

## Annex III: Policy notes

*These notes should be read in conjunction with the University's policy on research ethics ([www.leeds.ac.uk/ethics](http://www.leeds.ac.uk/ethics)). They anticipate some of the key ethical issues which may arise from research, particularly that involving human subjects, tissue or data or the risk of an adverse impact upon the physical environment. Practice on the use of the terms 'subject' and 'participant' varies. Herein, the term 'subject-participant' is employed (in order to preserve the distinction between subject- and researcher-participant) on each first occasion of use, then 'subject' thereafter.*

### 1.0 Introduction

Researchers will need to consider a wide range of issues, many of which will be specific to the discipline or situation in question. They will also need to ensure that they abide by University policy in areas such as health and safety, intellectual property, research integrity, data protection and whistleblowing (links).

The first step is always for the individual researcher or supervisor to consider carefully the potential ethical implications of their work, or that of their students, and members of the University are encouraged to reflect carefully upon the broad range of conceptual, as well as practical, issues that may arise. Individuals then have a responsibility to seek the appropriate advice – see <http://ris.leeds.ac.uk/UoLethicsapplication> - and/ or formal review and approval of the proposed work.

**Projects involving human participants or their data or the risk of significant environmental impact will require review – whether by the University or an external body (such as the Health Research Authority).**

Whilst not an exhaustive list, the following points provide, in no particular order of priority, an indication of ethical issues which may require consideration:

- the balance of risk and benefit;
- the physical and psychological health and safety of subject-participants;
- obtaining informed consent to participate;
- particular arrangements for vulnerable subjects;
- conflicts of interest;
- confidentiality and data protection;
- intellectual property issues;
- funding sources;
- monitoring and audit;
- proportionate and reasonable review.

For the avoidance of doubt, all relevant research proposals must be subject to appropriate review. The University already obtains consent, however, for routine data processing, including sensitive and personal data, from staff and students (see the Code of Practice on Data Protection. In addition, under the terms of the Data Protection Act and the University Code of Practice on Data Protection, the University can process data without consent 'where this is for the legitimate activities of the institution and is not to the detriment of individuals.' Therefore, as set out in paragraph 4 of the policy document, routine data collection and analysis does not require review under this policy.

### 2.0 Research design

In the case of original research, the project design should ensure that the project is necessary for the advancement of knowledge; that it will not duplicate work that has already been undertaken; and that it will address the question which has been posed. In the case of research conducted as part of a taught course, as an educational exercise, the project may duplicate work that has already been undertaken, but must be based upon sound pedagogic principles.

### **3.0 The Conduct of Research**

Research must be conducted with integrity. This means that in addition to the satisfactory resolution of issues surrounding consent, confidentiality and data protection, the principles of honesty and openness should be observed in both the conduct of the research and the publication of the results. Researchers, and research student supervisors, must be competent to undertake the research – for example, must have received adequate training in the methodology, techniques and equipment involved.

The University's policy statement on research integrity and good conduct is available at <http://ris.leeds.ac.uk/ResearchIntegrityPolicies>.

### **4.0 Risks and Benefits**

The expectation is that the likely benefits of research, including the advancement of knowledge, will outweigh the risks involved to subject-participants. Any risks, physical, psychological, financial or of any other type, must be clearly identified; must be manageable; and must be clearly explained to subjects before consent to participate is sought.

Researchers will also need to consider the potential for reputational risk, to both individuals and institutions. Advice can be sought, in confidence, from the Senior Research Ethics Administrator, the appropriate Faculty Research Ethics Committee, or the University Research Ethics Committee.

#### **4.1 Proportionate review**

The likelihood and severity of the risks posed by particular projects will, of course, vary, and will be reflected in the process of review and approval.

##### *4.1.1 Higher risk*

Projects which present higher risks or more serious or complex ethical issues will require full review by a School or Faculty Research Ethics Committee or, in certain cases, by the University Research Ethics Committee.

##### *4.1.2 Lower risk*

Projects which present lower risks may be reviewed through an expedited procedure proportionate to the nature of the issues arising.

### **5.0 Projects reviewed through other procedures**

As set out in the policy ([link](#)), certain categories of projects will be reviewed through other procedures, either internal or external, which will not require duplication through the ethical review framework. Further information is set out below.

#### **5.1 Research involving animals**

The University of Leeds has a separate procedure for the review of research proposals involving animal experimentation, which is regulated by the Home Office ([http://www.leeds.ac.uk/info/5000/about/136/values\\_and\\_responsibility](http://www.leeds.ac.uk/info/5000/about/136/values_and_responsibility)).

#### **5.2 Externally regulated research and data collection**

Certain research will be subject to external regulation which the University will accept in lieu of internal review. This is currently limited to:

- research involving NHS patients, personal data or tissue (which must be reviewed by the appropriate NHS Research Ethics Committee);

- research involving adults lacking the capacity to consent (which must be reviewed by the appropriate NHS Research Ethics Committee);
- research involving the release of genetically modified organisms into the environment (which must be reviewed by DEFRA and is subject to Health and Safety oversight);
- research classified as a Clinical Trial under the Medicine for Human Use Act (2004) and research involving human tissue, as defined by the Human Tissue Act (2004) and associated Regulations (2006)<sup>1</sup>;
- research that has been reviewed and approved by another UK Higher Education Institution (provided that evidence of sufficiently robust review is confirmed by the appropriate FREC).

The NHS does not require review by an NHS Research Ethics Committee for activities that they consider to be service evaluation, clinical audit, surveillance or usual practice in public health. Such studies *may*, however, require Health Research Authority approval and University research ethics review.

## **6.0 Treatment of subject-participants**

All reasonable measures must be taken to protect the health, safety and psychological wellbeing of researchers and all subjects. In particular, the location and environment of the study and any equipment or procedures will be subject to review under national Health and Safety legislation and University Health and Safety regulations.

Should an adverse incident occur during the course of research, this must be reported to the appropriate person. In most cases, this will be the researcher's line manager. In the case of a critical incident, researchers should be aware of their responsibility to notify the University Secretary (or, out of hours, the Security Office) at the first opportunity. More information about critical incidents is available at: [http://www.leeds.ac.uk/secretariat/critical\\_incidents.html](http://www.leeds.ac.uk/secretariat/critical_incidents.html).

### **6.1 Vulnerable subjects**

Due consideration must be given to the particular needs of 'non-competent' participants, who may be at risk of feeling pressured into participation or who may not be able to give adequate informed consent to participate. Examples might include children, those with mental disabilities and those only able to give consent through a carer. Consideration must also be given to the needs of 'compromised subjects' who have a dependent relationship with a researcher that may cloud their motives for participating and their perception of their right to withdraw at any time. Examples might include a tutor's own students, or a doctor's own patients. Appropriate and proportionate steps must be taken to safeguard the rights and dignity of such participants.

### **7.0 Informed consent**

The expectation is that researchers will obtain, and record, the informed consent of subject-participants. In order to achieve this, subjects must be given clear information about the study's aims, the risks and benefits, and the nature of their involvement. Subjects must be given sufficient time to reflect upon any information that they are given, and researchers must be satisfied that this information has been understood. A subject's right to withdraw at any time, without giving a reason, must also be clearly explained and understood. In no circumstances should coercion, disproportionate payment or inducement, or the expectation of any other inappropriate advantage be used to influence consent.

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<sup>1</sup> Both Clinical Trials and human tissue studies should be referred to the Secretariat's Research Governance and Integrity Team for advice.

There may be circumstances under which it would not be practicable to obtain participants' fully informed consent in advance – examples might include projects involving the use of covert observation or projects which depend upon the subject being unaware, at least initially, of the subject under investigation. Under such circumstances, researchers should consider carefully the justification for the methodology employed and be prepared to set out their reasoning. In any case, where it is practicable to do so, it is good practice to obtain subjects' consent to the use of their data (if necessary, retrospectively).

When using observational methodologies, researchers should be aware of whether members of the public who are not direct participants might also be observed, and whether their data might be recorded as a consequence of their interaction with a subject. Consideration should be given to whether such interaction takes place within a public or private sphere, and how data collection can be minimised and/or anonymised.

In the case of vulnerable groups, it may be necessary to obtain proxy consent from, for example, a parent or other competent adult. Such subjects will, of course, retain the right to refuse participation and to withdraw at any time.

## **7.1 Complaints**

A clear procedure should be in place for resolving complaints from participants, set out in the information given to them before seeking their consent. Appropriate contacts would include the Principal Investigator, research supervisor or research group director. The University's Research Ethics Governance Procedure is available at <http://ris.leeds.ac.uk/ResearchEthicsComplaintsProcedure>.

## **8.0 Data protection**

Confidentiality of subject-participants' data must be assured, including through adequate anonymisation or pseudonymisation. The storage and use of data must comply with the Data Protection Act 2018, the General Data Protection Regulation and the Human Rights Act and the University's Code of Practice on Data Protection (<https://dataprotection.leeds.ac.uk/data-protection-and-personal-data>).

The Data Protection Act contains eight basic principles, which state that personal data must:

- be obtained and processed fairly and lawfully and shall not be processed unless specified conditions are met;
- be obtained for a specified and lawful purpose and shall not be processed in any manner incompatible with that purpose;
- be adequate, relevant and not excessive for those purposes;
- be accurate and kept up to date;
- not be kept for longer than is necessary for that purpose;
- be processed in accordance with the data subject's rights;
- be kept safe from unauthorised access, accidental loss or destruction;
- not be transferred to a country outside the European Economic Area, unless that country has equivalent levels of protection for personal data.

The lawful basis for processing the data needs to be documented, (usually task in the public interest) and a Data Protection Impact Assessment will need to be undertaken: <https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2018/10/dpia.pdf>

## **9.0 Confidentiality and disclosure**

During the course of research it is possible that researchers may uncover information relating to illegal activity; to intent to engage in illegal activity; or information about topics that are sensitive or

that may carry particular obligations to consider disclosure to the appropriate authorities (such as potential harm to children or vulnerable adults). The law in this area is complex and it is likely that the question of whether to breach confidentiality in such cases, and to whom to disclose any information, would be best decided upon a case by case basis.

Advice upon individual cases is available from the University Secretary. However, there are a number of general principles which might apply in such cases:

- researchers should consider whether they can seek the subject's consent to breach confidentiality;
- there may be a legal obligation to breach confidentiality, for example if a court orders disclosure;
- under any circumstances, disclosure should be restricted to those who need to know the information concerned, and should be relevant and not excessive.

### **10.0 Ownership of research**

The ownership of research should be clearly documented, and there should be clear lines of responsibility for the conduct of the research. This includes, *inter alia*, issues of intellectual property; health and safety; and the training and competence of researchers.

### **11.0 Monitoring of research**

Research should be monitored to ensure compliance with the principles of good practice. Records should be kept for inspection by the appropriate FREC and/or the UREC, as required.

### **12.0 Research conducted externally**

If staff or students participate in collaborative studies, it is essential that these are conducted to a standard compatible with the University's requirements. This includes studies undertaken at, or conducted in partnership with, overseas institutions – although it is recognised that careful consideration will be required of local circumstances and of any limitations these might place upon the research protocol, such as difficulties with obtaining written consent. Researchers will be expected to demonstrate that the best possible practice has been adhered to under the circumstances pertaining.

### **13.0 Conclusion**

The advice set out above constitutes general guidance upon the type of ethical issues that researchers might encounter, and the expectations of the University and other research stakeholders about how such issues should be managed. It is not intended to be exhaustive, and further advice is available from the Senior Research Ethics Administrator, the Secretariat, and from the FRECs and the UREC.