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Research ethics support at the University of Leeds, UK

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University of Leeds, UK

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- One of the largest universities in the UK.
- More than 32,000 students and 7,700 staff from 147 countries.
- A world top 100 university
- Renowned globally for the quality of both its teaching and research.
- Recently named University of the Year 2017 by The Times and The Sunday Times' Good University Guide.

Research at the University of Leeds

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- A member of the UK Russell Group of research-intensive universities.
- A top 10 university for research power in the UK according to the 2014 UK Research Excellence Framework.
- Part of the Worldwide Universities Network (WUN).

Introduction

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- Why have an ethical review process at all?
- Link with research quality
- Embedding a culture of research integrity
- Ethical review requirements at Leeds
- Ethical review process at Leeds
- Support available
- Externally funded research
- Future challenges.

Do nothing…

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- “Bureaucratic nonsense”
- “Too busy”
- “There aren’t any ethical issues in my research.”

However…

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Increased risk of

- Harm (to research participants, to researchers, to wider society)
- Loss of reputation
- Financial penalties (for individuals, for the university)
- Criminal charges.

Purpose of ethical review

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- Helping ensure researchers
  - identify the ethical issues
  - put measures in place to address them
- Duty of care to researchers, especially students
- Protecting research participants and wider community
- Helping retain and build public trust in research
- Reducing reputational risks to the university while at the same time protecting academic freedom
- Increasingly a requirement of funders and publishers.

Connection between research ethics and research quality

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*"[Research] excellence and integrity are **inextricably linked**."*

Universities UK Concordat to Support Research Integrity.

*"High ethics standards also add to the quality of research and increase its likely **social impact**. They promote research integrity and a **better alignment of research with social needs and expectations.** They support the societal uptake of the new products, processes and services that are the result of scientific research, because high ethical standards generally merit **public trust**. This second aspect is equally relevant, as science and technology are vital for addressing the many economic, ecological and social challenges that confront us."*

Jean-Michel Baer, Director for Science, Economy and Society, European Commission.

Good research practice

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- Research at the University of Leeds is conducted according to the principles of **academic excellence, community, integrity, inclusiveness** and **professionalism**.
- The principles of good research practice encourage those involved in research to consider the **wider consequences** of their research, and engage with the practical, ethical and intellectual challenges inherent in high quality research.
- Supporting both the **academic freedom** of researchers and the **reputation of the University** as a centre for world-class research.
- https://www.leeds.ac.uk/info/5000/about/136/values_and_responsibility
- http://ris.leeds.ac.uk/researchintegrity

Embedding a culture of research integrity

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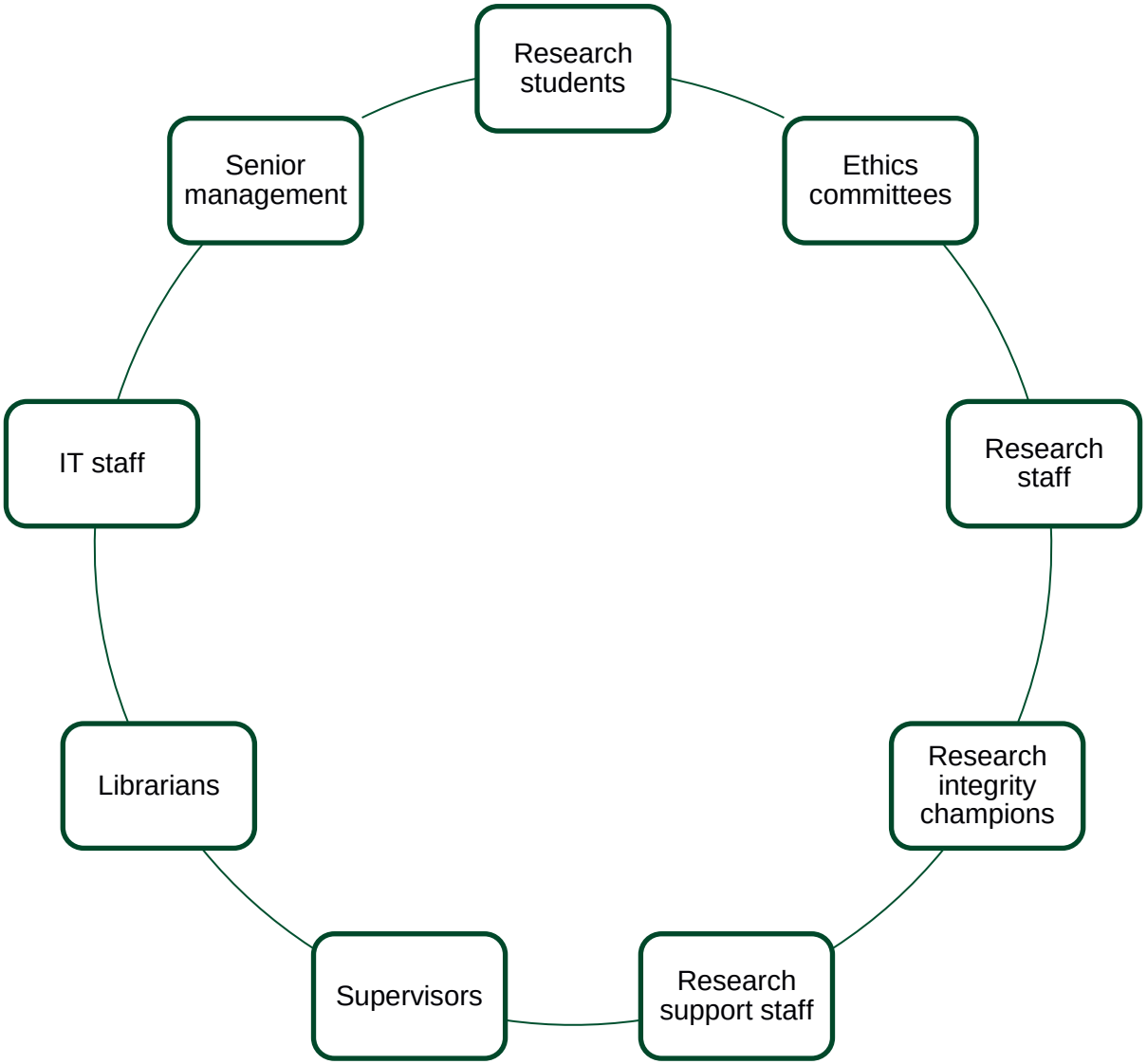

Ethical review requirements

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It is a requirement of the University of Leeds Research Ethics Policy that ethics approval is obtained for any research with ethical dimensions.

For example:

- research involving living human participants or the personal data of living human participants;
- research involving human tissue;
- research with the potential for adverse environmental impact;
- research involving animals.

Research ethics: responsibilities

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Individual researchers, have responsibility for ensuring that they consider ethical issues and obtain the appropriate ethical approval.

University Research Ethics Committee (UREC): considers matters of general principle and policy on research ethics.

Faculty Research Ethics Committees (FRECs): these review individual ethics applications from researchers in their Faculty.

Senior Research Ethics Administrator: provides guidance to researchers and the FRECs and makes recommendations to UREC. Responsible for the administration of research ethics policy and review.

Research Ethics Senior Training & Development Officer: Responsible for the development and delivery of research ethics training at the University for PhD students and staff.

Ethical review process

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Same process for students and staff

Microsoft Word Application forms

- Standard application from
- “Light touch” (proportionate) application form – for low risk projects
- A form for taught student modules – to request approval for a local process for reviewing individual student projects
- Timing.

Screening questions

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Section C1 – High Risk Ethical Issues – to be completed by all applicants	Yes	No
Does the study involve participants who are particularly vulnerable or unable to give informed consent (eg children, people with learning disabilities, your own students)?		
Will the study require the cooperation of a gatekeeper for initial access to groups or individuals who are taking part in the study (eg students at school, members of self-help groups, residents of a nursing home)?		
Will participants be taking part in the research without their knowledge and consent (eg covert observation of people in non-public places)?		
Will the study involve discussion of sensitive topics (eg sexual activity, drug use)?		
Are drugs, placebos or other substances (eg food substances, vitamins) going to be administered to the participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind?		
Will blood or tissue samples be obtained from the participants?		
Is pain or more than mild discomfort likely to result from the study?		
Could the study induce psychological stress or anxiety or cause harm or have negative consequences beyond the risks encountered in normal life?		
Will the study involve prolonged or repetitive testing?		
Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?		
Will the study involve research conducted outside the European Economic Area or collaborators located outside the EEA? NB: If the study involves research conducted inside the EEA please include a copy of your signed fieldwork risk assessment with your application: http://ris.leeds.ac.uk/HealthAndSafetyAdvice.		
Will the study involve the transfer of data outside the European Economic Area?		
Will the study involve participatory action research or members of the public in a research capacity?		
Are there any potential conflicts of interest?		
Does the research involve any risks to the researchers themselves, or individuals not directly involved in the research?		
Will the study require ethical review from the NHS? (Refer to http://ris.leeds.ac.uk/NHSethicalreview for guidance in identifying circumstances which require NHS review)		

Protocols

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Protocol	Tick if the protocol is applicable to the study	Will the study be carried out in accordance with this protocol? (only answer for protocols which are appropriate to the study)	
		Yes	No
Data protection, anonymisation and storage and sharing of research data			
Informed consent			
Verbal consent			
Reimbursement for participants			
Low risk observation			

Support for researchers

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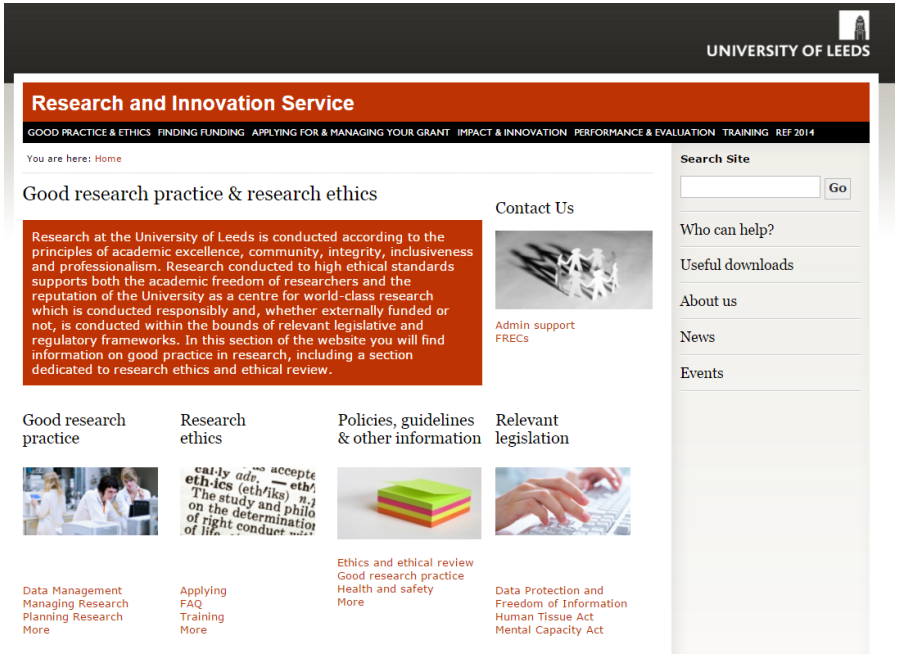
- Guidance on specific ethical issues or university policy
- Feedback on draft applications before being submitted to an ethics committee for review
- Support in interpreting and addressing feedback from the ethics committee
- Flexible service
- Prompt and facilitative
- Signposting – to information or to people
- Ethics website: www.leeds.ac.uk/ethics
- Training programme.



Training provision

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General training sessions including:

- Induction for new staff and for new research students
- On preparing for ethical review
- Induction for new research ethics committee members

and sessions on specific aspects, for example:

- Vulnerable People
- Data Protection
- Responsible Authorship
- Research with Human Participants
- Ownership
- Confidentiality and Secrecy
- Children
- Research Assistants and Translators.

Support for ethics committees

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- Managing the review process
- Consistency
- Quarterly committee meetings
- Intermediary between ethics committees and researchers
- Cross-institutional view
- Reporting
- Communication.

Student research projects

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- Supervisors are expected to support their student with the process, discussing their application with them, checking it and signing it off when they are happy with it prior to submission.
- Annual checks, including when theses are submitted for examination
- Tailored training programmes
- Training and guidance for supervisors.

Externally funded research

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- Ethical review requirements checked at various stages
  - Application stage
  - Post-award
  - Risk review dashboard
  - Is ethical review necessary? (It can be a condition of funding)
  - If it is needed, has it been obtained?
- Information is captured in our grant management IT system.
- Applications usually submitted once funding has been secured but before the research is due to start.

Externally funded research

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- Ethical review for multiple work packages
- Collaborative research
- Recognising and respecting different political and cultural considerations and ethical norms
- Access to participants
- Increased risk to researchers and participants where they are working remotely.

Ethical review process

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What works well

- Importance of communication
- Transparent process
- Efficient & responsive processes
- Proportionate
- Facilitative
- Flexible.

Ethical issues – some examples

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- 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;
- Impact and the potential for research misuse;
- Funding sources.

Ethical review in the UK

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The **Data Protection Act** controls how personal information is used by organisations, businesses or the government: https://www.gov.uk/data-protection/the-data-protection-act

The **Mental Capacity Act** ensures that those who lack capacity are empowered to make as many decisions for themselves as possible and that any decision made, or action taken, on their behalf is made in their best interests: http://www.nhs.uk/Conditions/social-care-and-support-guide/Pages/mental-capacity.aspx

NHS Health Research Authority protects and promotes the interests of patients and the public in health and social care research: http://www.hra.nhs.uk

The **Human Tissue Act** regulates the removal, storage, use and disposal of human bodies, organs and tissue: https://www.hta.gov.uk/policies/human-tissue-act-2004.

Future challenges

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Future challenges

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- Intellectual developments in the world of research ethics
- Changing research practices bring different ethical issues
  - Big Data
  - Internet research
  - Microworking
- Considering the scope of ethical review
  - Ethical issues associated with non-research activities
- Integrating good research practice.

Further information

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Association for Research Ethics: http://arec.org.uk

UK Research Integrity Office: http://ukrio.org/about-us

Economic and Social Research Council Framework for Research Ethics: http://www.esrc.ac.uk/funding/guidance-for-applicants/research-ethics

OECD guidelines on research ethics and new forms of data: http://www.oecd-ilibrary.org/content/workingpaper/5jln7vnpxs32-en

Singapore Statement: http://www.singaporestatement.org

European Science Foundation's European Code of Conduct for Research Integrity http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

Questions

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