Immersive Technologies and AI Generate Novel Challenges to Human Subjects' Protections Protocols

Brain and Memory Care Lab

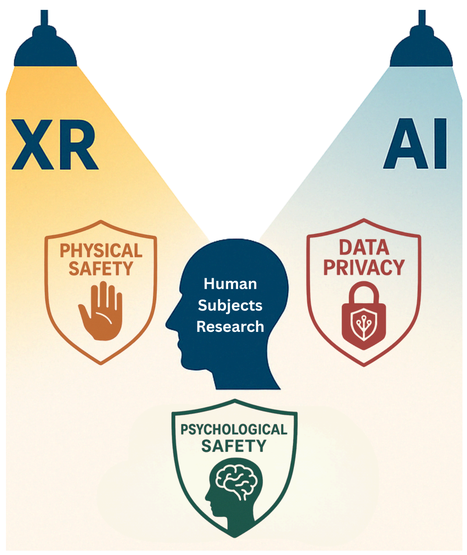
Rationale

As immersive technologies and AI become integrated into research, traditional IRB frameworks struggle to address the full scope of ethical and technical risks. These technologies introduce novel challenges in participant safety, data management, and informed consent.

Existing protocols do not adequately cover risks such as:

- Re-identification via motion data
- Psychological harm from AI-generated VR stimuli
- Neurological impact from non-invasive haptics like TMS

Without updated protections, research participants may face unintended harm and data privacy violations. This project aims to fill that gap with structured risk assessment tools.



Approach

A structured workshop involving over 100 IRB compliance officers was held during the 2024 PRIM&R Conference. Participants reviewed three immersive technology case studies covering:

1. **Biodata**: Psychological safety in VR using AI-driven biofeedback
2. **Haptics**: Physical safety risks of non-invasive brain stimulation
3. **Motion Tracking:** Privacy risks from XR motion data

Each group moved through four analytical stages:

1. Open Inquiry
2. Technical Analysis
3. Risk Assessment
4. Mitigation Strategy

Case Studies

Biodata

VR biofeedback study training users to manage stress via breathing/HR regulation.

Key Issues:

- Incomplete consent for VR stress
- Inadequate mental health screening
- Misalignment between subjective & physiological stress

Risks & Mitigation:

- Psychological distress → Add VR demo, gradual intensity
- Sensitive biodata → Strengthen anonymization

No clear withdrawal → Use safe words

Haptics

Brain stimulation via TMS paired with VR to simulate virtual touch.

Key Issues:

- Unclear long-term neuro impact
- Minimal medical oversight
- Lack in safety protocols
- Inadequate participant screening

Risks & Mitigation:

- Neurological risks → Biomedical review, EEG tracking
- Limited training → Interdisciplinary team & certifications
- Consent gaps → Clarify risks of TMS + VR

Motion Tracking

Motion data collected during XR tasks to study cognitive load and test re-ID via AI.

Key Issues:

- High re-ID risk from body data
- Data ownership (commercial devices)
- Weak anonymization

Risks & Mitigation:

- Privacy breach → Treat motion data as sensitive
- AI inference → Add data noise, restrict future use
- Consent issues → Use itemized, plain-language permissions

3C's of Ethical Consent in XR

Context

Inform how data is used
Explain participant experience

Control

Mechanisms to protect participants

Choice

Risk-based and informed decisions

Risk and Mitigation Categories

Request Case Studies

Email Dr. Scott at jscott1@scu.edu

Are IRBs Ready for XR + AI?

Many IRB officers noted that current review processes:

- Lack immersive technology literacy
- Struggle with adaptive environments
- Underestimate layered risks
- Fall short on dynamic consent models
- Rely on outdated risk frameworks not suited for generative AI
- Lack guidance on body data re-identification
- Overlook commercial data user agreements