

Assessing the Usability and Design of Immersive Virtual Reality for Adults with Upper Limb Complex Regional Pain Syndrome

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Overview of Study

The following study will be predominantly a feasibility and design study, which will determine whether immersive virtual reality (IVR) for adults with chronic pain is appropriate for further testing. The study will assess feasibility by taking into consideration the design and usability of the IVR intervention. Then, through data collection and analysis, the IVR intervention will be further developed and evaluated. The study will have two phases to test feasibility, design, and usability. Phase 1 will utilize relatively “healthy” subjects, while Phase 2 will utilize “pain” subjects with upper limb complex regional pain syndrome. Our study will have three aims in total, two aims for Phase 1 and one aim for Phase 2:

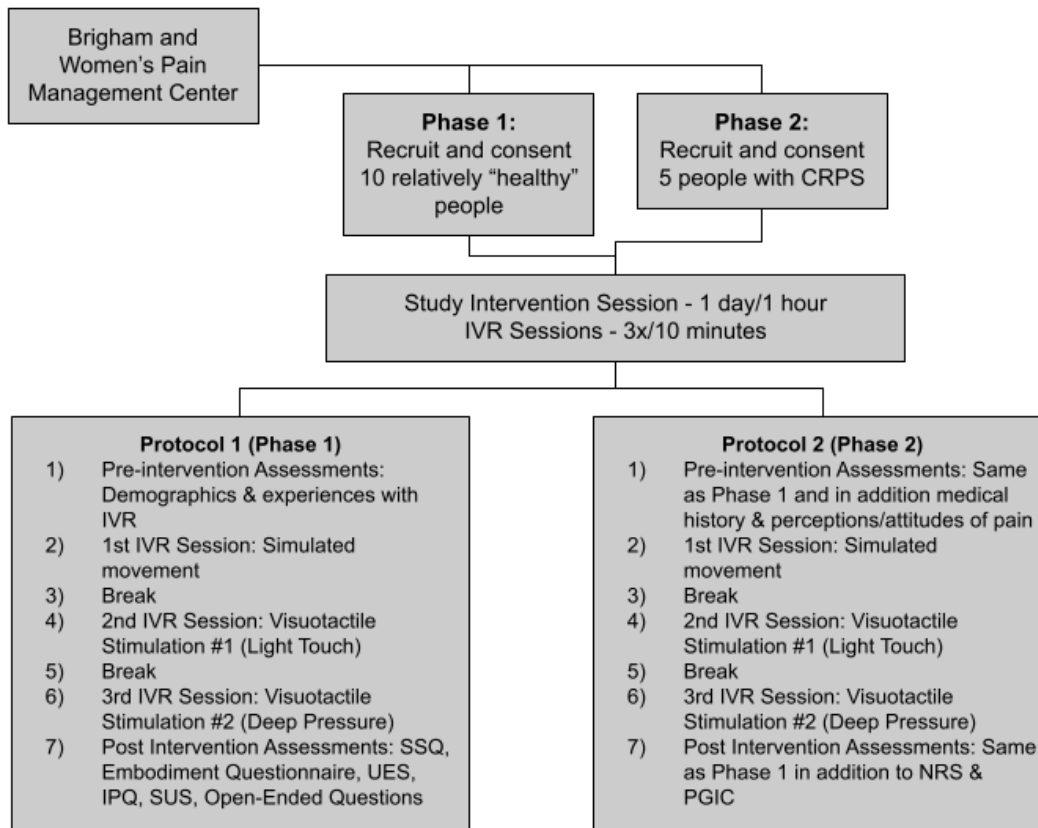
Aims for Phase 1

1. To test the feasibility of an immersive virtual reality (IVR) program in facilitating embodiment within adults.
2. To evaluate the usability and design of an IVR reality program for adults.

Aims for Phase 2

1. Evaluate the feasibility and usability of an immersive virtual reality program for adults with upper limb complex regional pain syndrome.

Flow Chart



Timeline

	Weeks													
Project Activities	1	2	3	4	5	6	7	8	9	10	11	12	13	14
IVR Program Development														
Research/Brainstorm														
Create 360 IVR Video														
Obtain Feedback														
Implement Feedback														
Recruitment														
Recruitment Materials														
Outreach														
Post on Rally														
Data Collection + Analysis														
Run Phase 1 Subjects														
Run Phase 2 Subjects														
Analyze Data														
Create charts/graphics														
Deliverables														
Protocol Manual														
Research Paper														
DEC Poster														
Finalize IVR Video														

Study Team Contact and Site Information

Name	Role	Site	Phone	Email
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Alexandro Guerrero	RA	Tufts	(323) 203-6956	aguerrero7@bwh.harvard.edu

Team Member Roles

- Principle Investigator (PI): Oversight of study
- Research Coordinator (RC): Assists with organization and implementation of project
- Research Assistant (RA): Helps PI with logistics of study

Meeting Schedule

Weekly: Lab Personnel

Monthly: All Study Personnel

Sites

Brigham and Women's Pain Management Research Lab (Suite 307G)
850 Boylston Street
Chestnut Hill, MA 02467

Tufts University Department of Occupational Therapy (Tufts)
574 Boston Ave
Medford, MA 02155

Study Materials (Files, Consent Forms, Checklists)/Data Storage

All study materials will be stored at Brigham and Women's Pain Management Research Lab (locked file drawer) (Suite 307G). Data will be inputted into a secure online REDCap portal. At the conclusion of the study, hard copies of the data will be collected from Brigham and Women's Pain Management Center and brought to Tufts University where they will be stored in a locked file.

Study Intervention Space

The visit and all study tasks will be completed in the Brigham and Women's Pain Management Research Lab (Suite 307G). The lab will have a VR system and a laptop provided by Tufts University.

Recruitment

Timeline

Phase 1

Total: Up to 10 “healthy” participants from around the Boston area

Phase 2

Total: Up to 5 “pain” participants with upper limb complex regional pain syndrome from Brigham and Women’s Hospital

Participants

Inclusion/Exclusion Criteria

Inclusion Criteria for Phase 1

1. Adults over the age of 18 (no upper limit)
2. English speaking
3. Willing and able to visit the Brigham and Women’s Pain Management Center to participate in the study

Inclusion Criteria for Phase 2

1. Adults over the age of 18 (no upper limit)
2. Diagnosis of upper limb complex regional pain syndrome
3. English speaking
4. Willing and able to visit the Brigham and Women’s Pain Management Center to participate in the study

Exclusion Criteria for Phase 1 and Phase 2

1. Unwilling to put on IVR headset
2. Diagnosed seizure disorder
3. Cognitive impairment
4. Hearing/visual deficit
5. Active, contagious skin infection
6. Eye infection
7. Has a pacemaker or defibrillator
8. Has an implanted hearing aid

Participant Recruitment

1. Recruitment Strategies

a. Phase 1

- i. Recruitment fliers will be posted in and around Tufts University buildings.

b. Phase 2

- i. Research invitations will be used for direct recruitment of any eligible subjects who had not opted out of receiving Research

- Invitations. Patients who opted out will be filtered out of the recruitment list and they will not be sent the Research Invitation.
- ii. Participant's names will be obtained through medical record and Rally.
 - iii. Recruitment filers will also be placed in Brigham and Women's Hospital Pain Management Center waiting room.
- c. For Both Phases
- i. Potential participants will be recruited from the Mass General Brigham Rally website. Using this website, participants are provided study information including the estimated time commitment, eligibility criteria, and activities required for participation (e.g., completion of surveys online).
2. A participant who self-identifies as a potential subject will contact study personnel.
- a. Contact by Phone
 - i. During the telephone screening the study personnel will complete the Eligibility Checklist Form.
 1. If eligible, study personnel will
 - a. Set up an appointment to visit the Brigham and Women's Pain Management Center
 2. If a message is left, study personnel will try to contact the participant up to 5x to complete the screening.
3. Outcome
- a. If the participant meets all eligibility requirements the researcher should schedule the participant for a visit
 - b. If the participant does not meet all eligibility requirements, thank the person.
4. The researcher will schedule the interested participant at the Brigham and Women's Pain Management Research Lab for a visit, which will include both the informed consent procedure and the intervention sessions.
5. Study personnel should complete the Recruitment Checklist for both those who are and who are not eligible.
6. The Eligibility Checklist (print out hard copy) and Recruitment Checklist should be stapled together and placed alphabetically in the locked file drawer for both eligible and non-eligible patients.

Informed Consent

1. Consent is obtained by study PI or research coordinators via visit.
2. Research personnel will provide a verbal overview of the study.
3. The participant will have as much time as they need to read the ICF.
 - a. Ensure the subject has read the ICF
 - b. Summarize key consent information

- i. The purpose of this study is to learn more about whether it is possible to develop an immersive virtual reality (IVR) program to facilitate a sense of embodiment and use as a therapeutic intervention for adults.
- ii. If you join this study as a relatively healthy individual, you will be part of Phase 1 of this study. If you join this study as an individual diagnosed with upper limb complex regional pain syndrome, you will be part of Phase 2 of this study.
- iii. We will first ask you some questions about your demographics and past experiences with virtual reality. These surveys will take about 10 minutes to complete. If you have complex regional pain syndrome, you will be asked specific questions regarding your current and past levels of pain and how it has interfered with your daily life in the last 24 hours.
- iv. Then there will be three immersive virtual reality sessions which will last approximately 5 to 10 minutes each with breaks in between. The first IVR session will include simulated movement, relaxing music, and a voice that will guide you through movement of your arms. The second and third IVR session will include simulated visuotactile stimulation by rubbing different objects on the both the virtual hands and your hands at the same time. The second IVR session will utilize light pressure objects, while the third IVR session will utilize dep pressure objects.
- v. After the IVR sessions, you will spend about 10-20 minutes filling out questionnaires that will collect data on you IVR experience, with questions related to comfort and pain if you are in Phase 2. You will also be asked a series of open-ended questions and probing questions.
- vi. You will be in the study for only 1 day.
- vii. There are some risks including motion sickness, potential fear triggers (dangerous objects), seizures, emotional responses to virtual reality, contamination from headset, and loss of confidentiality. All these risks are small.
- viii. There is the possibility of benefits. You may experience a sense of embodiment, which is the sensation that your self is located inside a virtual body; you control that body, and that body belongs to you. Some benefits to experiencing a sense of embodiment involve increased entertainment, social interactions, and/or health applications. There will be no long-term benefit to taking part in this study.
- ix. Will receive a \$25 gift card for taking part in this research study.
- x. You can leave the research at any time.

- c. Invite and answer question
 - d. Confirm understanding by asking the interested participant the following questions to determine that they understand the information provided. If the potential participant is unable to answer, recap information and then check for understanding
 - i. What is the purpose of this study?
 - ii. What kind of interventions will you receive?
 - iii. When will these interventions happen?
 - e. Ask if the interested participant still wishes to take part in the study
 - f. If the answer is affirmative
 - i. The interested participant will sign and date the Informed Consent Form
 - ii. Researcher will sign and date the ICF
 - iii. Researcher will either copy or email the signed ICF to the participant
 - iv. Researcher will keep and store the ICF in a designated, locked consent file
 - v. Researcher will complete the Informed Consent Checklist
 - g. If the answer is negative
 - i. Researcher will thank the interested participant for their time and terminate the recruitment
4. After obtaining consent the researcher will move on to the IVR Intervention Sessions

Scheduling

Ensure that the lab is available and be sure to write all scheduled visits on the lab calendar on Outlook

During the Visit

1. Consenting Process
 - a. Lasts 15 minutes to 30 minutes
 - b. Obtain informed consent
2. Complete Pre-Intervention/Baseline Surveys
 - a. Lasts 10 minutes
 - b. Determine if subject is in Phase 1 or Phase 2
 - i. Phase 1
 1. Demographics
 2. Experiences with VR
 - ii. Phase 2
 1. Demographics
 2. Medical History
 3. Perceptions/Attitudes of Pain

4. Experiences with VR
3. First IVR Intervention
 - a. Lasts 10 minutes
 - b. Simulated movement, relaxing music, and a voice that will guide the participant through movement of their arms
 - i. Gripping, flexing, and extending
 - ii. Placing pegs, drawing shapes, catching objects
4. 1st Break
 - a. 2 minutes
5. Second IVR Intervention
 - a. Lasts 10 minutes
 - b. Simulated visuotactile stimulation
 - i. Light pressure
6. 2nd Break
 - a. 2 minutes
7. Third IVR Intervention
 - a. Lasts 10 minutes
 - b. Simulated visuotactile stimulation
 - i. Deep pressure
8. Complete Post-Intervention Surveys
 - a. Lasts 10 minutes
 - b. Determine if subject is in Phase 2 or Phase 2
 - i. Phase 1
 1. Usability
 2. Design
 3. Embodiment
 4. Presence
 - ii. Phase 2
 1. Same as Phase 1
 2. Comfort
 3. Pain
9. If a subject misses an appointment reschedule as soon as possible

IVR Intervention Script

1. Prior to the visit, set up VR equipment. Check for updates and clean equipment.
2. Determine if participant is Phase 1 or Phase 2.
3. Introduce yourself
4. Have participant sit in chair
5. Explain the purpose of the study and obtain participation consent

“The purpose of this study is to understand whether virtual reality can be used as a tool to reduce chronic pain. In order to this, we need to find out if it is possible

to develop a VR program to create a sense of embodiment, which is the feeling that you are located inside a virtual body, that you control that virtual body, and that the virtual body belongs to you. In this case, we want to be able to embody you onto a virtual avatar within our VR program. In order to do this effectively, elements of usability and design will be tested and evaluated with your help.

6. Have participant fill out pre-intervention surveys

“Before we get you into the virtual reality headset, we just need you to fill out some pre- surveys. These surveys will ask you questions about your demographics as well as your past experiences with virtual reality. Answering these surveys will take about 10 minutes.”

7. Provide disclaimer

“The VR experiences can feel very real. If at any time you feel like you want the experience to end, simply take the headset off.”

8. Explain virtual reality headset

“This is the virtual reality headset [grab headset]. I am going to explain to you the best way to put it on. First, you are going to put the visor on your face and then put the head strap over your head [demonstrate action]. The Velcro strap on the top as well as the sliders on the side strap can be tightened or loosened to take some of the frontal weight off the headset. When adjusted correctly you should see the VR experience clearly. It might take a couple of minutes to find the best fit for you. To take off the headset, just reverse the actions. Pull the head strap off first and then remove the visor from your face.”

9. Move table in front of chair
 - a. Table should have rough outline of hand position
10. Instruct participant to put on VR headset and place hands flat in front of table after donning

“Now, let’s put on the headset. [Hand headset]. Hold the visor in one hand and the back of the head strap with the other. Make sure the cord is not covering the lens and is to the left of the headset. Tilt your head down. Your nose and upper cheeks should go in first. Then bring the head-strap down towards the back of your head. Reach up and grasp the Velcro strap. Bring it forward to release the Velcro, then gently pull it back until the headset feels like it is sitting comfortably. [Physically help them adjust the Velcro strap if needed]. Do you feel as if the headset is seated well, and you can see the experience well?”

If not: “Remove the headset and adjust the side straps. To loosen the side straps, move the sliders toward the top strap. To tighten the side strap, move the sliders away from the top strap. After you move the sliders, center the top strap between the sliders so that the two sides are equal, and the top strap is centered on your head when you put the headset on.”

“Before we start the session, I would like to make sure you are comfortable. Does the headset feel okay? Are you sitting comfortably in your chair with your feet on the floor? Please take the time to adjust the headset and your position so that you feel relaxed and comfortable. We will take a break when the first IVR video has finished.”

11. Launch 1st IVR Experience

- a. Let participant know VR is about to begin
 - b. Go to VR computer and open YouTube application in Oculus
 - c. Open the 360-video associated with 1st IVR experience
 - d. Verify that the participant can see the application both by looking at the computer screen and by asking them if they see it.
12. Instruct participant to follow along with the VR video and to imagine themselves completing the tasks and activities in the video

“As you follow along with the video, I want you to imagine that you and your body are actually doing the tasks and activities in the video.”

13. Log IVR experience start time
14. Log IVR experience end time
15. Provide the subject with a 2-minute break

“You may now take off your headset and take a quick break before we begin with the next IVR experience. If you need to adjust the headset again, please feel free to do so.”

16. Repeat the process for the 2nd and 3rd IVR experience

Study Session

Entering Subject into Study

- After the subject has been consented study personnel will do the following:
 - Assign subject a unique identifier
 - Track information
 - Place the Subject File in the locked file drawer

- Study personnel will complete the Informed Consent Checklist, append it to the Informed Consent Form, and place them alphabetically in the locked file drawer

Pre-Intervention/Baseline

1. Study personnel brings subject to lab room
2. The subject completes the following questionnaires in REDCap depending on which Phase they are in
 - a. **Phase 1**
 - i. Demographics
 - ii. Experiences with VR
 - b. **Phase 2**
 - i. Demographics
 - ii. Medical History
 - iii. Perceptions/attitudes of Pain
 1. Pain Catastrophizing Scale
 2. PainDetect Questionnaire
 3. Survey of Pain Attitudes
 - iv. Experiences with VR
3. Complete Baseline Session Checklist and place all forms in subject folder

Intervention/IVR Experiences

1. Refer to the IVR Intervention Script above

Post-Intervention

1. Have the subject complete the following questionnaires on REDCap depending on the Phase they are in
 - a. **Phase 1**
 - i. Simulator Sickness Questionnaire [SSQ]
 - ii. Embodiment Questionnaire
 - iii. User Engagement Scale [UES]
 - iv. iGroup Presence Questionnaire [IPQ]
 - v. System Usability Scale [SUS]
 - b. **Phase 2**
 - i. Same questionnaires as Phase 1 and...
 - ii. Pain Numerical Rating Scale [NRS]
 - iii. Patient Global Impression of Change [PGIC]
2. Ask subjects the following open-ended questions and any other probing questions depending on the Phase they are in
 - a. **Phase 1**
 - i. What did you particularly like about the IVR?
 - ii. What didn't you like about the IVR?

- iii. Was there anything about these IVR experiences that you found particularly interesting or engaging?
- iv. Did you have any expectations about what would happen? Were these expectations met?
- v. Did you experience any feelings/sensations that you consider new or different? What were they?
- vi. How did virtual reality affect your mood?
- vii. Based on this trial, do you believe that VR would help you? In what way?

b. Phase 2

- i. Same questions as Phase 1
 - ii. Did you experience a reduction in any symptoms? In what way?
 - iii. Did you experience an increase in any symptoms? In what way?
3. Audio record responses to open-ended questions and probing questions
 4. Store audio recordings in a password protected file that only study personnel have access to

REDCap Instructions

1. Open REDCap on iPad and login
2. On the left side bar select “Add/Edit Records” (text in red)
3. Select existing record – look at the Baseline Session Checklist to find REDCap ID of the subject and select that record number for the individual subject (each participant receives their unique REDCap ID at baseline visit)
4. Select the survey associated with the Phase the subject is in
5. Select “Generate survey QR code” on the top right corner
6. Select “Survey options” then “Open survey”
7. Have subject fill out and submit the survey

Discontinuing a Subject from the Study

1. Subjects can be discontinued from the study for the following reasons
 - a. Experienced epileptic type seizures during or after IVR activity
 - b. Has an injury or illness that prevents them from using the equipment
 - c. Subject requests to be discontinued from study
 - d. If study personnel believe that a subject should be discontinued for another reason, they should contact the PI and explain their rationale
2. If PI determines a subject should be discontinued, they will notify research personnel at site and remove the subject’s file from the active file

Subject Payment

1. Subjects will receive \$25 for participating in the study
2. After the subject has completed their participation in the study, RA will email the subject an Amazon gift card code

3. If the subject does not have an email address, RC will send a gift card by mail
4. RA will document gift code number with subject name and the date the email was send on subject linking file

Parking

Free self-parking and complimentary valet parking options are available for participants.

Unanticipated or Adverse Events

Contact with Objects: Participants' vision is occluded by the Immersive Virtual Reality (IVR) headset. In general, they will perform the IVR sitting, but the program may prompt them to move their arms during the session.

Simulator Sickness: Some participants experience simulator sickness while in the IVR experience particularly after prolonged exposure. Simulator sickness symptoms can include fatigue, headache, eye strain, difficulty focusing, increased saliva in mouth, sweating, or nausea. This risk is small. We have 3 methods to reduce this risk.

- 1) Dosage of each IVR session is 10 minutes which has been typically used in the literature, so risk for motion sickness is reduced.
- 2) Participants will complete the Simulator Sickness Questionnaire after each experience to monitor for motion sickness.
- 3) Participants can halt any IVR session at any time for any reason.

Seizures: Some people experience severe dizziness, seizures, eye or muscle twitching or blackouts triggered by light flashes or patterns during the IVR. This risk is small. We have 2 methods to reduce this risk.

- 1) People with a known risk for seizures will be excluded from this study.
- 2) If a subject experiences any of these symptoms we will immediately stop the IVR session. We will provide indicated immediate supportive care, we will recommend that they see a doctor, and they will be discontinued from the study.

Uncomfortable IVR Headset: Some people may find wearing the headset uncomfortable. This risk is small. We have 2 methods to reduce this risk.

- 1) We will work with the participant to adjust the headset to be as comfortable as possible.
- 2) Participants can stop the IVR experience at any time for any reason.

Contamination: The IVR headset is tightfitting and in close contact with the skin of the face. It is possible that participants may cross contaminate contagious skin or eye disorders. This risk is small. We have 2 methods to reduce this risk.

- 1) We will exclude people who have active, contagious skin or eye infections.
- 2) We will use a washable face protector for each visit. Each device will be wiped with antibacterial cleaners after each use.

Unintentional Loss of Confidentiality: People other than the research team may be exposed to individuals who are not part of the research team. This risk is small. We will use best practices for data collection, storage, and analysis. These include the following.

- 1) Research activities will take place in a private area.
- 2) Only members of the research team will be present.
- 3) All data will be stored under assigned ID numbers in protected servers.
- 4) Analysis will take place in a private area, and it will be kept in a locked file only accessible to the PI.

Overall: Throughout the study, investigators will be alert to any complaints or adverse reactions and will take appropriate steps to alleviate the difficulties as soon as possible. Patients will be given the names and phone numbers of individuals to contact in the event of an emergency, complaint, or question regarding the conduct of the study. Overall, we have attempted to minimize both participant risk and participant burden.

In a research study, unanticipated problems involving risk to subjects or others, non-compliances, and other events may occur that need to be reported to the IRB even if they do not necessarily have an unfortunate outcome. Unanticipated and Adverse events do not just have to happen to a subject, they can also be breaches of protocol. For example, the following are considered adverse or unanticipated events.

- While walking out to the waiting room after a VR session, a subject trips and falls. It is possible that their balance was impaired by the VR experience.
- A subject who does not meet eligibility requirements is enrolled
- A consent form is unsigned
- Breach of confidentiality

If you think that such an event has occurred, you should document it on the Adverse Event Tracking Log and send it to the PI for review. They will make the designated of what the next steps should be (report to the IRB, change in procedure, etc.)

If you have a Serious Adverse Event (SAE) during the intervention or if a participant reports an adverse event outside the study (even if it does not appear study related): Immediately call the PI (617 723-9468). Then complete the Adverse Event Tracking Log as soon as possible after the incident.

If you have an Adverse Event during the intervention or if a participant reports an adverse event outside of the study: Complete the Adverse Event Tracking Log and email it to the PI within 24 hours of the incident.

Below is information about Unexpected and Adverse Events. Use it to help you to determine if you should report an incident. **When in doubt, report it to the PI.**

Definitions of Unanticipated Problems and Adverse Events

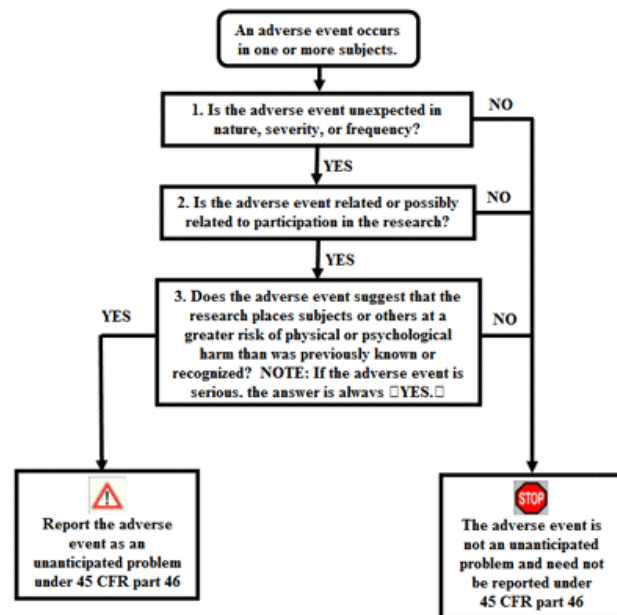
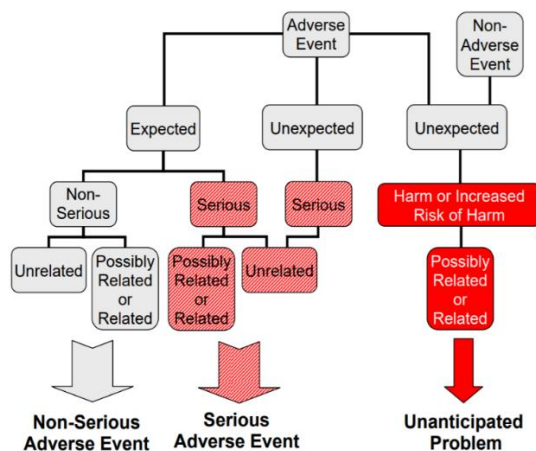
- Unanticipated Problem Definition: An incident, experience, or outcome that meets all of the following criteria:
 - Unexpected (in terms of nature, severity, or frequency) given:
 - the research procedures that are described in the protocol-related documents such as the IRB-approved research protocol and informed consent document
 - the characteristics of the subject population being studied
 - Related or possibly related to a subject's participation in the research
 - Suggests that the research places subjects or others at a greater risk of physical, psychological, economic, or social harm related to the research than was previously known or recognized
- Adverse Event (AE) Definition: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal physical exam or laboratory finding, symptom, or disease, temporally associated with a subject's participation in the research. Every AE is classified as:
 - Internal or External
 - Internal: The AE occurred at a study site where the Brigham and Women's Hospital/MGB IRB is the responsible approving body
 - External: The AE occurred at a research site not under the jurisdiction of the BWH/MGH IRB
 - Related (includes both definite and probable relationships), Possibly Related, or Unrelated to participation in the research
 - Expected or Unexpected based on the known:
 - Risks associated with drugs, devices, or other protocol activities described in the IRB approval protocol, supporting documents, and ICFs, or
 - Natural progression of an underlying illness, or
 - Health characteristics of the study population
 - Non-serious or Serious
 - Serious Adverse Event (SAE) is any AE that:
 - Results in death;
 - Is life-threatening (places the subject at immediate risk of death from the event as it occurred);
 - Results inpatient hospitalization or prolongation of existing hospitalization;
 - Results in a persistent or significant disability/incapacity;
 - Results in a congenital anomaly/birth defect; or
 - Any other adverse event that, based upon appropriate medical judgement, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed above

(Modified from the definition of serious adverse drug experience in FDA regulations at 21 CFR 312.32(a).)

Principle investigators are required to report to the PHRC any of the following *unanticipated problems* and *adverse events* that occur: 1) during the conduct of the study, 2) after study completion, or 3) after subject withdrawal or completion. **Reports are to be submitted within 5 working days/7 calendar days of the date the investigator first becomes aware of the problem.**

- *Internal adverse events* that are *unexpected*, and related or *possibly related to the research* and that indicate there are new or increased risks to subjects;
- *External adverse events* that are *serious*, *unexpected*, and related or *possibly related to the research* and that indicate there are new or increased risks to subjects that require some action (e.g., modification of the protocol, consent process, or informing subjects);
- *Unanticipated adverse device effects* that are *serious* and caused by, or associated with, the device;
- *Deviation* from the approved research protocol or plan without IRB approval in order to eliminate apparent immediate hazard to subjects or harm to others;
- *Deviation* from the approved research protocol or plan that placed subjects or others at an increased risk of harm regardless of whether there was actual harm to subjects or others;
- Any event that requires prompt reporting according to the research protocol or investigational plan or the sponsor;
- Breach of confidentiality or violation of HIPAA (e.g., lost or stolen laptop);
- Medication, procedural or laboratory error (e.g., errors in drug administration or dosing, surgical or other procedure, or testing of samples or test results) regardless of whether subjects experienced any harm;
- Interim analysis, safety monitoring report, publication in a peer-review journal, or other finding that indicates that there are new or increased risks to subjects or others or that subjects are less likely to receive any direct benefits from the research;
- Change in FDA labeling (e.g., black box warning), withdrawal from market, manufacturer alert from the sponsor, or recall of an FDA-approved drug, device, or biologic used in the research;
- Complaint by/on behalf of a research subject that indicates that the rights, welfare, or safety of the subject have been adversely affected or that cannot be resolved by the investigator;
- Incarceration of a research subject during participation in research that is not approved for involvement of *prisoners* as subjects;

- *Noncompliance* with applicable regulations or requirements or determinations of the IRB identified by the research team or others (e.g., FDA Form 483 or Warning Letter) that indicates that the rights, welfare, or safety of subjects has been adversely affected;
- *Suspension or termination* of the research, in whole or in part, based on information that indicates that the research places subjects at an increased risk of harm than previously known or recognized (e.g., FDA *clinical hold*);
- Suspension or disqualification of an investigator by FDA, sponsor, or others;
- *Scientific misconduct*; or
- Any other problem that indicates that the research places subjects or others at an increased risk of harm or otherwise adversely affect the rights, welfare or safety of subjects or others



Data Entry, Processing, and Storage

1. Any data not already electronic data will be entered in a protected REDCap database by trained research assistants
2. Any forms completed by hand will be collected by RA, RC, or PI and placed in the locked file drawer in the Brigham and Women’s Pain Management Research Lab (Suite 307G)

VR Experience General Information

1. Prior to session start
 - a. Turn on computer and start Meta Quest 2
 - b. Update any systems if prompted to do so
2. Seat subject in chair facing the table
 - a. If first time in system

- i. Explain safety
 1. Do not get up
 2. If IVR becomes upsetting ask personnel to remove headset
 3. Face shield
 - ii. Demonstrate how to fit the headset and have the subject put the headset on
 - *This is the headset for the VR experience. You put it on from the front first like this. (Demonstrate). Put on the headset and make sure it fits comfortably. Adjust the Velcro strap on top of the Meta Quest 2 until it sits comfortably on your head. It should fit snugly over your nose and the face shield should be between your face and the device.*
 - *To take off the headset, loosen it using the top strap. With both hands, pull the headset forward and then off.*
 - To wear the headset with glasses, check to make sure the width and height of the subject's frames are the following sizes:
 - Width: 142mm or less
 - Height: 50mm or less
 - The wear the headset with glasses:
 - Remove the facial interface foam from the headset
 - Attach the glasses spacer to the headset where the facial interface foam was
 - Place the facial interface foam on top of the glasses spacer, in the same orientation as it was originally
 - Loosen the side straps
 - Moving from front to back, put on the headset, first placing the facial interface foam against your face and glasses
 - Tighten the side straps to achieve a comfortable fit
 - If the subject's glasses do not fit in the headset or the lens of their glasses touches the Meta Quest 2 lens, have them take off their glasses while using the Meta Quest 2.
3. Run Program
 4. Remove headset
 - a. After subject is gone, clean headset with antibacterial wipes
 - b. Clean the VR lens with a lens cleaning cloth (do not clean the lens with antibacterial wipes)
 - i. Lightly blow across the lens to remove dust
 - ii. Gently clean lens by starting in the center and gently rubbing in a circular pattern

- iii. Note: Do not expose lens to sunlight, as this can damage the lens.
Place duct cover over lens when not in use

Troubleshooting the VR System

For general support: <https://www.meta.com/help/quest/>

For specific support: <https://www.meta.com/help/quest/articles/fix-a-problem/>

For community support: <https://communityforums.atmeta.com>

Contacting Meta: <https://www.meta.com/help/support/>

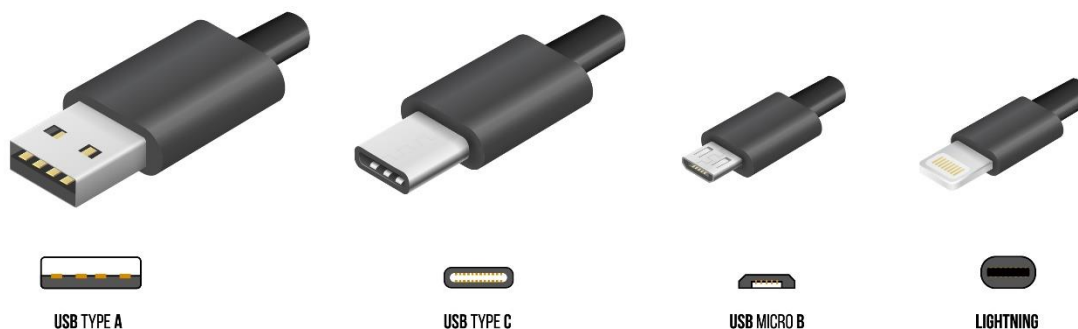
Quick Guide

Notes:

- Never force a cable into/out of a port
- Do not download anything from the internet that claims to fix or update the headset

List of steps to take if the headset unexpectedly stops working:

1. Ensure that the computer and the headset are up to date
 - a. Is Windows up to date?
 - b. Are the drivers up to date?
 - c. Is the Oculus up to date?
2. Confirm that all the cables are securely connected
 - a. USB-A cable leading to computer
 - b. USB-C cable leading to headset



3. Restart the Oculus app
 - a. In the Oculus app, click “Settings” on the left side of the window
 - b. Click “Beta” on the top of the settings options
 - c. Click “Restart Oculus”
4. Unplug and reconnect the headset

- a. Unplug both the USB-A cable leading to the computer and the USB-C cable leading to the headset
 - b. Wait five seconds and plug both cables back in
5. Plug the USB-A cable into another USB 3.0 port
6. Repair the Oculus software
 - a. Go to <https://www.meta.com/quest/setup/>
 - b. Scroll down to “Air Link and Link Cable”
 - c. Click on “Download Software”
 - d. Click on the downloaded file, “OculusSetup.exe”
 - e. A screen will appear saying, “Already Installed: Looks like you’ve already installed Oculus”
 - f. Click on “Repair”

Problem: The interactive element of the experience is off center or covered by something else

- a. Update system – If the system is not working correctly, the view moves around or is out of sync, it is because the system needs to update. This is usually states in the system. Unlike many programs, if the system needs to update, it will not run correctly. So, update as soon as you see this type of message
- b. Turn the computer off and on again. Make sure the headset is positioned approximately where you want the subject to stand
- c. Re-define the play space guardian system
 - a. Make sure you are facing in the direction you want the subject to face during activities
 - b. Put on the headset

Problem: The image is blurry

- a. Readjust the headset
- b. Clean the lens
 - a. Use lens cloth for light smudges
 - b. Use premoistened cloths for heavy smudges
- c. If the individual is wearing glasses, try the experience without the glasses

Problem: Buffering

- a. Close the program and restart the computer