Participant Information Sheet

This information sheet is intended for participants and/or their guardians involved in the research study conducted by Electronics and Telecommunication Engineering students from the University of Moratuwa.

Project: Development of an Assistive Care BCI for a Locked-In Pediatric Patient

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1.1 Introduction

This study aims to develop a simple brain-computer interface (BCI) for a 6-year-old boy with locked-in syndrome. The system will use non-invasive EEG (electroencephalography) signals to allow the child to interact with an application, providing opportunities for cognitive stimulation and engagement despite severe physical limitations.

1.2 Type of Research Intervention

The study involves placing a non-invasive EEG headset on the child's head to record brain signals. These signals will be processed in real-time and mapped to simple actions (e.g., balloon-popping).

1.3 Participant Selection

This study includes one paediatric participant (6 years old) with locked-in syndrome. The participant has been identified through the supervising physician and will be under parental supervision at all times.

1.4 Voluntary Participation

Participation in this study is entirely voluntary. Parents may choose to withdraw their child from the study at any time without any consequences or impact on medical care.

1.5 Procedure

During the study:

- Parents will be informed about the study in detail, and written consent will be obtained.
- A non-invasive EEG headset will be placed on the child's head.
- The child will be asked to focus on simple visual or auditory cues while playing a computer game designed for engagement.
- Sessions will last 15–30 minutes and will take place under parental supervision.
- EEG signals and task performance data will be securely recorded.

1.6 Duration

Each recording session will last approximately 15–30 minutes, with breaks as needed to avoid fatigue. The study period will run from **November 2025 to June 2026**.

1.7 Side Effects

There are no known harmful side effects of wearing a non-invasive EEG headset. The child may experience mild discomfort or restlessness during the session, but this will be closely monitored.

The EEG system used is based on standard electrodes and circuit designs that were validated by a previous group, which already received ethical clearance.

1.8 Risks, Hazards, and Discomforts

- **Non-Invasive Nature**: No invasive procedures are involved.
- **Mild Fatigue**: Sessions are kept short with rest breaks to prevent strain.

- **Psychological Well-being**: The games are designed to be engaging, child-friendly, and non-stressful.
- **Electrical Safety**: The EEG system used in this study is custom-built but designed with standard electrode principles and circuit designs. It follows the validated hardware developed by a previous group that already received ethical clearance.

1.9 Potential Benefits

- **To the participant:** Provides cognitive stimulation, fun engagement, and a novel way to interact with a computer game despite physical limitations.
- **To humanity generally:** Contributes to the development of assistive technologies for children with severe disabilities.

1.10 Reimbursements

No financial or material compensation will be provided for participation.

1.11 Confidentiality

All collected data (EEG recordings, game performance) will be kept strictly confidential. Personal identifiers will be removed, and the participant's identity will be anonymized. Data will be securely stored on a password-protected system and in the University repository.

1.12 Sharing the Results

The results may be published in academic journals, presented at conferences, or included in student theses. All publications will use anonymized data only. Parents may request access to results related to their child.

1.13 Right to Refuse or Withdraw

Participation is voluntary. Parents may withdraw their child at any point, without providing a reason, and this will not affect any future care or support.

1.14 Clarifications

If you have any questions or need more information, please contact:

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