COMMITTEE FOR ETHICAL CLEARANCE (CEC)
FACULTY OF SCIENCE
UNIVERSITY OF PERADENIYA

Application For Ethics Review of Research Projects (*Please complete all relevant sections in consultation with your supervisor.)*

1. **Applicant Details** *(This section needs to be completed by the applicant)*

Name of Applicant	
Registration Number	
Official Address	
Contact Information **Phone Number(s):** **Email Address:**	

2. **Project Details**

Title of the Project:	
Duration of Study:	From: ___ / ___ / ____ To: ___ / ___ /
Place where the research will be carried out	
Collaborating institute or outside Institute	

3. **Research Framework**

Research Type	**Yes / No**
Questionnaire Only	
Sampling Involved	
Observational Study	
Involving Human Subjects	
Involving Animal Subjects	

3.1 Description of Human Involvement (if applicable**):**

3.2 Description of Animal Subjects (if applicable):

3.2 Descriptions of any other subjects (E.g., Genetically Modified Organisms, Plants, animals, and any relevant)

3.3. Consent Obtained: ☐ Yes ☐ No ☐ Not Required

Attach relevant consent forms or documentation.

Section 4 (Complete only the relevant parts and tables in this section)

PART A- (Animal Involved Research Works)

Please answer all the relevant questions clearly and concisely. Where applicable, provide relevant justifications, protocols, or references. Each question is essential for assessing the ethical justification and animal welfare considerations of your study.

Table A1: Ethical Evaluation Criteria for Research Involving Animal Subjects

	Key questions	Detail Answer
1	Is it essential to use animal subjects in this study? • *Explain why non-animal alternatives (e.g., in vitro studies, computer models) are not suitable.*	
2	What is the species of animal(s) used, and why was this species selected? • *Include scientific reasoning such as relevance, existing literature, availability, or model suitability.*	
3	Is this an invasive study? • *Yes/No. If yes, describe the procedures involved (e.g., blood collection, tissue samples and etc.).*	
4	What is the total number of animals used in the study, and how was the sample size determined? • *Briefly describe your sample size calculation (statistical justification, pilot study data, etc.)*	
5	What is the source of the animals? • *Include the institution/facility..etc..*	
6	Will the animals be transported to the research site? • *If yes, describe transportation methods (e.g., vehicle type, duration, stress minimization techniques).*	
7	Are there any risks to animals during the study?	

	• *Describe the nature of possible harm and the steps taken to minimize pain, stress, or injury.*	
8	If an animal is found to be suffering severely, will you take steps to euthanize it to prevent further suffering? • *Describe the euthanasia protocol, agents used, and who is authorized to make this decision.*	
9	Are there any possible adverse effects (e.g., behavioral changes, infections, toxicity)? • *List potential adverse effects and their likelihood based on prior studies.*	
10	What is the procedure for dealing with adverse effects (including accidental death or severe illness**)?** • *Include veterinary intervention, treatment, observation logs, and humane endpoints.*	
11	Where applicable, what is the protocol for reporting adverse events to relevant authorities**?** • *Mention if you'll report to an institutional ethics board, animal care committee, or licensing authority.*	
12	What is the method of disposal of used animals after research? • *Specify whether animals will be rehomed, euthanized, or disposed of according to institutional guidelines.*	
13	What are the risks to the researcher, and what precautions are taken? • *Include protective gear, training, and biosafety procedures.*	

14	What are the procedures for dealing with accidental exposure or injury to researchers? • *State first-aid protocols, emergency contact points, and institutional safety procedures.*	
15	Is veterinary care essential for this study? If so, what steps are taken to ensure this? • *Include details of the veterinary consultant, frequency of checks, and treatment availability.*	
16	What arrangements are in place to ensure adequate veterinary support and welfare for animals throughout the research period? • *Include housing, feeding, environmental enrichment, and regular health checks.*	
17	How will you ensure animals are handled with care and compassion, and that pain or suffering is minimized during research? • *Describe training received, handling protocols, and use of anesthesia if needed.*	
18	If an owner or responsible party chooses to withdraw their animal after enrollment, what is your procedure? • *Explain how you will respect their decision and ensure the safety of the animal and data integrity.*	
19	Describe the anticipated benefits of this research in comparison to the risks involved. • *Justify the value of the expected knowledge gained relative to the risks to animal subjects.* ○ **Example:** "This study may help develop a novel treatment for parasitic infections with minimal animal discomfort due to non-invasive methods	

Table A2: Ethical Considerations for Research Involving Animals Owned

This section must be completed if your research involves animals that are privately owned or under the custody of individuals (e.g., pet owners, farmers, Zoo director, wildlife rehabilitation center administrator, etc.). Please answer all questions clearly and provide supporting documents (e.g., consent forms, information leaflets) where relevant. Use specific examples where applicable. If a question is not relevant, mark it as Not Applicable (N/A) with a brief explanation.

	Question	Detailed answer
1	Have you obtained permission from the relevant authority to use the said animal species for your research? *If yes, state the name of the authority (e.g., Pet owners, animal shelter managers, veterinary clinic administrators, Farm owners, Government departments (Police Canals) and etc..) and provide documentation, if available.*	
2	Describe the process of obtaining informed consent from animal owners. *Who will obtain the consent? Will it be written or verbal? Attach the consent form or script as applicable.*	
3	How will you ensure that the information provided to animal owners is clear, understandable, and available in appropriate languages? *What steps will be taken if owners have difficulty reading or understanding the content?*	
4	How will you ensure that consent is given voluntarily? *Describe how you will avoid coercion, deception, or undue influence, and how you will reassure owners that participation is optional.*	
5	Are you offering any incentives (financial or otherwise) to animal owners? *If yes, describe them and explain how you will ensure they do not create pressure to participate.*	

Table A3: Ethical Safeguards for Research Involving Vulnerable Animal Populations

This section must be completed if your study involves vulnerable animal groups. Vulnerable animal populations may include:

- Endangered or protected species
- Wild animals in sensitive ecosystems
- Domesticated but culturally or religiously significant animals (e.g., Domesticated elephants)
- Diseased or injured animals under special care (e.g., animals in rehabilitation centres)
- Animals under legal or institutional protection (e.g., zoo animals, wildlife rescue animals)

	Question	Detailed Answer
1	What is the scientific or ethical justification for selecting a vulnerable group *(e.g., wild, endangered, or diseased animals)* instead of the general animal population for this study?	
2	If the vulnerable animals have identified owners or caretakers (*e.g., domesticated elephants, rescued animals in sanctuaries),* how will you obtain informed consent or official permission?	
4	What arrangements are in place to ensure adequate veterinary support and continuous welfare monitoring for the vulnerable animals throughout the study period?	
5	Will the outcomes or benefits of the research *(e.g., new treatment, improved care practices, disease prevention)* be made reasonably accessible to the vulnerable animal population involved or their caretakers?	
6	Have you provided a clear and complete answer to Question Table 1, specifically describing how adverse effects, injuries, or distress in vulnerable animals will be identified, managed, and reported?	

Table A4. Ethical Safeguards for Research Involving Community Animals

This section must be completed if your study involves community animals, animals that roam freely and are not individually owned, but may be supported by or interact with local communities (e.g., stray dogs, monkeys, street cows, feral cats). These animals may be particularly vulnerable due to the absence of individual caretakers. Provide specific, realistic responses. Attach relevant community engagement or local authority approvals, if available.

	Question	Detailed answer
1	What is the intended impact and significance of your research on the health and welfare of the community animal population involved? *(e.g., stray dogs, temple monkeys, street cows)*	

2	What specific procedures will be followed to identify, approach, and recruit community animals for participation in the study? *Include humane capture methods, sedation if used, tagging, and any return-to-habitat protocols.*	
3	If the intervention proves beneficial, will the sponsor or research team ensure continued access to it for the community animals? *Explain any plans for post-study care, follow-up treatment, or community outreach.*	

Table A5. Ethical Safeguards for Research Involving Clinical Trials Involving Animals

This section must be completed if your study involves a clinical trial using animal subjects to evaluate drugs, vaccines, biological products, or medical interventions. Provide clear and complete responses to each question. Attach supporting documentation where applicable (e.g., trial registry information, preclinical study reports, SOPs for adverse event reporting).

	Question	**Answer**
1	What is the clinical trial phase being conducted? *Indicate whether this is a Phase I, II, III, or IV trial.* *Also, state whether it is a single-centre or multi-centre trial, and provide details of all participating sites*	
2	Is the trial registered with a recognized clinical trial registry? *If yes, provide the registry name and registration number.*	
3	Have all required preclinical studies been completed before this trial? *Include information on toxicity studies on animals. Attach summary reports or reference published data if applicable.*	
4		

Table A6: Ethical Considerations for Use of Dead Animals or Animal Body Parts
This section must be completed if your research involves the use of dead animals or animal-derived materials (e.g., organs, tissues, bones). Please answer all questions clearly and provide supporting documentation where applicable. If any material is obtained from an external source, ensure you have the necessary approvals or consent.

	Question	Remarks / Description
1	What is the species of the animal(s) to be used? *Include common and scientific names. Indicate if the species is protected, endangered, or invasive.*	
2	What is the source of the animal or body parts, and were the animals killed specifically for this study? *Clearly state the source (e.g., natural death, veterinary post-mortem, slaughterhouse by-product, previous research). If animals were euthanized for this study, provide an ethical justification.*	
3	What types of animal materials will be used and for what purpose? *Specify the tissues or organs (e.g., liver, femur, feathers) and clearly explain their use in the study.*	
4	How will the animal materials be stored, handled, and disposed of? *Describe protocols for biosafety, preservation (e.g., formalin, freezing), and disposal (e.g., incineration, biohazard bins).*	
5	Are all necessary approvals or permissions in place? *Include ethical clearance, institutional, or third-party consent if applicable. Attach or reference the documents.*	

PART B: Human-Involved Research Works

This section must be completed if your study involves human participants in any form (e.g., surveys, interviews, observations, medical interventions, collection of biological samples). Please answer all questions. Where applicable, provide specific justifications and supporting details.

Table H1: Participant Selection Criteria and Study Design Classification

	Key Questions	Detailed Answer
1	What is your target study population? *Specify characteristics such as age group, gender, health status, occupation, or geographic location.*	
2	Why was this population selected? *Explain the scientific, practical, or ethical justification for selecting this group.*	
	Have you obtained the necessary approvals or permissions from relevant authorities (e.g., hospitals, ministries, schools)? • *Yes / No* • *If Yes, name the authorities and attach relevant documents.*	
3	What are your inclusion and exclusion criteria? *Clearly define who will be included or excluded and justify how these criteria help minimize risk and ensure fair participant selection.*	
4	Will your study involve any vulnerable groups? • *Yes / No* • *If Yes, specify the group (e.g., minors, pregnant women, prisoners, individuals with disabilities, economically/psychologically disadvantaged), and complete Table H7*	
5	Is the research externally sponsored (by a foreign organization or institution)? • *Yes / No* • *If Yes, provide sponsor details and complete Table H8.*	
6	Community-Based Research • Is your study community-based (i.e., conducted in or on behalf of a specific community)?	

	○ *Yes / No* ○ *If yes, describe community involvement and complete Table H9*	
7	Is this study a clinical trial involving medical interventions, drug testing, or diagnostic procedures? • *Yes / No* • *If Yes, provide clinical trial details and complete Table H10.*	

Table H2: Assessment of Risk, Benefit, and Participant Safety in Human Subject Research

This section must be completed if your study involves human participants. Please respond to each question clearly and concisely. Where applicable, explain how you will ensure the safety and well-being of participants throughout the study.

	Key questions	**Detail Answer**
1	Is the involvement of human subjects essential to obtain the required information? *Yes / No – If yes, explain why alternative methods (e.g., animal models, simulations) are not suitable.*	
2	Are there any anticipated risks to participants? *Yes / No – Consider physical, psychological, social, legal, or economic risks.* *Example: Minimal psychological discomfort due to sensitive questionnaire content.* If yes, describe the risks and how they will be minimized or managed. *Example: Psychological discomfort will be mitigated by informing participants they may skip any question or withdraw at any time.*	
3	Are there any direct benefits to participants? *Yes / No – If yes, describe (e.g., free medical screening, health education).* *If No, explain the potential benefits to the wider community or health system.*	

	Example: The study may lead to improved disease surveillance strategies.	
4	Justify the potential benefits of the study about the risks involved. *Example: Minimal risk from survey participation is justified by the potential to inform targeted public health interventions.*	
5	Will any standard therapy be withheld from participants during the study? *Yes / No – If Yes, provide a strong justification.*	
6	Is adequate medical and psychological support available for participants? *Yes / No – Describe how and where participants can access support if needed.* *Example: A trained counsellor will be available for referral in case of distress.*	
7	What procedures are in place to manage any adverse events during the study? *Explain steps for detection, management, and follow-up.*	
8	What is the protocol for reporting adverse events to relevant authorities? *Outline the reporting process, timelines, and responsible persons.*	

Table H3: Assessment of Informed Consent Procedures in Human Subject Research

	Key questions	**Detail Answer**
1	Briefly describe the procedure for obtaining informed consent from human participants. *Describe how, when, and where participants will be informed about the study.* *Mention what information will be provided (e.g., purpose, risks, benefits, confidentiality, right to withdraw).* *Indicate whether participants will have time to ask questions and consider their decision.*	
2	Who will be responsible for obtaining informed consent? *Specify the person/people responsible (e.g., Principal Investigator, trained research assistant). Mention their qualifications or training in research ethics.*	
3	What type of consent will be obtained? *(If written, attach the consent form and translations. If verbal, provide a script in all applicable languages and describe how consent will be documented.)*	
4	Describe how you will ensure participants understand the study (e.g., using simple language, local language, visual aids, Q&A sessions).	

Table H4: Confidentiality, Privacy Safeguards, and Data Handling Procedures

Please respond to the following questions about how you will collect, store, manage, and protect participants' personal data and/or biological samples during and after your study. Your answers should demonstrate adherence to ethical research practices regarding privacy, confidentiality, and responsible data use.

	Key Questions	**Detailed Answer**
1	Describe how data or samples will be collected *(e.g., interviews, surveys, blood samples) and under what conditions (e.g., private setting, by trained staff).*	
2	For how long will data and/or samples be stored? *Specify the duration (e.g., 1 year, 5 years) and whether it is based on institutional or funder guidelines.*	
3	Are you collecting only the minimum information/samples required to meet the study objectives? *Confirm whether the study is collecting only essential data and justify briefly.*	
4	Who will have access to the personal data of research participants? *Identify who will have access (e.g., Principal Investigator, research assistants) and specify how access will be controlled.*	
5	How will the privacy of participants be safeguarded? *Describe measures to protect identity (e.g., coding, anonymization, private interview settings).*	
6	Describe the procedures for storage, confidentiality, and disposal of data/samples. *Explain where and how data/samples will be stored, how confidentiality will be maintained, and how materials will be securely destroyed after the retention period.*	
7	If planning future use of data/samples, will appropriate consent be obtained? *Indicate whether participants will be asked for consent for future use and how it will be documented.*	

Table H5: Participants' Rights, Complaints, and Post-Study Communication

This section addresses how you will uphold and protect participants' rights before, during, and after the study. Please explain clearly how participants can:

- Freely withdraw from the study, raise concerns or complaints, receive updates or results, Be informed about benefits post-study, and report any post-study complications.

Provide contact details and outline mechanisms to maintain transparency and ongoing communication with participants.

	Key Questions	Detailed Answer
1	How will you ensure participants have the unconditional right to withdraw from the study at any time?	
2	What procedures are available for participants to raise concerns or register complaints? *Describe how participants can voice concerns (e.g., phone, email, in person) and to whom.*	
3	Who will be the contact person for participants? *Provide the name, role, and contact information of the responsible individual.*	
4	Will participants receive relevant updates or information during the study? Please explain. *Indicate whether and how ongoing information will be shared.*	
5	Will participants be informed of the study results? Please explain. *State how and when results will be shared with participants.*	
6	If a study product/intervention is developed, will it be made available to participants post-study? Please explain. *If applicable, explain whether participants will benefit from any resulting product or service.*	
7	Specify the duration and the procedure provided for the participants to raise post-study complications (Eg, health conditions, etc) *Indicate the period during which participants can raise post-study concerns, and how they can do so.*	

Table H6: Researcher Responsibilities, Ethical Compliance, and Declarations

This section ensures that the research team understands and upholds its responsibilities toward participants, adheres to national and international ethical standards, and discloses any potential conflicts or concerns. Please provide honest and transparent responses to the following questions.

	Key Questions	Detailed Answer
1	What responsibilities do you have toward providing medical services to participants during the study? *Clarify if the study involves any medical risks and what support will be provided in case of adverse events.*	
2	What provisions have you made to ensure the continuation of care after the study is completed? *Explain any post-study care provisions, even if none are applicable.*	
5	Declare any possible conflict and explain how you will mitigate bias. If none, state "No conflict of interest."	
6	Are there any other ethical, legal, social, or financial concerns related to the study? If yes, list them and describe how they will be addressed. *Identify any other relevant concerns and describe how you will manage them. If none, state so.*	

Table H7: Research Involving Vulnerable Groups *(To be completed only if applicable)*

To be completed only if your study includes vulnerable populations such as children, pregnant women, elderly individuals with cognitive decline, prisoners, refugees, or others with limited autonomy. When working with vulnerable groups, additional ethical scrutiny and protections are required. Please explain:

- *Why is their inclusion essential,*
- *How consent (or proxy consent) will be ethically obtained,*
- *How their rights will be protected,*
- *And how their well-being and fair access to benefits will be ensured.*

	Key Questions	Detailed Answer
1	Why is it necessary to involve this vulnerable group in your research instead of the general population?	

	Justify the scientific or social need to include this group.	
2	What is the process for obtaining consent or proxy consent from this group? *Describe the consent procedures. For minors or cognitively impaired individuals, indicate who will provide proxy consent and how assent will be obtained.*	
3	How will participants be withdrawn if they express dissent or refuse participation? *Explain how dissent (verbal or non-verbal) will be respected and acted upon.*	
4	Will adequate medical and psychological support be provided during the study? If yes/no, explain. *Specify whether support will be accessible and what kind.*	
5	Will the benefits of the research be made reasonably available to this population? If yes/no, explain. *Indicate whether results, interventions, or services will benefit the group involved.*	

Table H8: Research Sponsored by Foreign Organizations: Ethical and Regulatory Considerations *(To be completed only if the study is funded, managed, or conducted in collaboration with a foreign institution or sponsor.) If your study involves foreign sponsorship, you must address ethical, regulatory, and contextual concerns regarding the conduct of international research in Sri Lanka. Ensure responses are aligned with national ethical guidelines and emphasize transparency, mutual benefit, and respect for local practices.*

	Key Questions	**Detailed Answer**
1	Has the study been approved by an Ethics Review Committee in the sponsoring country? *Attach documentary proof if applicable. If not approved yet, explain the status.*	
2	Why is this research being conducted in Sri Lanka rather than in the sponsor's country, and what is its relevance to Sri Lanka? *Combine justification and local relevance in one answer.*	
3	What benefits (e.g., training, technology transfer, capacity building) will this research provide to Sri Lanka or local institutions? *Outline any long-term academic, technical, or infrastructural benefits.*	

4	Are the applicable ethical and regulatory guidelines of both Sri Lanka and the sponsoring country being followed? *Cite specific guidelines or frameworks*	
5	Have Sri Lankan cultural, social, and traditional practices been considered in the study design? *Explain how local context has been respected (e.g., informed consent process, gender roles, language use).*	
6	Will participants receive appropriate care during and after the study (including ancillary or post-study care)? *Include details of any standard treatments, referrals, or post-study support offered.* .	
7	Will data and/or biological samples be transferred outside Sri Lanka? If yes, what are the procedures for transfer, use, and disposal? *Describe if materials will be exported and how this complies with national laws and ethics.*	
8	How will study results be shared with Sri Lankan stakeholders (e.g., authorities, institutions, or communities)? *Mention any plans for feedback, policy briefs, or knowledge sharing.*	

Table H9: Community-Based Research: Impact, Consent, and Benefits

This section is intended for studies involving communities as a whole (e.g., villages, neighbourhoods, community groups). Responses should describe how the research respects local context, ensures ethical engagement, and delivers meaningful benefits to the community. Be specific about consultation, consent, privacy, and sustainability of impact.

	Key Questions	**Detailed Answer**
1	What is the expected impact and relevance of the study on the community in which it will be conducted? *Describe how the community might benefit (e.g., knowledge, health improvements, environmental change).*	
2	What steps were taken to consult the community during the research design phase? *Explain if meetings, focus groups, or local leader discussions were held.*	
3	What procedures will be followed to obtain community consent?	

	Describe how community leaders or bodies will be approached and engaged.	
4	What procedures will be used to obtain individual consent? *State how individuals will be approached and how privacy and comprehension will be ensured.*	
5	How will the privacy of individual participants be protected? *Describe measures such as anonymized data, private interviews, or coded identifiers.*	

Table H10: Clinical Trials: Study Details, Safety, and Compliance *(To be completed only if applicable)*

	Key Questions	Detailed Answer
1	What phase of the clinical trial is being conducted, and has it been registered in a clinical trial registry? *Tick the relevant phase and provide the name of the registry (e.g., SLCTR, ClinicalTrials.gov).*	
2	Is the trial multicenter? If yes, list the participating institutions or hospitals. *Include local or international collaborating centers, if applicable*.	
3	Have sufficient preclinical (animal) toxicity and teratogenicity studies been conducted to justify human testing? *Refer to any animal model data or preclinical reports.*	
4	What measures are in place to ensure participants' safety, including management and reporting of adverse events? *Describe how adverse events will be monitored, reported, and managed.*	
5	Will participants in the control group receive standard care or a placebo? Justify your choice. *Explain ethical considerations regarding the control group.*	
6	Is there post-trial access to the investigational drug/device for participants, and is insurance provided for injury or harm? *Mention continuation of drug access and participant coverage.*	

PART C: Ethical Considerations for Genetically Modified (GM) Food Involvement

If your study involves the use, production, or administration of genetically modified (GM) food, whether in human or animal research, please complete the following section. This is to ensure ethical oversight regarding safety, transparency, and regulatory compliance. If not applicable, indicate "Not Applicable" next to each item.

No.	Question	Detailed answer
1	Does the study involve the use, production, or consumption of genetically modified (GM) food?	
2	Has the GM food used in the study been approved by relevant national or international regulatory authorities?	
3	What measures are in place to inform participants (human or animal) about the use of GM food in the study?	
4	Are there any known or potential risks (health, environmental, or societal) associated with the GM food used?	
5	How will GM food waste, if any, be disposed of to prevent unintended environmental exposure or contamination?	

4. Investigators

Details of the Principal Investigator and Co-Investigators

This section includes the names, qualifications, designations, affiliations, and contact information of the research team members involved in the study.

Principal Investigator	Title:	
	Name:	
	Qualifications:	
	Designation:	
	Adress and place of work	
	Contact number	
	E-mail address	
Co-Investigator 1	Title:	
	Name:	
	Qualifications:	
	Designation:	
	Adress and place of work	
	Contact number	
	E-mail address	
Co-Investigator 2	Title:	
	Name:	
	Qualifications:	
	Designation:	
	Adress and place of work	
	Contact number	

	E-mail address	

5. Scientific Justification and Summary of the Research Proposal

This section provides a plain-language summary of the study, outlines its scientific value, approval status by a scientific review committee, and plans for dissemination of results

		Description
1	A brief summary of the research proposal in simple language, describing the scientific validity (maximum 500 words)	
2	What is the scientific value of your study in improving animal/human health or advancing knowledge in the field?	
3	Is this research proposal been approved by a scientific review committee? If yes, what is name the committee	
4	How will the results of the study be disseminated?	
5	How will funding be allocated to support the health and welfare of human and/or animal participants involved in the study, including hospital care, veterinary care, food, transport, and other necessary support services? Please specify funding sources and mechanisms for covering these costs.	

6. Suggested Reviewers

(Please provide the names and contact details of 2–3 suitable reviewers who have relevant expertise but are not affiliated with the study or investigators. If there are any conflicts of interest, clearly state them.)

No.	Name of Reviewer	Institutional Affiliation	Email Address	Area of Expertise	Conflict of Interest (Yes/No)	If Yes, please explain
1.						
2.						
3.						

Note: Reviewers should not be current collaborators, co-authors in the last 3 years, or affiliated with the same institution as any of the investigators.

7. Declaration

Signature of Applicant: _____ Date: ___ / ___ / ____

Supervisor's Recommendation

Name of Supervisor: ----------

Official Address: ----------

Signature of Supervisor: _____ Date: ___ / ___ / ____

Annex I: Application Checklist

I declare that I have attached the following documents (please tick the check box and confirm):

No.	Document Description	Submitted (Yes/No)
1	Summary form	
2	Application form	
3	Ethics Review Evaluation Form	
4	The complete research proposal includes the justification, objectives, and methods in detail	
5	Information sheet for research participants (Provided in Sinhala, Tamil, and English)	
6	Consent forms (Provided in Sinhala, Tamil, and English)	
7	Data collection booklets/forms/questionnaires (Provided in Sinhala, Tamil, and English, if applicable)	
8	Copies of relevant permission letters	
9	Application checklist	

I understand that the application for ethics clearance will not be accepted unless all documents are submitted. I declare that I am not seeking approval for a study that has already commenced or has already been completed. I understand that at least two months are required for ethics review and granting ethics clearance.

Signature of the applicant Date (dd/mm/yyyy)