

RESEARCH ETHICS POLICY & REGULATIONS

UNIVERSITY OF LAW POLICY AND REGULATIONS ON STUDIES INVOLVING THE USE OF HUMAN PARTICIPANTS

The University of Law's Research Ethics Policy has been informed by the Office for Students Sector-Recognized Standards and the General Ongoing Conditions of Registration and has regard to the UK Quality Code for Higher Education. These definitive reference points for all English higher education institutions set out how academic standards are established and maintained and how excellence in the quality of learning opportunities is assured.

This policy sits within The University of Law's Quality and Standards Code, which provides a suite of policies designed to safeguard the academic standards of The University of Law and to assure the quality of learning opportunities offered; this policy should therefore be read in conjunction with other relevant policies within the code.

1 SCOPE

- 1.1 This policy and regulations ("the regulations") apply to any study involving the use of Human Participants which is:
- i. part of a programme of work approved by The University of Law; or
 - ii. part of a programme of work approved by another organisation and involving the use of Human Participants who either work for or study at The University of Law.

Human Participants (or human subjects) are defined as living human beings or human data (such as, but not restricted to, medical, financial, personal, criminal, administrative data or scholarly achievements).

- 1.2 Where the relevant programme of work is offered in collaboration with another organization, there is a requirement that these regulations apply.
- 1.3 These regulations apply to all studies falling within the scope of paragraph 1.1, including:
- i. studies conducted at any academic level;
 - ii. studies which include the use of questionnaires and/or interviews conducted either as part of a group or class programme or as individual project work;

- iii studies conducted on University premises or elsewhere.
- 1.6 All University staff, University students and researchers contracted or invited to work within the University are required to comply with these regulations.
- 1.7 The University is responsible for ensuring that students for are made aware of and comply with the University's regulations governing studies involving the use of Human Participants.
- 1.8 The regulations and procedures set out in this document have been approved by the Academic Board.

2 PURPOSE

- 2.1 The purpose of these regulations is to ensure that any study involving the use of Human Participants is conducted in accordance with proper ethical standards.
- 2.2 These standards require that any member of the academic staff responsible for any study involving the use of Human Participants ensures that:
 - i the study is well- designed;
 - ii there is an identifiable objective benefit to be gained from the participation of Human Participants in the study.
- 2.3 In particular, these standards are defined in order to ensure that:
 - i participants are safeguarded against procedures which may be harmful in any way;
 - iii confidentiality is maintained in respect of the identity of those participating in a study and of any personal information which participants may disclose in the course of the study;
 - iv participants understand the nature of the study which is to be undertaken and their involvement in it and have given a free and informed consent to their own participation and that, where participants are minors or otherwise unable to give an informed consent themselves, consent is obtained from a person recognised as having authority to give that consent;
 - v participants are informed that they may withdraw from the study at any time without disadvantage and without having to give a reason; and

- vi where payment is offered, either to an investigator or to a participant, in exchange for their agreement to participate in a study, such payment may compensate a participant for inconvenience or expense but should not constitute an inducement to submit to risk which the investigator or participant would otherwise decline.

3 ETHICAL STANDARDS

- 3.1 In determining the standards which should apply to studies carried out within these regulations, investigators and supervisors are required to observe:
 - i relevant statutory provisions;
 - ii standards laid down by the University itself; and
 - iii any codes of conduct appropriate to the legal or any other profession relevant to the study.

4 COMPLIANCE

- 4.1 The Academic Board has established an Ethics Committee for studies involving the Use of Human Participants, whose responsibility it is to ensure that proper ethical standards are defined and maintained in respect of all studies involving the use of Human Participants.
- 4.2 The adherence to those standards referred to in paragraph 2.2 above, is primarily the responsibility of academic staff devising and/or supervising or supporting particular programmes of study.
- 4.3 The standards referred to in paragraph 2.3 above are the direct responsibility of the Ethics Committee or of any other persons to whom the Ethics Committee delegates responsibility for ethical standards in respect of studies involving the use of Human Participants.
- 4.4 In order to ensure compliance:
 - i each study which involves the use of Human Participants must be covered by a protocol approved through the Ethics Committee;
 - ii The protocol must include the methodology to be applied and the means by which informed consent, *where required*, will be obtained;

- iii any proposed protocol to be approved must be submitted to the Ethics Committee and approved prior to the start of the investigative stage of the study; and
- iv studies with approved protocols must be monitored appropriately.

5 DELEGATED AUTHORITY

- 5.1 Under the authority of the Academic Board, the Ethics Committee may, as it sees fit, delegate its authority to approve or reject proposed protocols.

6. PROCEDURES FOR PROTOCOL APPROVAL

- 6.1 Where application is to be made to the Ethics Committee, the following procedure applies:
- i Form ER2(for internal applicants) or Form ER3(for external applicants) must be completed and submitted by the relevant dissertation or research supervisor to the Ethics Committee in-box at *ethics@law.ac.uk*. Failure to comply with these requirements may lead to delay in approval being granted;
 - ii applicants and their supervisors will be notified that the application has been received and is under consideration.
- 6.2 The outcome of the application by will be notified to the applicant by e-mail, normally within fifteen working days of receipt of the application into the Ethics Committee in-box. Where an application is not approved, the applicant will be given the reasons for non-approval. In appropriate instances, approval may be granted subject to certain conditions.
- 6.3 The applicant, as the investigator, must complete the application form, which must also be approved, by the applicant's supervisor/staff sponsor.
- 6.4 In the case of a classwork exercise or other group study, it is the member of staff responsible for the study who must complete and sign the application form.
- 6.5 Individual protocols will normally be approved for the limited period of time specified on the application. Application may be made for and extension of time.

7. STUDIES INVOLVING HUMAN PARTICIPANTS UNDERTAKEN WITHOUT AN APPROVED PROTOCOL

- 7.1 Studies undertaken without an approved protocol include both:
- i failure to obtain Ethics Committee approval prior to undertaking work involving Human Participants;
 - ii failure to comply with the terms and conditions of an ethics approval granted for undertaking work involving Human Participants.
- 7.2 Any employee of the University who acts in contravention of these regulations will normally be subject to the University's disciplinary procedures.
- 7.3 Any student of the University acting in contravention of these regulations may be penalised in accordance with the University's Student Discipline Policy.
- 7.4 Any researcher working with the University under paragraph 1.1.2 who acts in contravention of these regulations will be informed in writing of the breach and will be asked to provide to the Ethics Committee a written explanation of their conduct in relation to the contravention of the Ethics regulations. The Ethics Committee (with support as appropriate from Academic Registry) will decide the measures deemed necessary with regards to a breach of the regulations. Such measures might include (but are not limited to):
- i notifying other organisations involved in the research of the contravention;
 - ii notifying other employing organisations of the contravention;
 - iii notifying regulatory bodies of the contravention;
 - iv notifying the researcher that the data collected from the use of Human Participants who either work for or study at the University cannot be included in any thesis, dissertation, journal or other publication; and
 - v reviewing or withdrawing their visitor status.

Version history

Version	Amended by	Revision summary	Date
V1.0			March 2018
V1.1	Senior Quality Officer	Change to the document coding convention	30/03/20
V1.2	Head of Quality Assurance	Change the process for submitting documents – from student to supervisor	October 2020