

ETHICS REVIEW SUB-COMMITTEE STANDARD OPERATING PROCEDURE

ETHICS REVIEW SUB-COMMITTEE AND ETHICS REVIEW SUB-GROUPS PROCEDURES

Version History

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1. INTRODUCTION

This Standard Operating Procedure (SOP) describes the operation of the Loughborough University Ethics Review Sub-Committee and its Sub-Groups.

2. SCOPE

This SOP applies to the operation of the Ethics Review Sub-Committee and its Sub-Groups.

3. PRINCIPLES

The following principles relate specifically to the conduct of the Sub-Committee rather than the ethics of the research which the Sub-Committee and its Sub-Groups are designed to review.

3.1 Independence

The Ethics Review Sub-Committee will operate free from conflicts of interest so that the application of ethics principles and reasoning is neither impeded nor compromised.

- The Ethics Review Sub-Committee will include members from a range of disciplines, non-academic members and external lay members.
- The Ethics Review Sub-Committee has the freedom to make ethics judgements and issue opinions on submissions that are consistent with legal, policy and human rights standards.
- The Sub-Committee will maintain its objectivity and avoid bias and conflicts of interest.

- The Ethics Committee has oversight for the maintenance of consistent research ethics standards, monitors performance and manages appeals against Sub-Committee decisions.

3.2 Competence

Ethics review processes will be consistent, coherent and well-informed.

- The Ethics Review Sub-Committee will include members from each academic School.
- Contributing to ethics review processes and membership of the Sub-Committee is accepted and recognised institutional work.
- Standard operating procedures and Sub-Committee processes will be established and reviewed annually.
- Regular training for Sub-Committee members drawing on national and international developments in research ethics will be provided to ensure support for new and emerging research areas.

3.3 Facilitation

Facilitation of ethically sound research is the priority for ethics review processes.

- Procedures will balance duties of care with enabling and supporting ethical research and innovation.
- Training and guidance will be provided for researchers in ethics issues and the policies and procedures of ethics review.
- Ethics review will be conducted within defined timeframes and with proportionality of review.
- Ethics review forms will be clear and request only necessary details. Templates for routinely used documents and guidance will be provided.
- Informal advice on ethics issues will be available through Sub-Committee members or Research Governance administrators.

3.4 Transparency and Accountability

Decisions and advice will be open to scrutiny and responsibilities will be discharged consistently.

- Clear public statements of policies and processes for maintaining high standards of research ethics are available:
 - Code of Practice for Research
 - Ethical Policy Framework
 - Code of Practice on Investigations involving Human Participants
- The Secretary of the Sub-Committee is the primary contact for research ethics.
- Consistent records are maintained of ethics review and support processes and these are publicly available where appropriate.
- Annual reports are submitted to the Ethics Committee giving details of the Sub-Committee's performance.

4. Composition

The Composition of the Ethics Review Sub-Committee will reflect a broad range of expertise and experience from across the University.

- The Chair - a senior member of academic staff and is appointed by Ethics Committee.
- Deputy Chair(s) (appointed by the Sub-Committee from the School Representatives).
- Representatives from each of the Schools of the University.
- Students Union Representative
- Health Safety and Environmental Officer
- Up to 4 co-opted members
- Up to 2 lay members

Regularly in attendance: A member of the Research & Innovation Office

The Ethics Review Sub-Groups will be comprised from the Chair and School Representatives. The Sub-Group Chairs will be either the Chair or Deputy Chair(s) of the Sub-Committee.

The current membership will be available on the Sub-Committee's website.

5. Terms of Office

The Chair will be appointed by the Ethics Committee for an initial term of three years. They will be eligible for re-appointment on a consecutive basis twice only, so that the maximum period of continuous service for such a member will be nine years, after which the Chair will not be eligible for re-appointment until the expiration of one year after the end of their term of office.

Deputy Chair(s) of the Sub-Committee will be appointed by the Ethics Review Sub-Committee for an initial term of three years from the School Representatives. They will be eligible for re-appointment on a consecutive basis twice only, so that the maximum period of continuous service for such a member will be nine years, after which the Deputy Chair will not be eligible for re-appointment until the expiration of one year after the end of their term of office.

The Chair and/or Deputy Chair(s) will chair the Sub-Groups.

School Representatives will usually be appointed for an initial term of three years. They will be eligible for re-appointment on a consecutive basis twice only, so that the maximum period of continuous service for such a member will be nine years, after which the member will not be eligible for re-appointment until the expiration of one year after the end of their term of office.

The Health Safety and Environment Officer term is not limited.

The Student Union Representative is appointed annually by the Student Union.

Co-opted members can hold office, under normal circumstances, initially for three years and will be eligible for re-appointment twice only, so that the maximum period of continuous service will be nine years, after which such a member cannot be eligible for co-option until the expiration of one year from the end of their term of office.

Lay members, will be appointed who can bring an independent perspective to the work of the Sub-Committee, are not currently involved in medical or scientific research linked to the University and who are preferably from the local Leicestershire community. These are honorary positions for three years initially and will be eligible for re-appointment twice only, so that the maximum period of

continuous service will be nine years, after which such a member cannot be eligible for membership until the expiration of one year from the end of their term of office.

6. Training

Training will be provided for members of the Sub-Committee to ensure adequate expertise for supporting new and emerging research areas. The aim of the training is to enable Sub-Committee members to conduct thorough and consistent ethics scrutiny of all types of research.

7. Meetings

The Sub-Committee will meet three times a year to discuss ethical issues and consider proposals. There shall be a quorum at the Sub-Committee meeting when at least five members are present.

The Sub-Groups will meet each month (when the Sub-Committee does not meet) to discuss proposals relating to investigations involving human participants. There shall be a quorum at the Sub-Group meetings when at least three members are present.

Dates of meetings will be available on the Sub-Committee's website.

8. Annual Reports

The Sub-Committee will submit an annual report to the Ethics Committee and Health, Safety and Environmental Committee which will include a summary of all proposals reviewed, the type of review and opinions given, including time taken to complete the review.

The Sub-Groups will submit reports three times a year to the Sub-Committee meeting.