at 214-857-4582 or a member of the research team at 214-857-0304. You should also contact the study doctor or a member of the research team to discuss problems, concerns you may presently have, or offer input about the research.

If you have any questions about whether this is a VA North Texas Healthcare System approved research study, you may contact the Research Compliance Officer at 214-857-0341.

Participant Name: _____ Date: _____

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Principal Investigator: Gargi Raval, Thiru Annaswamy VA Facility: Dallas VA Medical Center

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 Dallas VAMC Patient Representative at 214-857-0482 if you have questions, complaints, or concerns about the study or if you would like to obtain information or offer input.

If you have a medical emergency, you should immediately call 911 for assistance.

14. AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The study doctor or 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

Name of person who obtained consent		
_____ Name	_____ Signature	_____ Date