Application to the IIIT Hyderabad - Institute Review Board (IRB) For Ethics Approval of a Research Project

Basic Information		
1. Title of the Project	Effects of Interaction Fidelity on task performance in VR	
2. Name of the Applicant	Ashutosh Rudrabhatla	
3. Principal Investigator	Ashutosh Rudrabhatla	
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4. Co-Investigator	Aaditya Vardhan Narain	
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5. Application Date	7 October, 2024	
6. Duration of the Project	~35 Days (Oct 15 to Nov 20)	

Outline of Proposed Research

1. Background:

(In 100-200 words, background about the study, rationale and need for the study. Provide relevant references)

- Previous Work:
- (Lopez et. al, 2016) looked at comparison between VR HMD and Desktop environments in spatial learning tasks. Here, both visual and interaction fidelity were varied, and it was found that HMD condition was better (high interaction and visual fidelity).

- (Srivastava et. al, 2019) tried to fix the interaction fidelity and vary just the display fidelity. It found that HMD devices were slightly worse than Desktop environments (Display fidelity does not have a significant effect).
- We are trying to explore what happens when **only interaction fidelity is varied**, **keeping display fidelity the same**.
- To vary interaction fidelity, we **use different methods of locomotion** in a VR environment: Joystick vs Walking.

• Rationale and need for the study:

- 1. VR helps us create stimuli which are more ecologically valid, due to heightened sense of presence.
- 2. This can help us understand human cognition and behavior, but also train them (for example, in the military).
- 3. However, a more ecologically valid setting might not produce more ecologically valid responses. Our study can be a small but significant step towards understanding this aspect of VR Technology.

2. Aims and Objectives:

- To study the effect of **Interaction Fidelity** (here, method of locomotion) on performance of a **spatial learning task** in a VR environment.
- To study the effect of method of locomotion on other factors such as sense of presence and simulator sickness while performing a spatial learning task in a VR environment.

3. Hypothesis (as applicable):

- **Ha:** There is an effect of interaction fidelity on spatial learning tasks in VR HMD environments.
- Ho: There is no effect of interaction fidelity on spatial learning tasks in VR HMD environments.

4. Research category (Quantitative, Qualitative, Mixed, Applied, Basic etc) and Research/Study Design:

• This research aims to be a Quantitative approach, and the experiment design is between-group/unrelated design.

5. Methodology:

- The experiment is divided into *four phases*, with each phase expected to take around 15 to 30 minutes.
- <u>Phase 1</u>: Participant fills out an initial demographic questionnaire and consent form. [2-5 minutes].
- <u>Phase 2</u>: Participant placed in a Virtual Environment via an HMD; familiarized with the Virtual Environment and the task. [5-10 minutes]

- <u>Phase 3</u>: Participant performs the task, which is divided into two parts, memory phase and recall phase, with a fixed gap between them.[5-10 minutes]
- <u>Phase 4</u>: Participant required to fill two questionnaires in the end- VRISE and presence questionnaire. [5-10 minutes]

Study Area:

• Virtual Reality, Presence, Spatial Memory, Simulator Sickness.

Institutions of collaboration:

• No other institutions are collaborating on this experiment.

Study/Performance Sites:

• Software Engineering Research Center (SERC, T-Hub 5th Floor)

Target Respondents & Age group + Gender (clearly mention vulnerability):

- Target Respondents: College Students, (not gender-specific).
- Age Group: 18-25 years old.

Sampling process and sample size:

- Convenience Sampling followed by Randomized distribution into different experimental conditions.
- Students will be asked to participate voluntarily.
- Sample Size: 55-60 participants.

Risks, Benefits, Safety & Other Controls

- 1. What are the potential risks involved? State any potential or known hazards of the procedure listed in the methodology and how does the investigator intend to overcome this aspect.
 - Simulator Sickness: This refers to feelings of nausea, dizziness, headache etc. associated with prolonged VR usage.
 - Steps taken to ensure this doesn't happen:
 - a) Keeping the experimental phase short (maximum of 20 minutes, with breaks every 5 minutes).
 - b) Alerting the participants beforehand of this possibility and urging them to immediately raise any issues they face during the experiment.
 - c) Keeping the experiment in ambient conditions (Air-Conditioned Room).
 - Further tweaks to experiment design and procedures are planned during the initial testing phase, after getting feedback from participants.
- 2. Does this study involve ionizing radiation, hazardous substances, invasive procedures (including radiological imaging, venipuncture, or any other invasive procedures or intimate physical examination)? If yes, please justify
 - No, our design does not include any such procedures.

- 3. What are the compensations for Unexpected Risks?
 - Not Applicable.
- 4. If there are any novel interventions to be used in the study which is not the medically-accepted 'treatment of choice' within the local context, explain why a novel intervention is being tested, and what arrangements will be made to switch subjects over to the 'treatment of choice' if the experimental intervention is not effective.
 - Not applicable to this experiment.
- 5. What are the potential benefits to the subjects?
 - Exposure to Virtual Reality HMD devices (Meta Quest).
 - Compensation for participation in the experiment.
- 6. What are the potential severe adverse events (SAE) anticipated in this proposed study? What will be the likelihood of occurrence and strategies to reduce the occurrence?
 - There is a very small possibility of the SAEs of seizures and epilepsy.
 - We shall not move forward with any participant that has reported any of these symptoms in the past (to be asked before the participant wears the VR HMD device).
- 7. Please state whether subjects will have to bear any expenses related to medicines or investigations or travel or if they have to forego their work/pay in relation to participation or any other costs in relation to the study. State how the expenses would be met.
 - No such Expenses are expected on the side of the participants.
- 8. Will the subjects receive financial benefit / other material benefit as a result of participation in this study? Please specify.
 - Participants shall receive a small compensation (A treat at one of the canteens, or coffee) after the completion of the experiment.
 - Specific rewards have not been decided yet.

Consent, Confidentiality

- 1. How will informed consent be obtained and by whom? (Mandatorily provide a copy of the participant information sheet and consent form)
- Every participant will be made to fill an informed consent form at the beginning of the experiment.
- 2. Is allocation involved in selection of participants i.e. will participants know they are part of the research? Yes / No, If yes (allocation random/nonrandom/selected etc), explain how and why?
- Yes, participants will know that they are part of the research. However, allocation of participants to one of the two conditions will be randomized, and participants will not be informed that the other condition exists.
- 3. What procedures will ensure the confidentiality of participants? Will the identifiable information be removed? How will data be stored and for how long?
- No identifiable information for any of the participants is acquired or stored.

- The data will be stored on the cloud with restricted access. It will be stored until the end of the experiment, so that proper analysis can be done.
- 4. How will results be disseminated? What information will be fed back to the subjects and/or participating organization?
- The results will be reported at the end of the project duration in the form of a presentation and report, as part of the BRED course.
- The participants will not get any feedback regarding the results of the study.

Conflict of Interest/Sponsored/Proprietary Interest

- 1. Please state any conflict of interest/sponsorship/proprietary interest is involved in the study and its team? (financial / non-financial) Provide supportive documents as annexures.
- The experiment is being conducted as part of the BRED course with it having 40% weightage overall. However, there is no conflict of interest present in the experiment.

Declaration by the Principal Investigator

I certify that the information provided by me is complete and correct. I understand that as principal Investigator, I will take full responsibility for the protection of rights and welfare of all participants/study subjects including the conduct of study and ethical performance of the project. I agree to comply will all rules and regulations of IRB and IIIT Hyderabad for the conduct of the study / trial.

I hereby declare that:

- Qualified personnel according to IRB guidelines will conduct the study.
- No change will be made in the protocol or consent form until approved by the IRB.
- Legally effective informed consent will be taken from Human subjects as applicable.
- Adverse events will be reported to IRB as per ICH GCP/DCGI Adverse event reporting policy.
- I further certify that the proposed research is not currently being conducted and will not begin until IRB approval has been obtained.

Sl.No	Research Team	Signature	Date
1	Principal Investigator		

2	Co-Investigator	

NOTE: All proposals submitted will be subjected to technical review or specialty expert sub-committee whetting and those comments will have to be clarified appropriately before it is taken up for consideration of the IRB.

Details of Exemption/Expedited from Full Review

- 1. Are you requesting for:
 - a) Exemption from full review No
 - b) Expedited Review No
- 2. Under which category are you claiming this? Please highlight in the list by encircling. A. Exemption from Full Review of IRB
- i. Research on data in the public domain/ systematic reviews or meta-analyses;
- ii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person;
- iii. Quality control and quality assurance audits in the institution;
- iv. Comparison among instructional techniques, curricula, or classroom management methods;
- v. Consumer acceptance studies related to taste and food quality;
- vi. Public health programs by government agencies.

B. Expedited review from IRB

- i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and of left-over clinical samples.
- ii. Involves clinical documentation materials that are non-identifiable (data, documents, records).
- iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)).
- iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposal.
- v. Minor deviation from originally approved research causing no risk or minimal risk.
- vi. Progress/annual report where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. vii. For multi-centre research where a designated EC has approved the proposal, a participating
- EC may review participating centre specific information and modifications in the study proposal through full committee meeting/expedited review depending on the importance of local consent related issues involved specific to the centre.
- viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017 -https://main.icmr.nic.in/sites/default/files/guidelines/ICMR Ethical Guidelines 2017.pdf)

3.	Justification for claim in Point 2 above:

Human Research during COVID-19 pandemic times

- 1. Will you be carrying out this Research during Covid-19 Pandemic times? No.
- 2. If Yes highlight the steps of how you will take to ensure health/safety/wellbeing/protection of stakeholders of this research.