# Virtual Reality (VR) & Human Subjects Research Guidance

## What are the main types of virtual reality?

**Virtual Reality:** The real world is hidden and the user is completely immersed in a digital experience, creating a computer simulation of a real environment.

**Augmented Reality:** Virtual simulations are overlaid with real-world environments to enhance or augment those environments.

**Mixed Reality:** A more advanced augmented reality environment that allows virtual objects to be manipulated. MR is a type of hybrid system that involves both physical and virtual elements.

## Risks of VR in Human Subjects Research:

The risks of VR studies are contingent on several factors. The equipment used, the type of interaction, the length of treatment, the content delivered, and participant differences (both ongoing conditions and temporary states) can affect a participant’s likelihood to experience side effects when using VR.

Thus, it is important to know what equipment researchers plan on using and what the physical space of the study will be. Will people be wearing a headset, or is it projection based? Will people be walking around a space or seated? Will other equipment be incorporated (controllers, backpacks, sensors/trackers)? Are they in a controlled lab setting or elsewhere? What is the space like? **It is also imperative for researchers to screen participants for conditions that may make them very prone to negative side effects.**

Many people are unaware of the various risks associated with VR equipment and immersion, such as:

* Cybersickness
* triggering of seizures or other conditions due to visual effects
* injury from tripping, falling, or colliding with physical objects
* contagions from sharing head-mounted displays

Cybersickness is a common side effect of VR immersion; symptoms include:

* headache
* feeling dizzy or lightheaded
* sudden drowsiness or fatigue
* vision problems
* nausea and vomiting

## Managing Risks in VR Research

* The study location should always be cleared of hazards and obstacles that could harm participants during immersion (e.g., tripping hazards such as wires or rugs). Floors should be kept dry.   
  Researchers should know where the nearest restroom is and be prepared to accompany the participant if needed. It is recommended that spaces are equipped with a lined trash can or plastic bags in case of vomiting. Researchers may wish to keep ginger ale or saltines on hand to settle upset stomachs.
* Before immersion, every participant should be prescreened for long-term and short-term conditions and excluded as appropriate. Sample screeners can be found below.
* Immediately before immersion, participants should be reminded that they can stop any time and should tell the researcher immediately if they are feeling any symptoms.
* During immersion, the researcher should conduct wellness checks on participants. For longer periods of immersion, the researcher should provide breaks. Please note that children and adults with cognitive impairments may not recognize the bodily onset of cybersickness. Different approaches may be necessary depending on the age and background of the children.
* If the participant reports any symptoms, the researcher should have the participant take a break or terminate the immersion.
* During immersion, one researcher should always be watching and monitoring the participant. Sufficient precautions should be taken to ensure participants do not harm themselves (e.g., running into walls, furniture, or other participants). If the participant is moving around the room and their vision is obscured by a headset, the study may need a “catcher,” or someone to follow the person around the room. Wired headsets can present tripping hazards; wireless headsets mean there is one less constraint keeping participants from running into a wall.
* After the immersion, the researcher should ensure the participant is not feeling any side effects. If they are, researchers should provide care as appropriate and monitor the participant as needed.
* Appropriate materials should be on hand to disinfect equipment between participants to minimize the possibility of contamination and transmission of germs.

## Prescreening of Participants

Prescreening should be conducted before the immersion. Researchers should consider:

* Pre-existing conditions that may increase the likelihood of side effects.
* States that may increase the likelihood of side effects, like having a cold or taking certain types of medications.
* Visual impairments or physical mobility, as relevant to the study.

Screening for long-term conditions should happen before participants are on site for the study. Regardless of prescreening for long-term conditions, physical state should also be assessed immediately before the immersion.

Longer-term conditions that may promote a greater likelihood of experiencing side effects include:

* A history of motion sickness or nausea.
* A history of migraines or headaches.
* A history of balance issues or dizziness.
* Epilepsy or neurological conditions where visual stimuli may trigger seizures or other issues.
* Pregnancy, recent concussions or other conditions where dizziness, nausea or headaches are more likely.

Short-term conditions include:

* Headache
* Nausea
* Dizziness or lightheadedness
* Recent illness (flu, hangover, etc.)
* Recent contagious condition (pink eye, head lice, flu, etc.)

## Monitoring During Immersion

Any immersion over a few minutes in length should include wellness checks. Equipment or content that is more likely to evoke cybersickness should be considered when determining the frequency and timing of these checks. Additionally, if participants indicate a higher potential for cybersickness in their prescreening, these checks may need to be earlier or more frequent during immersion. Some participants may be so engaged in the experience that they do not recognize the onset of cybersickness before it is too late.

If participants are feeling unwell, one of two courses of action should be taken. In most cases, the session should be terminated by the researcher immediately. However, if the participant wishes to continue, a break is advised until their symptoms resolve. When the participant is back in immersion, they should be reminded to speak up the moment they do not feel well. The frequency of wellness checks should also be increased by the researcher.

If participants are feeling unwell, the researcher should take appropriate steps to address the situation as symptoms could get worse after leaving the study. Participants who are feeling dizzy, for example, could fall down the stairs or faint. Participants who are experiencing dizziness or lightheadedness should be encouraged to sit down or perhaps close their eyes and put their heads down. If they are experiencing nausea or an upset stomach, they should sit close to the trash can or have access to a plastic bag for vomiting. The researcher may wish to offer them saltines or ginger ale. The researcher should ask them to stay until their symptoms subside and offer them a comfortable place to wait. Of course, the researcher cannot force them to stay; but should express their concern about leaving.

## Sample Screener

The screener questions should be administered before participants are scheduled for the VR session. Because of variations in equipment (e.g., is it a projection system or a head-mounted display?), interaction (e.g., are participants sitting or walking?), and content, there may be different levels applied for some of these questions. **Recommendations are provided for guidance.**

When submitting an IRB application, the researcher should specify in the application which responses to the screener would make a person ineligible to participate in the study but these should not be visible to the participant.

1. Do you experience motion sickness or car sickness? \_\_\_\_\_  
   0 – Never   
   1 – Has happened once or twice  
   2 – Rarely  
   3 – Sometimes  
   4 – Often  
   5 – Very often  
     
   *Recommendation: Participants who indicate 4 or 5 are not recommended for use in most VR studies. Participants who indicate 3 should be carefully considered based on equipment and content.*
2. Do you have any conditions that where flashing or intense light might affect you, such as epilepsy, migraines, unexplained seizures, recent concussions, or light sensitivity?  
     
   \_\_ Yes  
   \_\_ No  
     
   Please explain:  
     
     
   *Recommendation: In most cases, a “yes” should disqualify participants.*
3. Do you have any neurological or vestibular issues, or have you had any recent experiences (e.g., a head injury) that affect your balance or gait?  
     
   \_\_ Yes  
   \_\_ No  
     
   Please explain:   
     
     
   *Recommendation: In most cases a “yes” should disqualify participants.*
4. Do you have any uncorrected vision impairments, such as blindness, partial blindness, limited field of view, blurred vision, or stereo blindness? That is, do you have any issues affecting your vision that are not corrected with contacts, glasses, etc.?  
     
   \_\_ Yes  
   \_\_ No  
     
   Please explain:
5. Do you have any issues affecting your physical mobility or body movements?  
     
   \_\_ Yes  
   \_\_ No  
     
   Please explain:
6. Have you ever experienced virtual reality (VR), via a head mounted virtual reality display (e.g., Meta Quest, HTC Vive)?  
     
   \_\_ Yes, and I had no physical side effects.  
   \_\_ Yes, and I had some physical side effects.  
   \_\_ No  
     
   Please explain:
7. Do you experience blindness or issues affecting your field of view?  
     
   \_\_ Yes  
   \_\_ No  
   \_\_ Unsure  
     
   Please explain:
8. Do you experience colorblindness or issues with color perception?  
     
   \_\_ Yes  
   \_\_ No  
   \_\_ Unsure  
     
   Please explain:
9. Do you experience stereo blindness or issues with depth perception?  
     
   \_\_ Yes  
   \_\_ No  
   \_\_ Unsure  
     
   Please explain:
10. Do you have any issues affecting your ability to move your head and look around?  
      
    \_\_ Yes  
    \_\_ No  
      
    Please explain:
11. Do you have any issues affecting your ability to move your upper body, hands, or fingers, such as lifting your arms, grasping objects, etc.?  
      
    \_\_ Yes  
    \_\_ No  
      
    Please explain:
12. Do you have any issues affecting your ability to walk?  
    \_\_ Yes  
    \_\_ No  
      
    Please explain:

## Sample Screener on the Day of the Session to Assess Physical State Right Before the Immersion

1. How are you feeling right now? Are you experiencing headache, nausea or dizziness?
2. Have you recently been ill (flu, cold, pink eye, lice, etc.)?

*If they answer no, they would be eligible to participate that day.*

## References

*This guidance is adapted with permission from* [*Ohio State: Virtual Reality and Human Subjects Research*](https://ohiostateresearch.knowledgebase.co/article/virtual-reality-and-human-subjects-research-77.html)*.*

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