Human Subjects Research with AR/VR

Using Augmented Reality (AR) and Virtual Reality (VR)

This guidance is intended to aid researchers in developing research protocols involving human subjects and the use of Augmented Reality (AR) and Virtual Reality (VR). Along with this guidance, please review the NC State IRB guidance for Images and Recordings (Word document), Benign Behavioral Interventions (Word document), Use of Applications and Software (Google document), and NC State University's IRB's Exemption Request Unit Standard (Word document).

Augmented Reality (AR) uses technology that adds to a user's real-world environment and generates images and displays them for users on top of their surroundings. These images can be experienced through multiple devices, but a headset to eliminate the user's environment secured to the user's head is not required. Augmented reality as a concept is a digitally enhanced version of the natural world—hence the descriptor "augmented reality." AR looks a lot like our world, but there are digitally modified enhancements within it (Gamma Scientific - opens in a new window)

Virtual Reality (VR) is a technology that allows us to see universes outside of our own. VR displays (opens in a new window) project high-resolution, computer-generated images for viewers to enjoy and do require a head mounted display (HMD) or headset to eliminate the user's surroundings and immerse them into the developed virtual reality. These images are enhanced with digital stimuli like sound, color, and luminance. VR can project images that don't necessarily resemble the real world. VR is created by tracking users' natural movements (such as head rotation, arm movement, or walking) and rendering a digital environment in response to these movements. Unlike augmented reality (AR), VR is intended to immerse users in a virtual space and replace cues from the real world with digital ones. Note that many inexperienced researchers use the label "VR" when they are not employing VR; they are using desktop monitors with 3D virtual worlds or video games (The Ohio State University IRB - opens in a new window) and Gamma Scientific - opens in a new window).

The difference between AR and VR (Gamma Scientific - opens in a new window)

- VR requires headsets; AR experiences don't necessarily need them.
- VR creates environments; AR modifies the real-world.
- VR doesn't require as much bandwidth as AR to operate.
- AR enhances real and virtual worlds; VR can only replace them with a fictional reality.

AR Risk Categories and Mitigation Strategies

- Data Privacy
    - AR technology collects data about their users and the people viewing the users by capturing the existing world's environment, analyze the scene, and then manipulating it through filters and additional overlays of information to augment the reality presented to the subject. The data captured can include intimate biometrics, such as:
        - Facial expressions

    - Speech
    - Retina patterns
    - What individual people in the AR environment are seeing and/or hearing

- Risk mitigation strategies can include:
    - Have subjects use NC State University managed devices when AR technology is employed - this is preferred practice
    - If subjects will be using a personal device to access/use AR technology for research purposes which increases privacy and data protection risks:
        - Have the subject review the privacy policy(ies) of the AR platforms to be used
        - Provide the subjects with an information sheet that covers:
            - How to download the platform including proper settings for setup
            - How to use the platform
            - How to securely remove the platform
            - Information about what the platform accesses on the personal device (folders, camera, photos, GPS, etc)
            - Information about what data is recorded about the individual via the application, shared with a third party app, and what data is used as research data
- Physical risks
    - While using AR and walking, subjects are more likely to not look ahead and identify hazards to be avoided making physical injury more likely
    - Risk mitigation strategies can include:
        - Controlled research environment or walking path that removes all tripping hazards
        - Use of harness if tripping is likely, such as the walking path itself, the AR environment, the research subject's gait, etc.
        - Safety discussion with subject prior to donning AR
        - Advance planning by research team for what to do if a subject trips/falls during the research activities

VR Risks Categories and Mitigation Strategies

- Physical risks
    - Physical risks are contingent on the equipment used, the content and interaction(s) the subject has in the VR environment, the length of time the subject spends in the VR environment, and individual differences (temporary states and ongoing conditions). Some of the most common physical risks for the type of research that NC State University IRB office sees with VR research is:
        - Cybersickness (headache, feeling dizzy or lightheaded, sudden drowsiness or fatigue, vision issues, nausea, or vomiting).
        - 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
    - Risk mitigation strategies can include:
        - Screening and eligibility criteria
            - Exclusion of pre-existing conditions and states that may increase the likelihood of VR side effects, such as a history of:
                - motion sickness or nausea
                - migraines or headaches
                - balance/coordination issues
                - dizziness
                - epilepsy
                - any neurological conditions where visual stimuli may trigger seizures or other issues
                - recent concussions where their doctor has not approved them for these types of activities.
            - Exclusion of persons with temporary conditions that will impair data collection in the VR environment, such as:
                - active alcohol or illicit drug use
                - hangover
                - health contagions (e.g., pinkeye, head lice, COVID-19, RSV, or flu)
            - Exclusion of persons sensitive to the content of the VR environment (e.g., workplace bias, sexual harassment, gun violence, racial violence, car accidents, horror or thriller stimuli, etc.)
            - Exclusion of the following populations from VR research protocols only if data collection would not be practicable otherwise:
                - deaf or hard-of-hearing individuals
                - low or no-vision individuals
                - physical ability
            - Before VR immersion, every participant should be prescreened for long-term and short-term conditions and excluded as appropriate (before being onsite and once onsite).
        - Data Collection Space Preparations
            - The area should always be cleared of hazards and obstacles that could harm participants during VR immersion (e.g., tripping hazards such as wires or rugs)
            - Tile floors should be kept dry
            - Wired headsets can present tripping hazards; wireless headsets mean there is one less constraint keeping participants from running into a wall
            - Researchers should know where the nearest restroom is and be prepared to accompany the participant if needed
            - Research spaces should be equipped with a lined trash can or emesis bags in case of vomiting

- Research spaces should keep ginger ale or saltines on hand to settle upset stomachs.
- Appropriate materials should be on hand to clean reusable equipment to minimize the possibility of contagions

- Participant Monitoring
  - Immediately before immersion participants should be reminded that they can stop any time and should tell the researcher immediately if they are feeling unwell.
  - During immersion, the researcher should conduct welfare checks on participants and schedule breaks for longer periods of immersion. Keep in mind 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.
  - During immersion one researcher should always be watching and monitoring the participant. Sufficient precautions should be taken to ensure they 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.
  - If the participant reports any symptoms, the researcher should have the participant take a break from or terminate immersion.
  - After immersion, the researcher should ensure the participant is not feeling any side effects. If they are, researchers should render care and monitor the participant as needed.
  - Any treatment 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.
    - If participants indicate higher potential for cybersickness in their pre screenings, these checks may need to be earlier or more frequent during immersion.
    - Keep in mind some people may be so engaged in the experience that they do not recognize the onset of cybersickness before it’s too late.
  - Optimally a check would be administered by having the participant stop, sit down if they are not seated, and close their eyes to promote greater bodily awareness. At the very least, have the participant be still. Then administer a verbal check such as: “We’re going to pause here for a minute. How are you feeling? Are you getting a headache or feeling dizzy, drowsy, or nauseated?”

- Others, such as children or decisionally-impaired adults, may not recognize the bodily onset of cybersickness. Different approaches may be necessary depending on the age and background of the children. For example, you may need to ask them to focus more specifically on a part of their body. “How does your head feel? Does it hurt? Do you feel dizzy?” “How does your tummy feel? Does it feel OK or are you feeling yucky?” “Do you feel funny?”
- If participants are feeling unwell, one of two courses of action should be taken.
    - In most cases, the treatment should be terminated by the researcher immediately. Termination is always recommended for children or decisionally-impaired adult participants.
    - For neurotypical adult participants, researchers should ask them if they wish to continue or if they wish to stop the VR experience. If the subject wishes to continue, a break is advised until their symptoms resolve. When the subject is immersed back in VR, 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 experimenter.
- After VR immersion researchers should ensure that participants are not experiencing any side effects.
    - At the very least, researchers should administer a verbal check following immersion. “Are you feeling okay after the VR experience? Are you experiencing a headache, dizziness, nausea, vision problems, or sudden fatigue?”
    - 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 head down.
        - If they are experiencing nausea or an upset stomach, have them sit close to the trash can or offer an emesis bag. You may wish to offer them saltines or ginger ale.
        - Inform them that you would like them to stay until their symptoms subside and offer them a comfortable place to wait. Of course, you cannot force them to stay; if they wish to leave, express your concerns but allow them to leave.
        - If symptoms are severe enough, follow lab emergency procedures for calling 911
- Psychological Risks include:

    - These risks are directly associated with the content of the AR/VR experience. If the content addresses issues of violence, bullying, harassment, discrimination, and other difficult topics.
    - If these topics are a part of the AR/VR experience then appropriate screening and exclusion criteria must be put into place.
    - If these topics are a part of the AR/VR experience, then the topics must be noted in the informed consent form with “ratings” or descriptions so the participant understands the content to which they will be exposed.

Eligible Review/Approval Categories

- Some AR/VR studies are eligible for exemption (Word document) under the federal regulations or under NC State University’s IRB’s FLEX policy for unfunded/never funded research
- Some AR/AR studies require review at the mid-level review (also called expedited review) under expedited categories 4, 6, or 7 (opens in a new window).
- Some AR/AR studies require review at the full board level. This is rare but occurs when the content is considered more than minimal risk or when there are other procedures in the same protocol that require full board review and approval.
- Participant populations and other research procedures will affect review level.

Supporting Materials To Upload and Submit with an IRB Application using AR/VR

In addition to proof of human subjects training completion, recruitment materials for non-exempt studies, and informed consent materials, researchers should also submit:

- Screening materials (if being used)
    - Pre-screening before a subject is on-site
    - On-site screening
- Device information sheet (if AR/VR will be used on subject’s personal device)
- AR/VR information
    - Device usage information
        - What device(s) will be used for the AR/VR
        - Where will the participants use the AR/VR device (controlled lab? elsewhere?)
        - What is the space where the research procedures will take place like?
        - How will subjects interact with the AR/VR: wear a headset? projection based?
        - Will people be walking around a space or seated as they use the AR/VR?
        - Will other equipment be incorporated into the AR/VR system (e.g., controllers, backpacks, sensors/trackers, wires, etc.)?
        - If the participant breaks the device, do they have to pay for it?
        - How are the device(s) cleaned before/after use?
    - User experience information
        - Content overview
        - Full scripts
        - Screenshots

- What data the AR/VR device is collecting about the participant, for example:
    - Eye scanning
    - Movement sensors
    - Demographics
    - Location of subject
    - Brain-computer interface data (BCI) etc.