ETHICS REVIEW SUB-COMMITTEE

STANDARD OPERATING PROCEDURE

ETHICS REVIEW PROCESSES

Version History

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1. INTRODUCTION

This Standard Operating Procedure (SOP) describes the process that Loughborough University Ethics Review Sub-Committee and its Sub-Groups will follow when conducting ethics review of submissions.

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 must be made in accordance with the standard operating procedure for Submission for Ethics Review.

Guidance on completion is available through the Sub-Committee website, by contacting the Secretary or through the relevant School representative. Details of School representatives are available on the Sub-Committee website. Students must discuss their submission with their project supervisor in the first instance.

4. REVIEW

4.1 HUMAN PARTICIPANTS

The Sub-Committee operates a proportionate review system for studies involving human participants.

4.1.1 CHECKLIST (LOW ETHICAL RISK)

Human Participant studies which do not raise ethical concerns in Section A or Section B of the Ethics Review Form will receive a favourable decision once signed off by the relevant signatories.

A selection of these projects will be reviewed to ensure compliance with ethical processes. These will be reported to Schools if the appropriate processes have not been followed.

4.1.2 CHECKLIST+ (MEDIUM ETHICAL RISK)

An administrative review of studies that raise ethical concerns in Section B will be conducted by the Research Governance administrators in the first instance using the following criteria:

- For participants who are under the direct authority of investigators - has the applicant demonstrated an understanding of the risk of coercion and taken appropriate measures to mitigate this risk.
- For studies involving any incentives, reimbursements or payments being offered to the participants – is the incentive proportionate to the nature of the study. Could it be coercive. Is it a randomised prize or based on time commitment to the study. Is it clear that it is being paid pro-rata.
- For studies involving incentives, reimbursements or payments (additional to salary) being offered to the investigators to conduct the study or studies where investigators stand to gain from particular conclusions of the study – has this been explained to participants.
- For studies involving testing of new non-medical equipment/product/prototype – have the risks to participants been considered, have participants been appropriately informed about the nature of the testing, are there any factors which should have instigated an enhanced proposal.
- For studies involving working alone with participants or visiting them at home which conflict with the guidance and recommendations given in the Guidance Note on Conducting Interviews off Campus and Working Alone – have applicants understood the guidance and explained the reasons for not complying. Has this been clearly justified, and risks appropriately mitigated?
- For studies involving administrative or secure data that requires permission from the appropriate authorities before use – has appropriate permission been obtained from the data owner.
- For studies involving collecting personal information or sensitive personal information using assumed or opt-out consent – have investigators understood the consent process for collecting personal information. Is there a reasonable justification for the proposed consent process.
- For studies involving storage of data and personal information which is not in accordance with Data Protection legislation or the Guidance Note on Data Collection and Storage – is there a justifiable reason for this response.
- The studies involving the use of bodily samples previously collected with consent for further research – are investigators following the appropriate Human Tissue Act Licence procedures. Have the samples been appropriately sourced.
- For studies involving participants being identifiable in the resulting outcomes – is this clear within the participant information and is there an appropriate process for verifying attributed material. Has this been included in the Informed Consent Form.

Submissions may be returned for further clarification.

If the ethical concerns have been addressed in the additional comments and supporting documents a favourable opinion will be issued by the Research Governance administrators on behalf of the Sub-Committee.

For studies raising ethical concerns, submissions will be referred to the Chair in the first instance. Applicants may be asked to amend their responses to Section A to provide further information to the Ethics Review Sub-Committee for review.

4.1.3 ENHANCED (HIGH ETHICAL RISK, INCLUDING NEW GENERIC PROTOCOL PROPOSALS)

Applications which raise issues in the Section A checklist, or new Generic Protocols, 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.

4.2 STUDIES INVOLVING ANIMALS, ANIMAL CELLS OR TISSUES

Studies involving Animals, Animal Cells or Tissues will be considered by the Sub-Committee at its next available meeting or by online review if they are urgent.

Investigators should note that the University does not hold a Licence to conduct research which would be covered by the Animals (Scientific Procedures) Act 1986.

4.3 STUDIES INVOLVING SECURITY SENSITIVE MATERIAL

Studies involving Security Sensitive Materials will be considered by the Sub-Committee at its next available meeting or by online review if they are urgent.

4.4. OTHER SUBMISSIONS

Other studies raising ethical concerns will be considered by the Sub-Committee at its next available meeting or by online review if they are urgent.

5. PRINCIPLES

The Sub-Committee will apply the 'Belmont Principles' to the review of submissions:

- Respect for persons (and their autonomy) – studies should acknowledge the dignity and autonomy of individuals and give special protection to those with diminished autonomy. Participants must be fully informed of the purpose and intended use of the study, what their involvement requires and details of risks (unless explicit agreement otherwise is given, for instance in studies that involve deception). Consent must be given freely and with the ability to withdraw without adverse consequences.

- Beneficence – any risk of adverse effect, directly or indirectly, must be outweighed by the benefits.

- Non-maleficence – the design of the study and any risks and benefits must be examined carefully and, in some cases, alternative ways of obtaining the benefits must be considered.

- Distributive justice - ensuring benefits and burdens are shared equitably. Participants must be treated fairly, and care taken to ensure certain groups are not excluded unless this is academically or ethically justified. Unless there is careful justification research must not involve groups that are unlikely to benefit from the applications of the research.

6. ETHICAL CONSIDERATIONS

The Sub-Committee and its Sub-Groups will focus the review of the proposals on matters of ethics. These include:

- Does the study conform to the University's ethical values as stated in the Ethical Policy Framework.
- Does the proposal demonstrate respect for all life.
- Does the proposal explain the social or scientific value of the study; is the scientific design and conduct of the study clear – including public involvement.
- Are there appropriate recruitment arrangements and fair research participant selection.
  - Is the use of incentives appropriate.
  - Is there an appropriate inclusion/exclusion criteria (e.g. is there a justification for the participant group selected, is health screening being undertaken).
- Is there a favourable risk benefit ratio; anticipated benefits/ risks for research participants (present and future); recognising that innovative research may require taking risks.
- Does the proposal demonstrate care and protection of research participants; respect for potential and enrolled research participants' welfare and dignity.
  - Is appropriate support provided for participants
  - Does the study require review under the Mental Capacity Act
  - Is the consent/assent process appropriate for vulnerable participants.
- Does the proposal explain the informed consent process and demonstrate the adequacy and completeness of research participant information.
  - Is the Informed Consent process appropriate
  - Is there an appropriate re-consenting process where participants have been deceived
  - Is the participant given sufficient detail to give informed consent
  - Is the documentation appropriate to the participant group.
- Does the proposal explain the suitability (in terms of experience and skills) of the applicant, responsible investigator and other investigators.
  - Is sufficient information provided on the previous experience of investigators.
  - Have the risks to the investigators been considered and addressed.
- Does the proposal explain the suitability of the location
  - Have local ethics reviews been obtained for studies conducted overseas.
  - Are local support networks in place for studies conducted overseas.
  - Have risks been appropriately considered.

7. EXPERT GUIDANCE

The Sub-Committee may seek expert guidance or advice on submissions in the event of failure to agree. Such requests for additional information will be referred to the relevant Dean. The updated submission must then be returned to the Sub-Committee for further review.

8. AREAS OUTSIDE OF REVIEW PROCESS

The following areas are outside of the ethics review process:

- The Sub-Committee will not review matters of methodology and design unless they raise ethical issues such as exposing participants to avoidable risks and burdens.

- The Sub-Committee will not provide a proof reading service unless participant documents are so badly constructed that they do not serve the ethical purpose for which they are designed.
- The Sub-Committee does not provide legal or policy review.
- The Sub-Committee does not review compliance with internal or external policy.
- The Sub-Committee does not review the contents of risk assessments. This is the responsibility of the relevant School.
- The Sub-Committee will not assess compliance with data protection legislation. It is the responsibility of the investigators to confirm compliance.

9. APPEALS

Appeals can be submitted to the Ethics Committee on the grounds that:

- There were procedural irregularities in the review of the proposal.
- There is evidence of prejudice or bias against the investigators on the part of the Sub-Committee or its Sub-Groups.

Appeals must be submitted within 10 working days of receiving the decision from the Sub-Committee or its Sub-Groups.