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## 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

1<sup>st</sup> of Month  
Submit Signature  
Requests to School





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-C (m)-9.4 (e)4.9 (n)-0.8 (t)-5.9 (s)-40.7 (l)-0.7 (6 (v)-fTs) (P)-3.7Td( (m(R)0.5 (EV)2.8 (l2 0 Td(30)11 ( d)7.2 (a)4.

### 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.