Policy on research ethics

October 2018

Policy on ethical approval for research involving human participants, tissues or personal data

The University is committed to maintaining the highest standards of rigour and integrity in its research. As a component of this commitment, the University requires that all research projects which involve human participants, or their tissues¹, or their personal data² should receive research ethics approval before they commence.

This policy provides a framework to ensure that all research is conducted in accordance with fundamental ethical principles. It applies with equal force to projects undertaken by staff or students of the University in any location, including joint work with third party organisations.

Principles

This policy aims to ensure that University research projects involving human participants, their tissues or their data are carried out safely, with their informed and voluntary consent and with due respect to confidentiality and privacy. Below are the guiding principles that the University expects its researchers to abide by:

- Except where the nature of the research makes this impossible, research staff and
 participants must be fully informed about the purpose, methods, and intended possible uses
 of the research. On the basis of this information they must give their voluntary consent to
 take part in the project, free from coercion.
- The confidentiality of the information supplied by research participants and the anonymity of
 respondents must be respected. Wherever possible data should be anonymised and there
 should be full compliance with the principles within the Data Protection Act 2018. Personal
 data can only be disclosed when permission to disclose is part of the consent procedure.
- Risks to those involved in the research must be minimised, and harm to research participants
 and researchers must be avoided. Participants must be warned in advance about any
 potential risks of harm.
- The independence of the research must be clear, and any conflict of interest or partiality must be explicit.

¹ 'Tissue' includes all <u>relevant material under the Human Tissue Act 2004</u> - as well as nucleic acids; and the requirement for ethical review extends to commercially purchased relevant material

² For a definition of 'personal data', please see Article 4(1) of the General Data Protection Regulation

 The research must conform to all relevant statutory requirements and to the requirements of the institution in which the research is undertaken.

Responsibilities

The Committee on Research Ethics, and its subcommittees, are responsible to the University Council for ensuring that research is conducted in accordance with these principles.

Staff members undertaking research falling within this policy are responsible for:

- consideration of the ethical implications of any research project which involves human participants, human tissue, or personal data;
- obtaining formal ethical approval from the University before the research commences;
- and conducting the research in accordance with these principles.

In the case of research undertaken by undergraduate or postgraduate students, the Supervisor is responsible for ensuring that the above responsibilities are met.

The University regards a failure to meet these responsibilities as a serious matter, which may constitute research misconduct.

Process and Procedure

The University is committed to providing a rigorous and independent process of ethical review that is proportionate to the potential risk. This process includes a range of procedures for specific application types. Further information on the processes for ethical review can be found on the research ethics webpages (requires a University of Liverpool log-in), or by contacting ethics@liverpool.ac.uk.

Training

All students and staff involved in research are required to undertake appropriate training before embarking on an evaluation of the ethical implications of their research. Details of available training can be found on the <u>research ethics webpages</u>.

Adverse events and complaints

Staff should ensure that they are familiar with the procedure for <u>managing adverse events in</u> research.

Audit and quality assurance

The Central University Research Ethics Committees may periodically institute a selective audit of research projects. Where a Central University Committee considers that a study is being conducted in a way which is not in accord with the conditions of its original approval, it may consider withdrawal of its approval and require that the research be suspended or discontinued.

Scope and exemptions

Third parties

This policy applies to staff, students, and anyone else conducting research under the auspices of the University. This includes research in wholly owned subsidiaries and the research undertaken or commissioned by University staff and students while working in a joint venture with a third party³. Research should be interpreted broadly to include all investigation undertaken in order to acquire knowledge and understanding, whether funded or unfunded.

In some cases, as part of their assessed degree course, students are seconded to a third party organisation. During this secondment, they may work on research projects in which the research is directed by that organisation and not the University; and which may involve human participants, human tissues or personal data. The ethical assessment of this research is not covered by this policy. However the relevant Faculty, School or Department of the University who are sponsoring the secondment should obtain formal written reassurance from the organisation hosting the student that it has procedures to ensure that the research will be undertaken in an ethically responsible way.

External research ethics review processes

In some cases, the University will accept the ethical approval granted by other organisations as a substitute for its own procedures. This is most commonly the case for research covered by the

³ The policy only applies to University spin out companies if the University retains a controlling interest. Individual members of the University staff may be directly involved in spin-out companies that are not owned by the University. In these cases they should ensure that their involvement in the work of the company will not compromise the reputation of the University. If in doubt they should seek guidance from the Committee on Research Ethics.

ethical procedures of the National Health Service. Reliance solely on external ethical approval must be explicitly authorised by a subcommittee of the Committee on Research Ethics.

Scientific research involving animals

This policy does not apply to research and testing using animals where a Home Office Licence is required under the Animals (Scientific Procedures) Act 1986.

Contacts

This policy will be regularly reviewed in the light of experience and revisions to codes of practice laid down by any relevant professional or learned society. Any comments should be sent to ethics@liverpool.ac.uk.