REB AMENDMENT COVER LETTER (#2023-6992)

Project Title: Haptics and spatial-audio based navigational approach in VR for the visually impaired

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LAY SUMMARY

2.1.1 It says in the text that this is a pilot study, but the box for 'fully developed study' is checked. Please clarify.

(Section: 2.1.1, Page:4)

We have removed the confusing wording and clarified that this is a fully developed study.

2.3 RECRUITMENT

2.3.1 Please justify why participants who are pregnant or elderly are excluded. If there are concerns with physical mobility issues, for example, then it should be those specific issues that result in exclusion, not a particular state of being. Additionally, what does it mean to be 'elderly'? This term is open to individual interpretation.

(Section: 2.3.1, Page:5)

We have removed this ambiguous exclusion criteria and modified the third bullet point of the exclusion criteria to make collective sense as:

- Individuals who have a previous neurological illness, heart condition, or any medical condition that significantly restricts full-body mobility, inhibiting them from standing and walking comfortably.

2.4 INFORMED CONSENT PROCESS

2.4.2 Why would the data not be able to be removed after they complete the study? Feasibly, the data could be removed before it is included in the analysis.

(Section: 2.4.2, Page:6)

We have updated the data removal process as follows:

If participants request the removal of their user-specific data, it will be completely deleted from all mediums. This request can only be considered within the first two weeks from the date of the user study, as after that point, the data will have already been used in the analysis phase.

2.5 METHODS AND ANALYSIS

2.5.1 C) The questionnaire information is unclear. How many questionnaires will the participants be asked to complete?

(Section: 2.5.1 C, Page:8-9)

We have clarified that the participants will be asked to complete a total of four questionnaires. One will be a demographic questionnaire, two will be NASA-TLX for workload assessment, and one will be a usability survey.

2.5.3 Specify the pro-rating schedule and include this information here and in the consent form.

(Section: 2.5.3, Page:10)
The pro-rated compensation will be as follows:

Participation level	Study hours invested (minutes)	Compensation Amount (CA$)
Baseline participation	0-44	10
Partial participation	45-59	15
Completed user study	60-90	20

2.6 PRIVACY AND CONFIDENTIALITY
2.6.1 B) Please specify the level of identifiability of the study data, as requested. Review the link to the TCPS2 for information about identifiability.

(Section: 2.6.1 B, Page:10)
The level of identifiability of the study data is "de-identified/coded."

Point 4: Please provide specific information about the secure storage of video data. Where precisely will it be held?

(Section: 2.6.1 B, Page:11)
After each user study session, the video recording from the camera's SD card is transferred and uploaded to a private folder hosted on Dalhousie University's institutional cloud storage platform - Microsoft SharePoint. This ensures that the camera's SD card doesn't contain any participant information whatsoever.

The lead researcher will maintain this SharePoint folder, and access to it will be restricted to only members of the research team. The access is maintained by providing explicit permission to access, view, and edit data within the folder. Moreover, since it will be on institutional SharePoint, even members of the research team with permission to access it will require authorized credentials to sign in, which provides an added layer of security.

2.6.1 D) Will there be a key-code? If so, explain how it will be kept securely, yet separate from the data.

(Section: 2.6.1 D, Page:11)
A physical key code will be stored separately from any de-identified data inside a locked file cabinet in the lead researcher's office space, which has restricted access.

How will data be shared/transferred between team members?

(Section: 2.6.1 D, Page:11)
Storing the data on SharePoint will serve as a centralized and secure platform for the research team to access and modify the data. This approach eliminates the need for physical data transfer between team members through any online or offline medium.

Where will the paper consent forms be stored?

(Section: 2.6.1 D, Page:11)
Following each user study session, the paper consent forms will be stored separately from any de-identified data inside a locked file cabinet in the lead researcher's office space with restricted access.

2.6.2 Please specify the length of time data will be stored. When will data be eventually destroyed?

(Section: 2.6.2, Page:12)
The data will be stored for a maximum of 2 years, after which it will be eventually destroyed from all mediums.

Please clarify why videos are being kept. The application reads as though only the interviews are recorded, but after transcription, why will videos need to be kept?

(Section: 2.5.1 and 2.5.2, Page:9)
Only the video recordings of the participants performing the tasks will be stored; however, our initial plan of video recording interviews has now been revised only to record audio of the interview session using a microphone. These audio recordings, once transcribed during the analysis phase, can then be deleted from the storage medium. In any scenario, the video data, as well as the audio data, is de-identified/coded.

RECRUITMENT MATERIAL
Not all exclusions are listed. Careful revision is needed to align with the study inclusion/exclusion criteria as listed in the application form.

The revised REB application includes the required changes *(Appendix B, Page 21).*

CONSENT FORM
State that Dr. Malloch is also the supervisor.

Please include a phone number for someone on the research team.

Please revise the consent form to remove jargon and explain the study purpose in lay language. The REB suggests consent forms be written at a grade 8 level at most.

Ensure the full list of eligibility criteria is included.

Under what you will be asked to do, it seems as if participants do the study tasks and are then asked to consent to participate ("you continue the experiment, you will be given a consent form to read and sign"). Revise for clarity, as participants need to consent before participating.

Include the pro-rated payment schedule.

It is confusing to say both of the following: "Electronic records will be password-protected and securely stored on an encrypted external hard drive, kept in a locked filing cabinet within the researcher's office." And "The anonymous data collected in this study will be stored temporarily on Microsoft OneDrive and then moved to a private SharePoint list, the institutional cloud storage platform of Dalhousie University." Please provide clarity around where the data will be stored. (Further, where will non-anonymous data be stored?)

The "stop participating" section reads as if the study is only a survey; please revise.

The information provided in this same section about removing data from the study does not match what is in the application and speaks only to the survey component. Please revise.

The consent form lacks an actual consent statement. Please include an express statement of consent for participants to sign. In this format it is simply a signature element at the end of an information sheet.

The revised REB application includes the required changes (Appendix C, *Page:22-25).*

RESEARCH INSTRUMENTS

There are three questionnaires included as appendices, but it is not clear when each will be used. Please clarify in section 2.5.1.

The revised REB application includes the required changes *(Section 2.5.1 B and 2.5.1 C, Page 9).*