ETHICS REVIEW SUB-COMMITTEE

STANDARD OPERATING PROCEDURE

SUBMISSION FOR ETHICS REVIEW

Version History

Effective Date:	**October 2020**
Date of Modification:	**October 2023**
Date of next Review:	**October 2024**
Author (s):	**Jackie Green**
Approved by:	**David Stensel**

---

1. INTRODUCTION

This Standard Operating Procedure (SOP) describes the process for submitting requests for ethics review to the Loughborough University Ethics Review Sub-Committee or its Sub-Groups.

2. SCOPE

This SOP applies to all submissions for ethics review in accordance with the University's Ethical Policy Framework and the Code of Practice for Investigations Involving Human Participants.

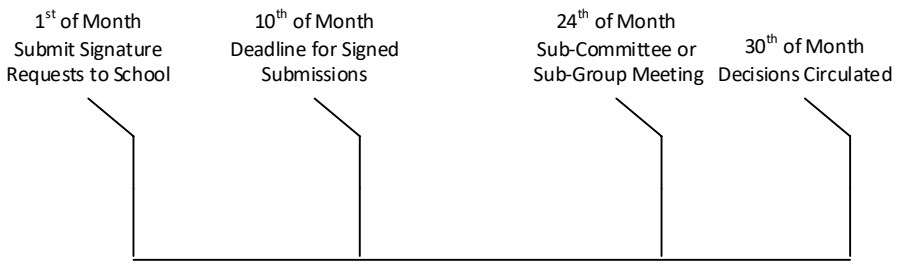
3. SUBMISSION

Submissions for ethics review from staff and students must be submitted via the online ethics system, LEON, for studies involving human participants. All studies involving human participants conducted by staff, students or those claiming affiliation with the institution require ethics review.

Studies involving Security Sensitive Material or Animals, Animal Cells or Tissues must also be submitted via the online ethics system, LEON.

All other submissions must be made in writing following the process detailed in the Ethical Policy Framework.

Submission deadlines are provided on the Sub-Committee's website. It is recommended that signature requests are sent by the first of the month to provided sufficient time for review within the relevant School to meet the submission deadline. A typical timeline for submissions to the Sub-Committee meeting is shown below (deadlines and meeting dates will vary).



4. ETHICS REVIEW FORM

For studies involving Human Participants, Security Sensitive Material or Animals, Animal Cells or Tissues the Ethics Review Form in the online ethics system, LEON, must be completed. The Ethics Review Form must be completed by the applicant. Student applicants must include details of the Responsible Investigator, this will be their project supervisor.

All other submissions must be made in writing following the process set out in the Ethical Policy Framework.

Submissions must be made in language that is suitable for an educated lay audience rather than a subject specialist.

5. DOCUMENTATON

5.1 Human Participants

For studies involving Human Participants it is expected that as a minimum, the submitted documentation will consist of the following:

- Participant Information Sheet(s)
- Informed Consent Form(s)
- Risk Assessment

Other documentation relevant to the study must also be submitted, for instance

- Questionnaire
- Interview/Focus Group Questions
- Health Screen Questionnaire
- Study Recruitment Documents

5.2 Other Proposals

Applicants should refer to the relevant procedures in LEON and the Ethical Policy Framework for details of required documentation.

6. SIGNATURES

Submissions through LEON must be signed as indicated on the form. For studies involving human participants applications must be signed by the applicant, the responsible investigator (if not the applicant), and on behalf of the School (if required). The form will be submitted once all signatures are obtained.

For other submissions made in writing the relevant signatures must be obtained as indicated in the Ethical Policy Framework or the relevant forms.

7. GENERIC PROTOCOLS

The Sub-Committee is prepared to consider protocols on a 'generic' basis where it is the intention to adopt the same procedure in a number of related investigations. A generic protocol will be cleared by the Sub-Committee for use by those investigators named on the submission. Generic protocol submissions can be made through the online ethics system, LEON, and will be considered by the Sub-Committee or its Sub-Groups at their next meeting.

Individuals wishing to use the approved protocol who are not named on the submission must apply to the protocol holder or named staff investigators for permission to practise the generic procedure. An amendment must be submitted through the online ethics system to add investigators to the protocol.

8. EXTERNAL REVIEWS

For studies involving Human Participants that have been reviewed by external ethics review bodies (e.g. NHS Research Ethics Committee, MODREC, a University Research Ethics Committee), a copy of this ethics decision must be submitted via LEON. The Sub-Committee will confirm whether this is acceptable in lieu of a separate submission or whether additional submission is required.

9. REVIEW

The Sub-Committee operates a proportionate review system. For further details refer to the Standard Operating Procedure for Ethics Review Processes.

Staff or doctoral student studies that require only a Checklist submission (e.g. low ethical risk) are given a favourable decision following review by the School. Taught student (ug or pgt) studies that require only a Checklist submission (e.g. low ethical risk) are given a favourable decision following review by the supervisor. The Research Governance administrators will spot check submissions for compliance.

Studies that require the submission of additional information, raising issues in the Section B checklist, will require a Checklist+ submission which will be checked for compliance initially by the Research Governance administrators. If these do not raise ethical concerns they will receive a favourable opinion. If they raise concerns, they will be referred to the Chair in the first instance. For further details of parameters for review see the Standard Operating Procedure on Ethics Review Processes.

Applications which are classed as raising ethical issues, based on the Section A checklist, require an Enhanced submission which will be validated, and quality checked by the Secretary before they are presented to the Sub-Committee or its Sub-Groups. Applications which are not of the required standard will be returned to the applicant for resubmission.

The Sub-Committee will consider validated submissions at the next available meeting or by online review.

In exceptional circumstances, submissions that require urgent review outside of the Sub-Committee schedule will be circulated to Sub-Committee members for online review.

10. DECISION FOR ENHANCED SUBMISSIONS

A decision will be provided no more than 10 days following the meeting of the Sub-Committee or its Sub-Group (or within 10 days of receipt for medium risk submissions). The decision will be communicated to the investigators by the Secretary of the Sub-Committee by email.

Decisions will be:

- Favourable, with no alterations needed (may include requests for minor changes not requiring resubmission).
- Favourable with conditions (Conditional). Feedback will be returned to the investigators. Investigators will have 30 days after receiving the comments to respond. If investigators do not respond to the comments within 30 days, the decision will change to unfavourable. Extensions and reminders regarding the 30 day deadline will be provided.
- Provisional, further details required for review to be undertaken.
- Unfavourable.

Studies must not be undertaken without a favourable ethics review having been confirmed.

11. RETROSPECTIVE REVIEW

The Sub-Committee and its Sub-Groups cannot give a retrospective favourable decision for studies which have already been conducted or have already commenced.

12. AMENDMENTS

For submissions made through LEON, amendments to studies must be submitted using the relevant amendment form. Copies of any revised documentation must also be attached.

For submissions which fall outside LEON and are made in writing to the Sub-Committee, amendments must be submitted in writing by email to the Secretary of the Sub-Committee.

13. ADVERSE EVENTS

Adverse Events arising during studies must be reported to the Secretary of the Sub-Committee using the relevant form in LEON or in writing.

14. FINAL REPORTS

Final reports for studies submitted through LEON must be submitted using the relevant form in LEON.