University of Moratuwa

ETHICS APPLICATION - FORM B
FOR ABOVE-LOW RISK RESEARCH

In order to find out whether you do require to submit the human ethics application form B please read the **general guidelines page**.

Incomplete or inadequate applications or applications prepared on out-dated application forms will not be considered by the ethics committee.

Submission Details:

University Ethics applications: The completed application should be submitted via e-mail to **ar-fgs@uom.lk** in the form of a **pdf document** either scanned with signature(s) or signed electronically of the application plus all attached documents, **also in pdf format**.

University of Moratuwa respects the privacy of your personal information. We collect personal information about you on this form to review and process your human research ethics application with respect to the University Ethics Committee's responsibilities. For this purpose, we will use this information and typically disclose it to funding or regulatory bodies pertaining to the research under consideration. Information provided in this application will be treated confidentially.

YOU ARE REMINDED THAT NO RESEARCH STUDY (DATA COLLECTION OR ANALYSIS OF SECONDARY DATA) SHOULD BE CONDUCTED WITHOUT THE PRIOR ERC APPROVAL

University of Moratuwa

ETHICS APPLICATION - FORM B
FOR ABOVE LOW- RISK RESEARCH

1. Project Title:	*Development of a Brain-Computer Interface (BCI) for a Locked-In Paediatric Patient*
2. Chief Investigator / Supervisor: (academic staff members only)	Name: *Dr. Joshua Pranjeevan Kulasingham* Position: *Senior Lecturer* Department: *Department of Electronic and Telecommunication Engineering*
Student (if appropriate)	Name: *Chathura Nirmal Weerasinghe,* *Dinujaya Wijewikrama,* *Jayamadu Gammune,* *Risini Dinara Kumarasinghe* Course of Study: *Final Year Undergraduate Project (B.Sc. Eng.)* *Department: Department of Electronic and Telecommunication Engineering*
3. Project Duration: (subject to annual review)	Project commences: *October 2025* Project concludes: *July 2026*

4 PROJECT

(a) **Please provide a two sentence lay summary of the project** (50 words or less. Please ensure the description is in plain language to prevent the return of the application)

This project will develop a simple brain-computer interface (BCI) application for a 6-year-old boy with locked-in syndrome. Using non-invasive electroencephalography (EEG) signals recorded through custom EEG circuits developed by a previous group (Ethics Declaration Number: ERN/2025/001), the system enables interaction with games, communication, and learning activities despite severe physical limitations.

(b) Please attach your **complete research proposal**

5 PERIOD DURING WHICH ACTIVITIES REQUIRING ETHICS APPROVAL WILL OCCUR

From: *November 2025* **To:** *June 2026*

Indicate what areas in the project require ERC approval:

- *Data collection from the pediatric participant using EEG recordings.*
- *Interaction testing of the BCI-controlled game.*

6 FUNDING (tick whichever is applicable)

(a) [✓] Will not be sought
[ ] Will be sought
[ ] Has been sought
[ ]Has been obtained

Name of funding agency:

Project title under which funding sought:

Please attach a copy of the funding application.

(b) Will participants be informed of funding source(s)?

[ ] No (please explain)

[ ] Yes (provide details)

[✓] Not applicable

7 DESCRIPTION OF PROJECT

Aims*:*
To design and implement a non-invasive BCI-based interface to enhance engagement and interaction for a child with locked-in syndrome.

Participants:
One pediatric patient (6 years old) with locked-in syndrome, under parental supervision.

Brief Description:
The project will record EEG signals using a custom headset, decode brain activity using SSVEP (Steady State Visually Evoked Potentials)/P300 paradigms, and map responses to simple game controls (e.g., balloon-popping). It is planned to test motor imagery paradigms for more advanced controls in later phases.

Methods of Data Analysis*:*
Signals will be preprocessed (artifact removal, filtering), features extracted (frequency/Event-Related Potentials(ERP) detection), and classified using Python/MATLAB algorithms. Performance will be validated using example metrics such as classification accuracy, precision, recall, F1-score, and confusion matrices to assess reliability.

8 PARTICIPANT DETAILS

(a) **Number of Participants:** *1*

(b) Age Range*:* *6 years*

(c) Are there any criteria that will determine whether participants are included or excluded from the research?

[✓] No

[ ] Yes (provide details of all inclusion and exclusion criteria and explain why each criterion is important to the purpose of the research)

(d) Recruitment Method

Please state how names and contact details of potential participants will be obtained, from where they will be recruited, how they will be invited to participate, and who will approach potential participants to seek their participation.

Note: Where participants are recruited from schools, hospitals, prisons or other institutions, permission/approval from the institution or appropriate authority must be sought. See Question 11.

The participant is identified through the supervising physician (Prof. Jithangi Wanigasinghe). Parents will be approached, informed, and consent obtained.

(e) Compensation to Participants

[✓] Not applicable

[ ] Applicable (provide details if any financial or other reward or compensation will be offered to participants)

(f) Involvement of Special Groups

If the project involves groups requiring special permission (e.g. people such as children or the intellectually disabled who are in a dependent relationship requiring permission from a parent or guardian, describe the nature of the group(s), justify the inclusion of people from the group(s), and specify the procedures to be used to obtain permission, and complete Question 12. (Please note that <u>If participants are from a vulnerable group, their inclusion is justified only if the study cannot be done in any other group.)</u>

[ ] Not applicable

[✓] Applicable (provide details)

Child participant with disability. Inclusion is necessary since the system is designed for this clinical context. Parental consent will be obtained.

(g) Are any of the participants Motatuwa University students?

[✓] No

[ ] Yes (Please explain the steps taken by the investigators to ensure that the subject's participation is purely voluntary)

(h) Are any of the participants (other than Moratuwa University students) in a dependent relationship with any of the investigators (including those involved in recruiting, interviewing etc)?

[✓] No

[ ] Yes (Please explain the relationship and the steps taken by the investigators to ensure that the subject's participation is purely voluntary)

9 RESEARCH USING EXISTING DATA BASES

Not applicable.

If research involves access to existing data bases provided by an institution(s), please indicate:

(a) source(s) and number of records;

(b) whether data to be used will be de-identified, potentially identifiable (eg. coded), or identified; and

(c) whether permission has been granted by donors to use these data for research purposes.

(d) whether formal permission/clearance has been sought or obtained from the relevant institution(s) (see also Question 12 below).

10 LOCATION OF STUDY

Identify the location of the study, if other than Moratuwa University. If permission is required to use the location, indicate how permission will be obtained.

The study will be conducted at the participant's home under parental supervision. Permission will be obtained from parents and the physician.

11 EXTERNAL APPROVALS

If a project requires approval from other institutions, next of kin or guardian, or representative or authority in the case of special groups, copies of such approvals must be provided to the UERC at the time of application or be made available as soon as possible thereafter.

Please indicate as appropriate if formal clearance/permission has been sought or obtained.

(a) Institutional

Name(s) of institution/ethics committee/authority:

[ ] Yes, attached

[ ] Yes, to follow (estimate when likely to be obtained

[✓] No (please explain)

(b) Next of Kin (or representative or authority in the case of special groups)

[✓] Yes, attached

[ ] Yes, to follow (estimate when likely to be obtained):

[ ] No (please explain) *Not applicable.*

12 INFORMED CONSENT

(a) Indicate whether individual Information Statements/Information and Consent Forms will be used.

[✓] Yes (please provide copies).

[ ] Alternative method of obtaining consent will be used (please specify)

[ ] No (please explain)

(b) Will the Information Statement/Information and Consent Form (ICF) be translated into the participants' first language?
(Note: if there is an ICF it MUST be translated. If the Informed consent is not being obtained,

then the applicant has to make a strong justification.)

[✓] Yes (please provide copies of translations)

[ ] No (please explain)

(c) Will ALL participants have the capacity to give voluntary and informed consent?

Yes [ ] No [✓]

If No, who will be asked to provide consent?

[✓] Parent/guardian

[ ] Other - give details
(e.g. Normally a Legally Authorized Person as defined by Law)

How will consent be obtained?

[✓] Written consent form

[ ] Verbal - explain below how consent will be recorded
(Note: Verbal is not acceptable unless there is an extremely unusual circumstances such as illiteracy, physical disability or other limiting condition)

13 DESCRIPTION OF PROCEDURES

(a) **Describe in detail exactly what you will be asking of participants, and emphasise anything that may have adverse consequences.**

The EEG headset will be placed on the child's head for non-invasive while engaging in a task (e.g., playing a computer based game). Sessions will last 15–30 minutes, under parental supervision. There will be no invasive procedures.

(b) If questionnaire(s) (including those that are published or commercially available) will be used in the project, please attach a copy to this application. (Please provide the questioner in a language in which it is to be administered. If it is in a language other than English please provide a translation
Not applicable.

(c) If interviews or focus groups are to be held, please attach the interview guide or focus group guide.
Not applicable.

(d) Will any form of deception, concealment or covert observation be used?

[✓] Not applicable

[ ] Details of deception, concealment or covert observation, justification for deception, debriefing procedures and debriefing documentation for participants attached.

14 SAFETY

The following check list has been developed to help identify specific safety issues:

YES NO N/A	
[✓] [ ] [ ]	**(a) Will participants come into contact with any equipment or apparatus?**
[✓] [ ] [ ]	**(b) Will participants come into contact with any equipment connected to or powered by an electricity supply in any form?**
[ ] [✓] [ ]	**(c) If the response to (a) or (b) above is yes, is the equipment standard, unmodified or commonly used, such as a computer or tape recorder? If no, please proceed with the questions below.**
[ ] [✓] [ ]	**(d) Will any equipment be used in any way that is different to its intended use or to the manufacturer's instructions?**
[ ] [✓] [ ]	**(e) Will participants be exposed to electrical or magnetic stimulation or non-ionizing radiation of any kind?**
[ ] [✓] [ ]	**(f) Will participants be exposed to external irradiation of ionizing radiation or be administered any radionuclides**
[ ] [✓] [ ]	**(g) Will participants be exposed to noise levels exceeding a peak sound level of 140dB or an 8 hour sound level of 85 dB equivalent?**
[ ] [✓] [ ]	**(h) Will participants come into contact with or be required to operate or use plant or machinery?**

If the response to "Yes" is ticked, please provide full details of the equipment, venue and procedures to be used. Provide details of all safety and protective measures to be in place if needed, evidence that your equipment has passed relevant electrical or other safety assessments. In addition, research projects involving the use of ionising radiation require approval from a relevant Radiation Safety Body or Health Department). Please attach evidence that such approvals have been obtained or have been sought.

The details are given in the research proposal.

15 POTENTIAL BENEFITS

(a) **To the participant**

This study provides direct benefits to the participant by offering cognitive stimulation, engagement, and interactive experiences that would otherwise be unavailable. The system is designed to enhance quality of life by enabling communication, supporting learning activities, and reducing isolation. Unlike many research projects where the benefits are indirect, this study prioritizes the participant's immediate well-being and daily functioning.

(b) **To humanity generally**

The study contributes to the broader field of assistive technology by demonstrating the feasibility of pediatric brain-computer interface systems which is quiet rare in research studies. It advances knowledge in non-invasive BCI design, supports the development of inclusive technologies for children with severe physical limitations, and informs future research on accessible communication tools..

16 RECORDING AND SECURITY OF PROJECT DOCUMENTATION

(a) **How will data be recorded? (eg. written questionnaires, interview notes, photographs, audio/video recording, direct electronic data entry)**

EEG signals will be stored electronically; session notes will be maintained.

(b) Will confidentiality of results be maintained?

[✓] Yes (detail below)

Anonymized; personal identifiers removed.

[ ] No (please explain)

(c) Indicate how the security of project documentation will be maintained and specify the precise location of the storage place(s):

(normally 5 years for non clinical trial data and 15 years for clinical trial data following publication).

(i) **during the study**
Password-protected laptop, access restricted to investigators.

(ii) **following completion of the study**
Data stored securely in a university document management system (DMS) for 5 years.

(d) Will data (including samples) be preserved for possible future use <u>in another project</u>?

[ ] No

[✓] Yes (please explain the nature of the data to be preserved, when the data might be used in another project, how that data might be used, for what purpose it might be used, and who might be given access to the data for another project).
Data may be used by future research projects, and only authorized researchers will be given access, subject to ethics clearance.

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17 DISSEMINATION OF RESULTS

(a) Will participants be informed that results from the study may appear in publications, be included in a thesis or report, or be presented at conferences? (if relevant, this information should be included in the Information Sheet given to participants prior to obtaining informed consent).

[✓] Yes (give details)
Results may appear in publications, theses, or conference presentations.

[ ] No (please explain)

(b) Will participants be informed that results from the study will be available to them on request? (If relevant, this information should be included in the Information Sheet given to participants prior to obtaining informed consent).

[✓] Yes

[ ] No (please explain)

Will participants be informed that their personal data collected in the course of the research will be available to them on request? (if relevant, this information should be included in the Information Sheet given to participants prior to obtaining informed consent).

[✓] Yes

[ ] No (please explain)

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18 . Identify any other potential ethical issues not listed above-

Participant fatigue: Sessions will be short with breaks as needed.

Psychological well-being of the participant: Games will be designed to be engaging and non-stressful.

Involvement of a medically fragile child: Sessions will conducted under parental supervision

Electrical safety of custom EEG equipment: The EEG device is a custom-built system designed with standard electrodes and circuit designs validated via laboratory and human testing. It is battery-powered, low-voltage, and has already been used safely in a prior study (Ethics Declaration Number: ERN/2025/001).

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19. Investigators Working on Procedures that Involve humans:

By signing each investigator acknowledges that the information provided is true and they are aware of the procedures they are to perform.

Chief Investigator/ Principal Supervisor (University of Moratuwa academic staff only) Name: Dr. Pranjeevan Kulasingham Signature:    Date: 23/08/2025
Student/ Investigator 2 Name: Chathura Nirmal Weerasinghe - 210687X Signature:    Date: 25/08/2025

Student/ Investigator 3

Name: Jayamadu Gammune - 210179R

Signature: 

Date: 25/08/2025

Student/ Investigator 4

Name: Dinujaya Wijewickrama - 210728C

Signature: 

Date: 25/08/2025

Student/ Investigator 5

Name: Risini Dinara Kumarasinghe - 210321X

Signature: 

Date: 25/08/2025

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[ ] Clearance from a medical faculty not required

[ ] Clearance from the Faculty of Medicine, University of ..... has been obtained. Approval is attached herewith.

[ ] Clearance from the Faculty of Medicine, University of ……, if the research involves animals,..... has been obtained. Approval is attached herewith.

Ethics Approval Number: .....

Chairperson of UERC

.....	.....	.....
Name	Signature	Date

19 ATTACHMENT CHECKLIST

The following documents are attached (please tick where appropriate):

[✓] copy of the research proposal

[ ] copy of funding application (s)

[✓] evidence of permission to use places off-University

[✓] evidence of external approvals (Questions 11(a) and (b))

[✓] copy of the proposed Information Sheet(s)

[✓] copy of the proposed Consent Form(s)

[✓] copy of certified translations of Information Sheet(s) and Consent Form(s)

[ ] copy of questionnaire(s) and/or proposed interview/focus group outline

[ ] copy of relevant safety approvals