Code of Practice on Investigations Involving Human Participants

Introduction

Investigations on human beings are governed by a number of codes and guidelines such as those issued by the World Medical Association (The Declaration of Helsinki, 1964; revised 1975) and of the Medical Research Council. A number of professional associations and learned societies have issued statements of ethical principles to guide their members, amongst them the British Psychological Society and the British Sociological Association, and many institutions where investigations involving human participants are carried out have formulated codes of practice to provide more detailed guidance for their staff involved in such activity. It is now commonplace for ethical committees to have been established to oversee the ethical conduct of investigations involving human participants and to consider individual proposals. Indeed, an increasing number of Research Councils require ethical consideration of projects prior to making a grant award.

Investigations involving human participants are undertaken within Schools at Loughborough University in the course of teaching, enterprise and research. The University seeks to ensure that the conduct of all its staff and students carrying out such work, whether human biological, psychological or sociological, conforms to accepted professional standards and is known to do so and that visiting investigators carrying out investigations on campus conform to the relevant sections of the University's Code of Practice. The University **Ethics Committee**, which looks at all aspects of ethical conduct at the University delegates responsibility for investigations on Human Participants to the **Ethics Review Sub-Committee**. The Sub-Committee's remit is to guide and assist investigators and ensure that full consideration is given to the dignity, safety and well-being of all participants taking part and that the rights of the participants are protected. A favourable ethical opinion from the Sub-Committee is required before any investigation involving human participants can commence. Investigators are expected to work within the spirit of this Code of Practice and the University's Ethical Policy Framework.

This Code of Practice was initially approved by Senate on 22 July 1988 and by Council on 6 July 1988, and revised by Senate on 11 March 1992. It was further revised by the Ethical Advisory Committee in May 2003 and approved by Senate on 25 June 2003 and Council on 15 July 2003. It was further revised due to changes in the University ethics structure on 31 July 2012 and approved by the Loughborough University Ethics Committee on 18 June 2012. The current version was approved by the Ethics Committee on 25 May 2021.

1. Ethics Review Sub-Committee

The Ethics Review Sub-Committee website gives details of the current membership, remit, meeting dates and submission deadlines.

The Sub-Committee has published the following **Standard Operating Procedures** setting out how it conducts ethics review of submissions.

1.1 Ethics Review Sub-Committee and Ethics Review Sub-Groups Procedures

This Standard Operating Procedure sets out the principles by which the Sub-Committee will operate, the composition and terms of office for Sub-Committee members and the meeting schedule.

1.2 Ethical Review Processes

This Standard Operating Procedure describes the process that the Ethics Review Sub-Committee and its Sub-Groups will follow when conducting ethical review of submissions.

1.3 Submission for Ethical Review

This Standard Operating Procedure describes the process for submitting requests for ethical review to the Ethics Review Sub-Committee or its Sub-Groups.

2. Decisions

Decisions from the Ethics Review Sub-Committee and its Sub-Groups will be:

- Favourable (may include requests for minor changes not requiring re-submission).
- Favourable with conditions (Conditional). Feedback will be returned to the investigators. Investigators will have 30 working days after receiving the comments to submit a response. If investigators do not respond to the comments within 30 working days, the decision will change to unfavourable. Extensions and reminders regarding the deadline will be provided.
- Provisional, further details required for review to be undertaken.
- Unfavourable.

Studies must not be undertaken without a favourable ethical review having been confirmed. Favourable opinions can be withdrawn, and research studies halted, if ethical issues arise during the progress of the study until these concerns have been addressed.

3. Scope of the Code

3.1 Context of investigation

All investigations involving human participants fall within the scope of the Code and must conform with the appropriate University and/or external guidelines. This includes, but is not limited to, research investigations, teaching experiments/demonstrations/investigations, student projects, surveys and questionnaires.

Details of investigations involving human participants must be submitted to the Ethics Review Sub-Committee through the online ethics system, Loughborough Ethics Online (LEON).

All investigators are responsible for familiarising themselves with the appropriate external guidelines for their own discipline/area of research.

3.2 Investigations conducted off campus

Loughborough University staff or students who wish to carry out investigations involving human participants at premises other than those of the University will be expected to obtain a favourable decision or written permission from any collaborating organisation as well as from the Ethics Review Sub-Committee. Where collaborating organisations have their own ethics committees their review may be accepted by the Ethics Review Sub-Committee in lieu of a separate submission. Details must be submitted through LEON for review to confirm that they meet the Sub-Committee's requirements.

3.3 Visiting investigators

Investigators from outside the University who wish to carry out investigations involving human participants in the University will be expected to conform to the relevant sections of the University's Code of Practice and, as appropriate, submit their proposals through the Dean of a University School to the Ethics Review Sub-Committee for review.

3.4 Ethics Review from External Bodies

Where ethical review has been obtained from external bodies, such as an NHS Research Ethics Committee, Social Care Research Ethics Committee, MODREC, another University etc, a separate application to the Sub-Committee may not be required. A copy of the external decision must be submitted through LEON for review. The Secretary will confirm whether this can be accepted instead of requiring a separate submission.

3.5 Retrospective Review

The Ethics Review Sub-Committee cannot give a retrospective ethical opinion for studies which have already been conducted or have already commenced. Please refer to the University's Research Misconduct Policy.

3.6 Exclusions from Code

The code does not apply to:

- procedures undertaken as part of NHS patient-care which are expected to contribute to the benefit of the individual participant. Advice must be sought from the relevant NHS body.
- research which involves working only from anonymous historical data and/or literary databases and documents and does not involve working with 'live' participants
- experimentation and anatomical examination in human morbid anatomy. This is strictly controlled by the 1984 Anatomy Act, under licence from the Secretary of State for Social Services and therefore falls outside the scope of the Code. Staff and students are advised that it is an offence to carry out dissection or experimentation on cadavers outside the control of a Licensed Teacher of Anatomy or in unlicensed premises.
- experimentation on animals which is covered by a separate ethics review process. This is strictly regulated by the Home Office under the provisions of the Animals (Scientific Procedures) Act 1986 and also falls outside the scope of the Code. Staff are advised that it is an offence to carry out scientific work controlled by the Act without the appropriate licence or certificate.
- Patient and Public Involvement (PPI) events undertaken as part of the design of a study do not require ethical review providing it does not involve increased risk to participants, vulnerable participants or invasive procedures.
- Service evaluation/Audit and Operational Activities carried out in the course of the University's business (e.g. the Staff Survey, module feedback from students, experiments of new operational processes etc.) do not require ethical review.
- Peer feedback or feedback from tutors/technicians/technical experts on students' academic work as part of a teaching activity or coursework does not need ethical review. (Formal collection of study data from peers is not excluded.)

4. Submission of Proposals

Submissions for review of investigations involving human participants must be made using the online ethics system, Loughborough Ethics Online (LEON).

Details of the system, including guidance notes and demonstration video, are available on the LEON website.

5. Generic Protocols

The Ethics Review 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 under the direction of the Responsible Investigator.

Individuals wishing to use the protocol who are not named on the submission document must apply to a named investigator for permission to practise the generic procedure. It will be the responsibility of the named investigator to ensure that such individuals are fully competent to use the protocol before permission is given. The names of individuals cleared through this procedure must be added to the list of investigators in the copies of the protocol document held by both the School concerned and the Sub-Committee Secretary or through LEON.

Investigators wishing to use generic protocols in combination, rather than as isolated techniques, must seek clearance from the Sub-Committee.

6. Module Review

The Ethics Review Sub-Committee will consider submissions from academic staff for module level review where students complete low-risk studies. Module applications can be made when students taking the module will all be conducting the same type of low-risk research, and using the same broad methods and procedures. This will usually apply to part A and B modules, e.g. research methods modules. The Sub-Committee will not review separate submissions from each student on the module.

Students undertaking distinct research projects (e.g. dissertations), or whose plans deviate significantly from the module review submission, must each submit their own submission.

7. Supervision

It is essential that early career researchers and students acting as investigators are under the supervision of a senior researcher/member of academic staff. It is the responsibility of the supervisor to see that the early career researchers/students are aware of the relevant guidelines and to ensure that they are supervised and that investigations are carried out within the spirit of this Code of Practice and the University's Ethical Policy Framework.

In the case of student projects, the student's project supervisor will be the Responsible Investigator for the study. The Ethics Review Sub-Committee expects supervisors/responsible investigators to take responsibility for submitting details of proposed investigations for review.

8. Supporting Documents

Relevant supporting documents must be provided with the submission for ethical review in LEON. Templates for supporting documents, including Participant Information Sheet, Informed Consent Form, Assent Form etc., are available through

LEON, in the Templates section under the Help tab at the top of the LEON Homepage.

8.1 Participant Information Sheets (or online equivalent)

The Participant Information Sheet should give a clear description of the study to participants which will allow them to provide fully informed consent to take part. Investigators must give each participant full details of the nature, purpose and duration of the proposed investigation in a form that is readily understood (this may be written or verbal depending on the targeted participants). The participant must be informed clearly about the investigation and what it will involve and whether any discomfort or inconvenience is likely to be entailed during the investigation or afterwards. Investigators must also provide information and advice about any foreseeable risks to health to which participants may be exposed. Details on how long data and/or samples will be retained must be included. It is good practice to offer participants the opportunity for a familiarisation visit to the location of the study, to have procedures demonstrated and/or inspect/test equipment before the commencement of the investigation. This ensures that participants are fully informed about what will happen during the investigation.

Participants must be given sufficient time to consider the Participant Information Sheet before being asked to give their consent. For studies involving invasive measures or physical activity this must be at least 24 hours.

Simplified Information Sheets must be provided for children under the age of 18. These must be written and presented in a format that is accessible to children and appropriate to the range of ages involved in the study.

8.2 Informed Consent Form (or online equivalent)

The fully informed and voluntary consent of the participant must be obtained before the investigation begins; that is to say, consent freely given with proper understanding of the nature and consequences of what is proposed. In the cases of participants under the age of 18, or with some other potentially vulnerable groups, it may be necessary to obtain consent from the parent/guardian or carer.

The Ethics Review Sub-Committee has produced a template Informed Consent Form which can be used/adapted by all investigators.

Written consent may be dispensed with only with the agreement of the Ethics Review Sub-Committee.

Online Questionnaires must include a consent section so that participants can confirm their willingness to take part in the study. Consent cannot be assumed by completion of the questionnaire or by selecting ‘next’ to continue the questionnaire. The consent section should list the relevant clauses from the Informed Consent template, but it is not necessary for each clause to be initialled. We recommend that there should be one box for participants to tick confirming their consent to take part in the study.

8.3 Risk Assessment

All studies require the completion of a risk assessment which must be included with the proposal. Templates and examples are available in the Templates section on LEON.

8.4 Other Documents

Any other documents being used during the study must be provided with the proposal such as copies of questionnaires, draft interview questions, assent forms for children, posters.

9. Participants

9.1 Recruitment of Participants

The recruitment of participants must wherever possible be via a notice, or, if verbally, through a group approach rather than to individuals. Recruitment notices must clearly explain the scientific purpose of the research and details of what participants can expect if they agree to participate.

Staff or students of the School concerned may be invited to volunteer to take part, but special consideration must be given to the motives that might prompt them to volunteer. It is not normally desirable for students in close contact with a member of staff acting as investigator to be recruited, as they may feel vulnerable to pressure from someone in a position to influence their careers. On the other hand, it is normally reasonable for students to be recruited to take part in teaching exercises where one of the primary objectives is to enable them to make their own observations.

9.2 Vulnerable Groups

Recruitment from vulnerable groups may raise ethical issues which require special consideration. Vulnerable individuals include, but are not limited to, those who lack capacity under the Mental Capacity Act (see above), people detained under the Mental Health Act, those in carer homes, prisoners, and people under the age of 18. It may be necessary in some cases to approach the legal authority or individual with legal responsibility for the participant to obtain consent. Special care must be taken in considering investigations involving vulnerable participants. Women of childbearing potential must not be recruited for any study which could be harmful to pregnancy.

Participants must be considered vulnerable if they are likely to be distressed by the nature of the study or may feel coerced into taking part.

The Ethics Review Sub-Committee has produced guidance on Research with Children and Young People. Investigators are advised to read the guidance carefully before embarking upon a research project which involves participants under the age of 18. Participants under the age of 18 are considered children and parental consent is required. Opt-out consent can only be considered in low risk studies and requires review by the Sub-Committee. Investigators must also give careful consideration to ensuring that study documentation is appropriate to

the age of the participants. Investigators must read the University's guidance to establish whether or not they need to seek Disclosure and Barring Service (formerly CRB) clearance.

9.3 Deception

It is recognised that some studies involve deception of the participant and would be invalid if this were not so. If deception is considered necessary in a study, it must not involve the participant in any risk, such as unexpected anxiety or distress, lowering of self-esteem, or any form of long-term psychological or physical harm. There must be no deception that might affect a person's willingness to participate in an investigation, nor about the possible risks involved.

Where deception is necessary, participants must normally be debriefed immediately following the completion of their participation as a matter of course and this must be designed into the experimental procedure. Participants must be debriefed on the true nature of the study as soon as is possible and must be re-consented.

9.4 Inclusion/Exclusion criteria

It is essential that the Ethics Review Sub-Committee is given full details of the basis for the selection of participants including any inclusion/exclusion criteria. Particular care must be taken to exclude participants who suffer from physical, physiological or emotional conditions which could be affected/aggravated by the proposed procedures. Submissions must include any questionnaire which will be used in the selection process.

Where appropriate, for example, in studies involving physical activity or invasive procedures, participants must be asked about their previous medical history and be given advice on the relation of this to the proposed study. Investigators must note that such health information is considered sensitive personal information under data protection regulations. If necessary, participant's should be given sufficient time to allow them to consult their doctor before they agree to participate in the investigation. A generic Health Screen Questionnaire is available in the Templates section on LEON and investigators must modify this (i.e. add or remove questions) to suit their individual study. Participants must be asked to give permission for the investigator to contact their doctor for studies that may involve incidental findings.

9.5 Incidental Findings

Investigators have a duty of care to participants. When planning research, investigators must consider what, if any, arrangements are needed to inform participants (or those legally responsible for the participants) of any health related (or other) problems previously unrecognised in the participant. This is particularly important if it is believed that by not doing so the participants well-being is endangered. Investigators must consider whether or not it is appropriate to recommend that participants (or those legally responsible for the participants) seek qualified professional advice, but must not offer this advice personally.

In studies where incidental findings are possible, for example, studies involving blood tests or MRI scans, investigators must request permission to inform the participant's GP of incidental findings before the start of the study. GP details must be collected for this purpose from participants before they commence the study.

9.6 Minimising Risks to Participants

Investigations involving human participants must not involve more than minimal risk to their physical or mental well-being. All risks must be measured/weighed against the scientific benefit of the study. All risks must be fully explained to participants, including precautions taken to minimise those risks.

In certain circumstances, to minimise risk, the Ethics Review Sub-Committee may require that a person with suitable medical qualifications must be responsible for an investigation or in attendance when certain procedures are carried out, or that facilities for emergency medical care must be at hand. Where appropriate, safeguards regarding communicable diseases must be taken to protect the participant, the investigator and others involved in the work.

9.7 Withdrawal from Investigations

Participants must be free to withdraw from the investigation at any stage, without having to give any reasons or completing additional forms and must be told they have this right. However, an opportunity must be provided in this event for participants to discuss privately their decision to withdraw if they want to provide details.

It is recognised that it may not always be possible to disaggregate data from the study once it has been anonymised and this must be clearly explained to participants at an early stage.

9.8 Coercion

Where investigators are in a position of authority over participants, e.g. if they are students on a module taught by the investigator, team members being recruited by their coach or school pupils recruited by their teacher, they must be assured that their participation is entirely voluntary and that they are free to withdraw at any point. Their decision on whether to take part should not have any impact on their future prospects, team selection or progression.

9. Specific Considerations

9.1 University class teaching experiments and demonstrations

Undergraduate or postgraduate students may be invited to participate in experiments or studies as a normal part of their programme, provided:

- that they have the right to decline to participate in a particular procedure or, having accepted, to withdraw at any time;
- that they are assured that neither declining nor agreeing to participate in a particular procedure will affect their academic assessment in any way;

- that no coercion, actual or implied, or any financial inducement must be used to persuade students to participate.

9.2 Drug Studies and Experimental Medical Devices

Drug studies involving human participants, involving new chemical entities or new combinations of drugs, and/or testing of experimental medical devices, will need to be reviewed via the Health Research Authority and NHS Research Ethics Committees. Drug trials are strictly regulated by the MHRA and the University must obtain the appropriate licencing before any study of this nature can be carried out.

In the case of prescription drugs (i.e. not available over the counter), investigators must consult the checklist developed by the Ethics Review Sub-Committee: Guidance Note on Pharmaceutical Drugs

9.3 Investigations involving contact with Human Body Fluids

All proposals for investigations involving contact with human body fluids must adhere to the guidance drawn up by the Health Safety Office.

9.4 Investigations involving Human Tissue Act Relevant Material

All investigations involving 'relevant material' under the Human Tissue Act 2004 must refer to the University HTA Licence Compliance Quality Manual.

Details of the storage and retention of samples must be included in the Participant Information Sheet and the Informed Consent Form.

9.5 Investigations involving the use of Ionising Radiation (e.g. x-rays)

All investigators seeking review of proposals involving the use of Ionising Radiation (e.g. x-rays) must contact the University Radiological Protection Officer for advice and must follow the guidance on Exposure to Ionising Radiation: Guidance Notes on Ionising Radiation, as drawn up by the Ethics Review Sub-Committee, and must make reference to this guidance within the submission form.

Investigations will need to be reviewed via the Health Research Authority and NHS Research Ethics Committees.

9.6 Investigations involving the use of Hazardous Substances

All investigators seeking review of proposals involving the use of hazardous substances must contact the Health and Safety Office for advice and must follow the Guidance on Hazardous Substances, as drawn up by the Ethics Review Sub-Committee, and must make reference to this guidance within the submission form.

9.7 Investigations under the Mental Capacity Act 2005

The research provisions in the Mental Capacity Act apply in England and Wales to anyone over the age of 16 years old who lacks the capacity to give or withhold their consent to participate in a study. Fundamentally a person must be assumed

to have capacity unless established otherwise. A person is unable to make a decision if s/he is unable to:

- understand the information relevant to the decision,
- retain that information,
- use, or weigh up, that information in the process of coming to a decision, or
- communicate the decision (by any means).

Studies involving participants who are 'lacking capacity' e.g. who are unable to give consent under the Mental Capacity Act 2005, require approval from the National Social Care REC. The Social Care REC is recognised by the Secretary of State as an 'appropriate body' for this purpose. University Research Ethics Committees are **not** recognised as appropriate bodies under the terms of the Act.

9.8 Research outside the UK

Researchers must be mindful of the different civil, legal, financial and cultural conditions when working overseas, or conducting research involving participants who are located overseas, and are expected to refer to international guidelines and conform to relevant local regulations for the country or countries where the research is taking place.

Where necessary researchers working overseas must obtain local ethical review in addition to a favourable decision from Loughborough University when conducting research overseas involving human participants. Where a local ethics committee does not exist, permission from any organisation or location where the research will be conducted must be sought in addition to a favourable decision from Loughborough University.

It is expected that the research will comply with Loughborough University's research ethics policies and guidelines as well as other relevant policies and procedures.

9.9 Location of Investigation

The locations of investigations involving human participants must be appropriate to the type of study and the risk involved. The Ethics Review Sub-Committee may, at its discretion, request an inspection of the premises concerned.

9.10 New Equipment

Investigations involving testing new equipment on human participants must be undertaken in an appropriate location and a full risk analysis conducted to ensure that appropriate medical assistance is available if required. The Ethics Review Sub-Committee may, at its discretion, request an inspection and/or demonstration of the new equipment before the commencement of the investigation.

9.11 Incentives

There must be no excessive financial inducement that may cause coercion, actual or implied, and that might persuade people to take part in an investigation against their better judgement. Any payment made to volunteers must be for expenses, time, inconvenience or discomfort and never for hazard to the person. All payments to participants, in the form of cash, vouchers, merchandise or entry into prize draws, must be reviewed by the Ethics Review Sub-Committee. For further details please see the guidance on Incentives.

9.12 Data Protection Legislation and Confidentiality

There must be an acknowledged obligation to protect the participants from possible harm and to preserve their right to privacy. The confidentiality of the participants personal information must be maintained and the investigator's intentions in the matter of confidentiality must be made known to the participants. A full research proposal must be submitted for studies which intend to reveal the names or identifiable personal information of participants. Any investigator intending to process personal data must be aware of and comply with the provisions of the Data Protection legislation.

The University's Data Protection Policy can be found on the University's Data Protection Policy webpages. The Ethics Review Sub-Committee has issued specific guidance to help investigators to comply with the requirements of the Data Protection Act which can be found at: Guidance on Compliance with Data Protection

10. Insurance

The University maintains in force a Public Liability Policy, which indemnifies it against its legal liability for accidental injury to persons (other than its employees) and for accidental damage to the property of others. Any unavoidable injury or damage therefore falls outside the scope of the policy.

The Insurance relates to claims arising out of all normal activities of the University (see Appendix 1), but Insurers require notification of anything of an unusual nature by submission of an Insurance Questionnaire along with a copy of the research proposal. In particular, where tests on new drugs or equipment are sponsored by an external body, the trials may need to be covered by the insurance policy of the sponsoring organisation rather than the University.

It is the responsibility of the applicant to arrange insurance cover for the project if it falls outside of the scope of the University's Public Liability Policy. Details of such cover must be included in the submission.

Participants must be told their position with regard to insurance cover in the event of an accident, injury, or ill-health befalling them as a result of taking part in the investigation.

11. During the Study

11.1 Adverse Events

Any unusual or unexpected symptoms arising or any significant adverse event affecting a participant during or after an investigation must be communicated promptly with the individual's consent to the participant's own doctor, and to the Ethics Review Sub-Committee using the Adverse Events Report form in LEON. The study must be stopped for the individual concerned and it must be considered whether it is advisable to stop the investigation as a whole.

If a participant withdraws from an investigation, for whatever reason, the investigator must take reasonable steps to find out whether any harm has come to the individual as a result of participation in the study.

11.2 Amendments

A request for review of any changes to the study design or procedures or the addition of investigators must be submitted to the Ethics Review Sub-Committee using the appropriate amendment procedure. Guidance on amendments is available on the LEON website.

11.3 Study End Date/Final Report

The favourable opinion on the study will end on the study end date provided on the Ethics Review Form in LEON. Requests for extensions can be submitted to the Ethics Review Sub-Committee using the amendment form in LEON. Final reports will be requested from selected studies.

11.4 Records of Investigations and Participants

The investigator must keep full records of all procedures carried out in a form appropriate for consultation by the Ethics Review Sub-Committee and keep a register of participants involved.

Appendix 1- Insurance: Normal Activities

Cover is automatic if the research is within the UK & limited to the following normal activities:

i. Questionnaires, interviews, focus groups, physical activity/exercise, psychological activity including CBT;
ii. Venepuncture (withdrawal of blood);
iii. Muscle biopsy;
iv. Measurements or monitoring of physiological processes including scanning;
v. Collections of body secretions by non invasive methods;
vi. Intake of foods or nutrients or variation of diet (other than administration of drugs).

All other Research involving human participants, including studies outside of the UK, should be referred to the Insurance Officer along with the completed **Insurance Questionnaire** to arrange cover - which may incur a charge. Early submission is recommended.