



Introduction

Ethical Clearance Committee (ECC) Faculty of Agriculture, University of Peradeniya

1. Scope

Universities are expected to conduct high quality research in a responsible manner ensuring that ethical conduct is practiced at all time. Hence, each academic staff member is expected to undertake research in her/ his field of study, develop new knowledge and disseminate such new understandings to relevant stakeholders. Ethical conduct of research carry out by the academic staff of Faculty of Agriculture is to be ensured by an authorized body. The main role of the proposed Ethical Clearance Committee (ECC) is to provide ethical clearance for the research proposals submitted by the academic staff members of the Faculty of Agriculture. The committee is expected to provide an independent and timely review with suggestion for improvement of ethical aspects of objects used in the research, process for data collection and management at the outset of research. Thus, the approval process should serve as supporting mechanism for researchers but not as a barrier for timely submission of proposals, conducting of research and publication of research findings. Committee may also advice on getting approval from relevant regulatory agencies and laws applicable for certain activities of the proposed study.

2. Ethical Clearance Committee (ECC)

The ECC is an independent committee of the Faculty of Agriculture and shall be appointed by the Faculty Board. The committee along with the Faculty Research Committee (FRC) will prepare guidelines and operational procedures adhering to the University policies and giving due consideration to the diverse interests and the needs of the researcher. The guidelines and operational procedures for ethical clearance process have to be approved by the Faculty Board of Agriculture. The committee has a liberty to review the guidelines/operational procedures and update/ modify if necessary, once in every 3 years and obtain the approval of the Faculty Board accordingly.

- The committee will work independently without any interference from the appointing body.
- The committee will be comprised of 12-15 members from the Faculty of Agriculture and from outside representing different disciplines as listed in Table 1.
- Appointment of members is valid for a period of three years. Reappointing for another term will be possible. The Faculty Board reserves the right for reappointment and termination of the membership.
- Provisions will be available to obtain the opinion of an outside expert when the required expertise is not available in the committee.
- If a situation of conflict of interest arises, relevant member/s should refrain from being involved in the review process.

The Faculty Board approved and confirmed the nominations of the following members for the Ethical Clearance Committee for a period of 3 years from 2019 – 2021 (FB - 276).

Table 1. Committee members representing different disciplines (2019-2021)

Discipline	Member
Molecular Biology - Plant Science*	Dr. N.U. Jayawardana, (Secretary), Department of Agricultural Biology, Faculty of Agriculture
Molecular Biology - Animal Science *	Dr. K.K.S.P. Kodituwakku, Department of Animal Science, Faculty of Agriculture
Animal Welfare*	Dr. T.S. Samarakone, Department of Animal Science, Faculty of Agriculture
Human Behavior*	Dr. S. Kumar, Department of Agricultural Economics & Business Management, Faculty of Agriculture
Social Sciences*	Dr. L.N.A.C. Jayawardena, Department of Agricultural Extension, Faculty of Agriculture
Animal Science*	Prof. J.K. Vidanarachchi, Department of Animal Science, Faculty of Agriculture
Animal Nutrition*	Mr. M.B.P.K. Mahipala, Department of Animal Science, Faculty of Agriculture
Food & Nutrition of Human*	Prof. D.G.N.G. Wijesinghe, Department of Food Science & Technology, Faculty of Agriculture
Environmental Science*	Prof. M.I.M. Mowjood, (Chairperson), Department of Agricultural Engineering, Faculty of Agriculture
Clinical Sciences	Dr. Arinda Dharmapala , Department of Surgery, Faculty of Medicine
Medical Sciences	Dr. Eranga Siriweera, Department of Pathology, Faculty of Medicine
Psychology	Dr. Ramila Usoof-Thowfeek, Department of Psychology, Faculty of Arts
Legal Aspects	Mr. Romesh Karalliyadda
Chairman/Faculty Research Committee*	Prof. S.P. Nissanka, Department of Crop Science, Faculty of Agriculture

* *Preferably from the Faculty of Agriculture, University of Peradeniya.*

3. Disclaimer

Scholarly review, issues with authorship and plagiarism will not be considered by the committee. The committee will not monitor the conduct of research projects unless there is a necessity. The committee will not be responsible on aspects pertaining to the integrity and privacy of data, responsible use of data and interpreting and disclosing of data to public.



Responsibilities of Committee Members

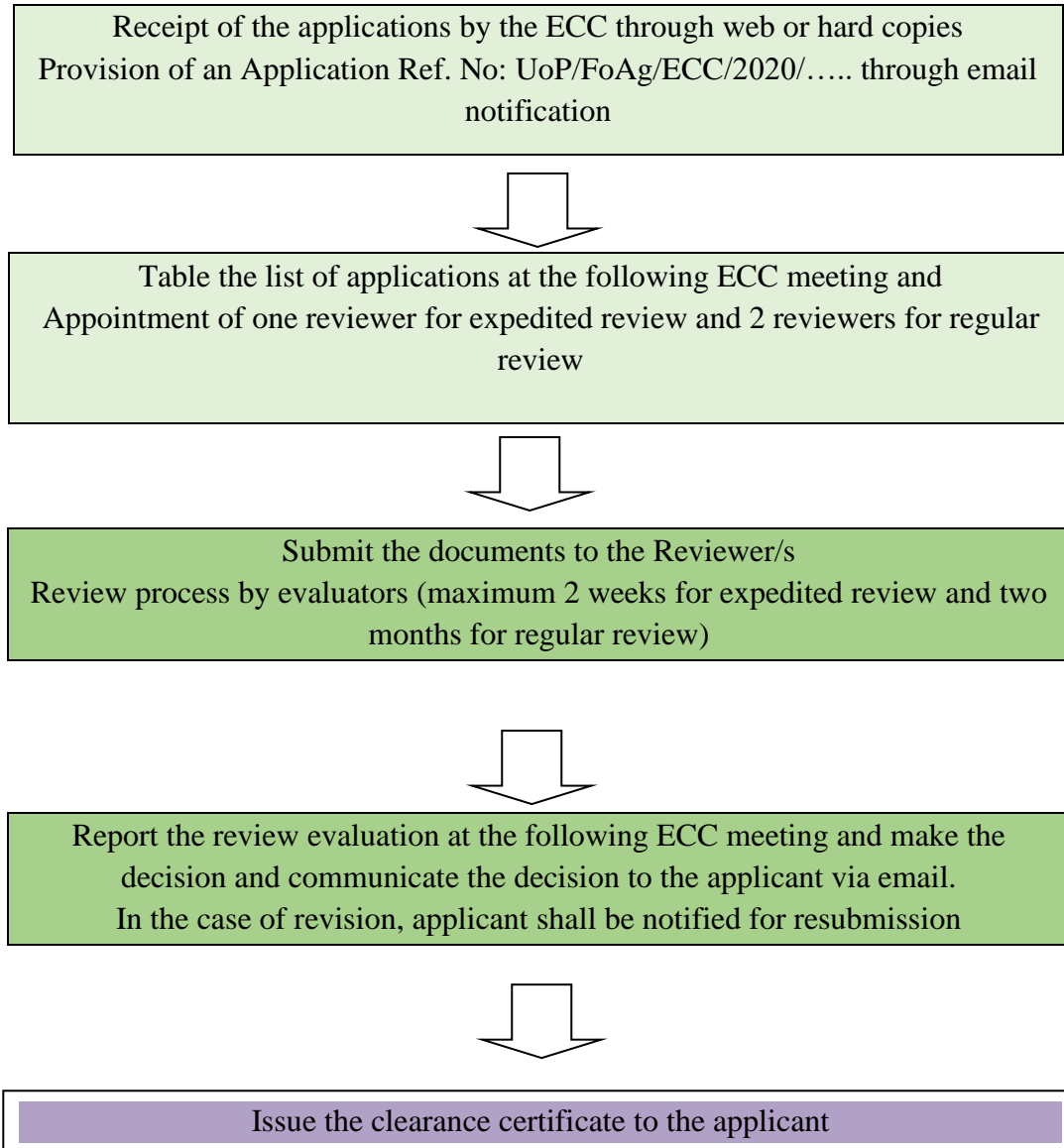
Ethical Clearance Committee (ECC) Faculty of Agriculture, University of Peradeniya

- 1) Members agree to follow the general responsibilities to:
 - a) Read and understand their functions as members of the ECC.
 - b) Keep up-to-date with national and international research ethics and regulatory guidance and take part in research ethics-related education.
 - c) Support the functions of the ECC
- 2) With respect to confidentiality, transparency and disclosure of conflicts of interest, members agree to:
 - a) Have their names, designations and affiliations publicly available as members of this committee.
 - b) Maintain confidentiality regarding deliberations during the meetings, applicants and content of the applications submitted.
 - c) Disclose all potential conflicts of interest that may arise with respect to an application that is submitted.
 - d) Remain impartial and objective when reviewing proposal/protocols. Decide independently whether the design and conduct of proposed studies will protect safety, rights and welfare of participants.
- 3) When participating at meetings, members agree to:
 - a) Attend meetings on a regular basis and remain until meetings are adjourned.
 - b) When a member is deemed to have a potential conflict of interest, abstain from reviewing the relevant protocol and leave the room during discussion of and voting on the protocol.
 - c) Present and lead discussions of applications assigned.
- 4) When conducting meetings and the review process, members agree to:
 - a) Respect the views of other members and the deliberative process.
 - b) Perform expedited reviews of minimal risk research.
 - c) Serve as primary reviewers for research in their areas of expertise.
 - d) Actively participate in the decision, by vote or consensus, whether to approve, request revisions, not approve or defer following deliberation at full committee meetings.
- 5) With respect to membership, members are aware of that:
 - a) Members are appointed for a period of three years.
 - b) Membership will lapse if a member fails to attend three consecutive meetings of the ECC without reasonable excuse, unless exceptional circumstances exist.
 - c) A member may resign from ECC at any time upon giving notice in writing. Chairperson shall inform to the Dean to fill the vacancy.



Review process for Ethical Clearance

Ethical Clearance Committee (ECC)
Faculty of Agriculture, University of Peradeniya





Guidelines for Application for Ethical Clearance

Ethical Clearance Committee (ECC)
Faculty of Agriculture, University of Peradeniya

1. Ethical review shall be conducted only for research projects dealing with human and animal subjects using primary or secondary data.
2. The applicant/principal investigator should be a probationary/permanent staff member of a University or an Institution. With respect to undergraduate or postgraduate research projects, the applicant shall be the research supervisor.
3. Applicants are advised to submit the documents according to the format provided by the ECC of Faculty of Agriculture.
4. Applications shall not be reviewed by the ECC until all the required documents are received (web upload in pdf format or in person submission)
5. The following documents must be submitted for Ethical Clearance.
 - a. Cover letter
 - b. Completed and signed Checklist
 - c. Completed and signed Application form
 - d. Research proposal
 - e. Study instruments and translation into Sinhala and Tamil (if relevant).
 - f. Information sheets, Consent form and Assent form and translation into Sinhala and Tamil (if relevant).
 - g. Review Sheet
 - h. Any other relevant documents
6. Applications must be forwarded to the ECC through proper channel (Head of the Department /Institution).
7. ECC shall issue a reference number upon receiving the application
8. Review process shall take maximum of 2 weeks for expedited review and two months for regular review.
9. The applicant can request for expedited review if there is a tight time frame for the research project and research involves minimal risk to participants. However, the decision remains within the ECC based on the content of the research project.
10. The status (approval/ revision/ rejection) of the application shall be notified via e-mail and an ethical clearance certificate will be issued on approved applications.
11. Retrospective approval shall not be granted for research already started or completed.



Check list of Application for Ethical Clearance

Ethical Clearance Committee (ECC)
Faculty of Agriculture, University of Peradeniya

Title of the Research:

Type of the review: Expedited/Regular

Name of the Applicant:

.....

(Mark “✓” in appropriate box)

		To be marked by applicant	For office use
1	Cover letter signed by the applicant		
2	Completed and signed application form		
3	Research proposal		
4	Study instruments in English		
4a	Study instruments Sinhala translation (if relevant)		
4b	Study instruments Tamil translation (if relevant)		
5	Information sheet in English		
5a	Information sheet Sinhala translation (if relevant)		
5b	Information sheet Tamil translation (if relevant)		
6	Consent form in English		
6a	Consent form Sinhala translation (if relevant)		
6b	Consent form Tamil translation (if relevant)		
7	Review sheet filled with the column for page Number/s in proposal/protocol		
8	Other documents (Specify) 1. 2. 3. 4. 5.		

Note : All documents should be in pdf format



Application form for Ethical Clearance

Ethical Clearance Committee (ECC)
Faculty of Agriculture, University of Peradeniya

For office use

Reference No.		Date received	
Date of ECC meeting 1		Type of review	Expedited/Regular
Date of ECC meeting 2			
Decision		Date informed	
Date of resubmission			

To be filled by the Applicant

Section I: Basic information

1.1 Applicant (Principal investigator)

Title:

Name:

Affiliation:

Email:

Tel No:

1.2 Co-investigators (Other collaborative researchers/partners) if any

Name with title	Affiliation	Signature

Section II: Research Project

2.1 Title of the research project:

2.2 Project starting and ending dates (proposed):

Start:	End:	Period:
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2.3 Funding Agency:

2.4 Type of the review: Expedited/Regular

2.5 Will consent be sought if the participants are minors: Yes/No

2.6 a) Has the research proposal received a scholarly review: Yes/No

b) If Yes, please provide the details:

2.7 Nature of the study

	Yes	No	Specification
1a. Involves animals			
1b. Involves humans			
2a. Questionnaire only			
2b. Questionnaire + sample collection			
2c. Observation			
3. Others (Specify)			

Section III: Declaration

I certify that the information given above is true and correct to the best of my knowledge. If there is change in the protocol or the research project, I shall inform the ECC. I also confirm that I have provided on the Review Form the relevant page numbers of the proposal on which each specified issue is addressed.

.....

Signature of the applicant and date



Participant's Information Sheet (Sample)

Ethical Clearance Committee (ECC)
Faculty of Agriculture, University of Peradeniya

Ethical Clearance Ref No:

Title of the project:

I/We(name of principal investigator/s), a(designation) attached to (institute/s of affiliation) would like to invite you to take part in a research project titled(in non-technical term) conducted by (Names of Investigator) at (Study Site).

1. Purpose

.....(The objective/s of the study in non-technical terms)

2. Voluntary participation

Your participation in this study is voluntary. You are free to not participate at all or to withdraw from the study at any time despite consenting to take part earlier. There will be no impact on the rights/services which you are otherwise entitled. If you decide not to participate or withdraw from the study you may do so at any time.

3. Duration, procedures of the study and participant's responsibilities

This study will be conducted over a period of (anticipated duration of study). If you volunteer to participate in this study, we will ask you to take part in the study. It will take approximately (time duration) to complete the task.

4. Potential benefits

Participation in this study may benefit you/others by (benefits)

5. Risks, hazards and discomforts

(Any potential or actual risks, hazards and discomforts should be clearly mentioned)

6. Payments

You would be paid an honorarium of Rs. (if any payment to the participant indicating the amount), OR You will not be paid any honorarium for participating in this study

7. Termination of study participation

You may withdraw from this study at any time with no penalty. Please notify the investigator as soon as you decide to withdraw your consent.

8. Confidentiality

Confidentiality of all records is guaranteed and no information by which you can be identified shall be released or published. These data will never be used in such a way that the participant could be identified in any way in any public presentation or publication without the permission of the participant.

9. Clarifications

Clarifications/questions about any of the tests / procedures or information could be directed to the persons listed below.

Names and contact information of investigator/s:.....

Postal address, email address, telephone numbers:
.....
.....
.....
.....

If you have any clarification, concerns, or complaints related to this research project, you may contact the address given below.

Email: ecc@agri.pdn.ac.lk

Tel No:

Address:

Chairperson
Ethical Clearance Committee
Faculty of Agriculture
University of Peradeniya
Peradeniya



Consent Form (Sample)

Ethical Clearance Committee (ECC)
 Faculty of Agriculture, University of Peradeniya

Ethical Clearance Ref No:

Title of the project:

To be completed by the participant (Please tick the appropriate box)

	Yes	No
Have you read the information sheet which is in your mother language?		
Have you had an opportunity to discuss this study and ask questions?		
Have you had satisfactory answers to all your questions?		
Do you understand that you are free to withdraw from the study at any time?		
Have you had sufficient time to come to your decision regarding participation?		
Do you agree to take part in this study?		

Who explained the study to you?.....

Signature of the participant:..... Date:.....

Full name:

.....

Address :

.....

To be completed by the investigator/ person obtaining consent

I have explained the study to the above participant and he/she has indicated his/her willingness to take part in this study.

Signature of Investigator:..... Date:.....

Full

name:.....



Review form for Ethical Clearance

Ethical Clearance Committee (ECC)
Faculty of Agriculture, University of Peradeniya

Title of the project:

Type of the review: Expedited/Regular

(Applicant should indicate the page number of the proposal/protocol where each issue is addressed in their research proposal. If a particular issue is not relevant to your study indicate that as 'NA')

A	Social Value	Page Number/s in Proposal/protocol	Reviewer Evaluation			Comments
			Acceptable			
			Yes	No	N/A	
1	Benefits of the study to the community / society					
2	Plan for dissemination of study findings					
3	Scientific importance of the study					

B	Scientific Validity	Page Number/s in Proposal/protocol	Reviewer Evaluation			Comments
			Acceptable			
			Yes	No	N/A	
1	Research problem					
2	Research questions/hypothesis					
3	Objectives					
4	Study setting					
5	Study design and interventions					
6	Study population (giving inclusion exclusion criteria)					
7	Sample size					
8	Sampling method					
9	Measurements / variables					
10	Study instruments					
11	Procedures to ensure quality of data					
12	Plan for analysis					
13	Ethical considerations					
14	Budget (if relevant)					
16	Work plan and time frame					

C	Risk Benefit Assessment	Page Number/s in Proposal/protocol	Reviewer Evaluation			
			Acceptable			Comments
			Yes	No	N/A	
1	Potential risks to the participants/society					
2	Potential benefits to the participants/society					
3	Potential risks to the environment					
4	Potential benefits to the environment					
5	Justification for risks against benefits					
6	Preventive measures to minimize risks					
7	Remedial measures provided to participants					
8	Periodic monitoring and reporting to the ECC (if applicable)					

D	Participants Rights and Consent	Page Number/s in Proposal/protocol	Reviewer Evaluation			
			Acceptable			Comments
			Yes	No	N/A	
1	Procedure for recruiting the participants					
2	Information provided to the participants					
3	Procedure for obtaining informed consent					
4	Procedure for obtaining proxy consent					
5	Procedure for obtaining assent					
6	Procedure for withdrawing consent					
7	Incentives provided to participants					
8	Procedure for participants to ask questions / register complaints					
9	Participants right to decline consent without losing entitled benefits					

E	Confidentiality and Privacy	Page Number/s in Proposal/protocol	Reviewer Evaluation			
			Acceptable			Comments
			Yes	No	N/A	
1	Steps to ensure confidentiality of data					
2	Justification for collecting personal identification data					
3	Steps taken to ensure privacy during data collection					
4	How long data and samples will be kept with investigators					
5	Who will have access to the data					

6	Procedure for storage of data and samples					
7	Reporting and dissemination of data					
8	Procedure for disposal of data/samples					

F	Fair participant selection and vulnerability	Page Number/s in Proposal/protocol	Reviewer Evaluation			Comments
			Acceptable			
			Yes	No	N/A	
1	Justification for selection of study population					
2	Justification for conducting the study in a vulnerable population					

G	Responsibilities of the researcher	Page Number/s in Proposal/protocol	Reviewer Evaluation			Comments
			Acceptable			
			Yes	No	N/A	
1	Ethical, legal, financial issues related to the study					
2	Any conflicts of interest and how the researcher plans to manage them					
3	Permissions from relevant institutions / authorities					

Other comments:

Decision of the Reviewer:	Approved	
	Conditional Approval (Please mention the conditions below)	
	Resubmit	
	Reject	

.....
Name of the Reviewer

.....
Signature

.....
Date



ETHICAL CLEARANCE CERTIFICATE

Ethical Clearance Committee (ECC)
Faculty of Agriculture
University of Peradeniya

The Ethical Clearance Committee (ECC), Faculty of Agriculture, University of Peradeniya has received and discussed the proposal/protocol/revised proposal/ revised protocol, amendment of proposal/ amendment of protocol of the following Research Project.

Ethical Clearance Ref . No:

Title:.....

Applicant Name: Prof/Dr/Mr/Ms.

The ECC has decided to approve the proposal/protocol/revised proposal/ revised protocol, amendment of proposal/amendment of protocol at it's meeting held on .../.../....., subject to the following conditions:

1. This certificate is valid until In an event that an extension is required; a written request should be submitted to the ECC through the proper channel, three months before the termination date of the certificate.
2. Any amendment or deviation to this study protocol should not be implemented until it is reviewed and approved by the ECC. The required amendments/deviations should be submitted to ECC for approval.
3. Any serious adverse effect related to ethical concern that occur during the conduct of the study should be reported to the ECC immediately.
4. The study should be conducted after obtaining informed consent from participants.
5. The study has to be conducted in compliance with the approved proposal/protocol/revised proposal/ revised protocol, amendment of proposal/ amendment of protocol failing to adhere shall result in the termination of the approval.
6. Applicants receiving approval are advised to submit progress reports periodically.
7. Specific conditions:

Secretary

Date:

Chairperson

Date:

Email : ecc@agri.pdn.ac.lk Tel (official) : +94812395013 Web: <http://agri.pdn.ac.lk>