Northeastern University
Human Research

Guidance: Research using Virtual and Extended Reality

Overview

When using **extended reality (XR)** in human-subjects research, investigators should consider the risks of these technologies and implement appropriate safeguards. XR is an umbrella term including **virtual reality (VR)**, **augmented reality (AR)**, and **mixed reality (MR)**.

XR may use wearable technology such as a headset or non-wearable equipment such as a driving/flight simulator, smartphone, or desktop monitor.

How to submit XR content for review

The IRB must review all participant-facing material, including all content participants will see and hear during an XR immersion activity. A video (from the user's perspective) is usually the most straightforward way to submit this content. If a video is not feasible, screen captures and a script may be accepted.

The study protocol should thoroughly describe:

- All equipment being used (user manuals may be requested)
- The duration of the immersion session(s)
- What participants will be instructed to do throughout the session (written instructions or scripts may be submitted separately)
- Any other elements of the experience that are not clear from the video (e.g. haptic feedback, physical setup)

Common risks

Risks of XR depend on several factors including the equipment used, the content, the nature of participants' interaction with the content, the duration of immersion, and the participant population. These risks will be considered for each study individually.

Researchers should review their equipment's user manual for any risks, warnings, and contraindications.

Simulator sickness

Simulator sickness (a type of motion sickness, also called cybersickness) is a common side effect of XR, caused by mismatched input from the visual, vestibular, and somatosensory systems. Symptoms include nausea/queasiness, headache, fatigue/drowsiness, dizziness, vertigo, vision problems, and others.

Risk and severity of simulator sickness tend to increase with longer immersion times; it can be fairly common even with a 15-minute immersion.

Strategies to reduce the risk of simulator sickness may include:

Procedures and session design

- Using XR programs designed by an experienced XR designer
- When designing programs yourself:
    - limit the amount of detail and structure in the periphery of the scene
    - match visual movement to actual movement where possible (e.g., use hand gestures for interactions rather than static controllers; if the participant will be seated, avoid using visual movement to simulate walking/running)
    - if visual movement does not correspond to actual movement, limit the acceleration of visual movement
    - simulate physical movement (e.g. with haptic feedback from a chair)
- Designing/choosing programs where the participant will be stationary
- Limiting XR immersion time to the minimum necessary
- Including frequent breaks and check-ins
- Explaining simulator-sickness symptoms to participants in advance, and instructing them to pause the simulation immediately if symptoms begin

Eligibility criteria

- Only enrolling people who have prior experience with the type of XR used in the study, with no ill effects
- Excluding participants with a history of chronic headaches or migraines, syncope, recent concussion, or pregnancy
- Limiting participation to younger adults (older adults may be more prone to motion sickness)
- Excluding participants who wear eyeglasses that don't fit under the wearable tech (rather than allowing them to participate with eyeglasses removed)
- Excluding or rescheduling participants who are feeling sick or tired or have a headache

Addressing simulator sickness when it occurs

- Ensuring easy access to a restroom or trash bag in case of vomiting
- Offering food such as ginger ale or saltines
- Offering space for participants to rest after the session ends in case of prolonged symptoms

Falling

Postural control is negatively affected during XR. Strategies to reduce the risk of falling may include:

- If participants will walk or move in the physical space, the space should be clear of obstacles and tripping hazards. A researcher should monitor the participant and warn them if they are approaching an obstacle.

- Soft, waist-high barriers may be used to safely mark the boundaries of the space.
- If appropriate for your program, equipment with visual pass-through can allow participants to see obstacles during the XR immersion. Pass-through can also be used to automatically exit the program when the participant leaves the designated boundaries of the physical space.
- If participants are able to remain stationary during the immersion, they should be seated rather than standing.
- If a participant is experiencing dizziness or vertigo, they should be encouraged to remain seated until the symptoms pass.
- Excluding people with pre-existing conditions that affect balance or postural control, including physical injuries, neurological issues, and vestibular issues.

Seizure and other conditions triggered by visual effects

Seizures may be triggered by the visual effects of XR, especially (but not exclusively) in participants with epilepsy or other neurological conditions. Migraines are also triggered by visual effects in some people. Gaze-based activities tend to reduce blinking, which can exacerbate some conditions.

People with epilepsy or other seizure disorders, unexplained seizures, migraines, light sensitivity, or recent concussions should generally be excluded. This is particularly important for sessions using wearable tech like goggles, since the participant cannot look away from the stimulus in goggles as easily as they might look away from stimuli on an external screen.

Researchers should have a plan for responding to seizures or other serious problems. Response plans are study-specific, but may include elements such as training personnel to recognize signs of medical emergencies and call emergency services, having medically trained personnel present for XR sessions, etc. One example of a general seizure response plan is: *researchers will remain calm; the subject will be helped to the floor and the area cleared; emergency medical personnel will be contacted via 911; nothing will be placed in the subject's mouth; one researcher will remain with the subject while the other meets medical personnel.*

Prolonged effects and long-term effects

Symptoms of simulator sickness may last for several hours after exposure. This should be included in the discussion of risks in the protocol and consent document.

Potential long-term effects of XR on vision development are not well understood. Children should generally not be included in studies that involve long XR sessions or multiple XR sessions.

Contagion

Researchers should clean all equipment between participants, particularly in the case of equipment touching the face such as headsets and goggles.

Participants with a current or recent contagious condition that could be passed through contact with the face (respiratory infection, conjunctivitis, head lice, etc.) should be excluded or rescheduled.

Monitoring

Researchers should consider using a simulator sickness questionnaire to enable ongoing monitoring of risk prevalence and severity. This may be required for non-exempt research if appropriate to ensure the safety of the participants. If monitoring indicates the risks are more frequent or severe than indicated in the protocol and/or consent, this information must be promptly reported to the IRB.

Confidentiality

If a device records or processes any information, the protocol form should clearly explain how this data will be recorded and transferred. If third-party servers are involved, this must be clearly explained on the consent as well.

References

Ohio State University

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Laessoe, U. et al., 2023. "Motion sickness and cybersickness – Sensory mismatch."

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