ETHICS REVIEW SUB-COMMITTEE

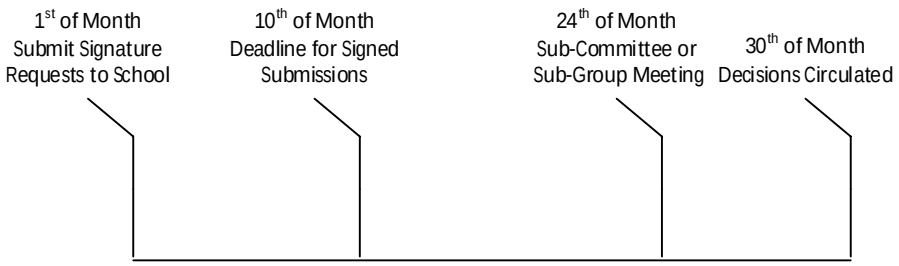
STANDARD OPERATING PROCEDURE

SUBMISSION FOR ETHICS REVIEW

Version History

Effective Date:

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



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.

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.

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13. ADVERSE EVENTS

Adverse Events arising during studies must be reported to the Secretary of the Sub-