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OVERVIEW OF RESEARCH ETHICS & RESEARCH INTEGRITY

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Aims of the session

This session aims to outline:

- Key dates relating to ethics
- Belmont principles
- Principles for ethics and integrity
- University Research related policies
- Research Integrity
- Research Misconduct
- Working with Human Tissue
- Ethical applications at Lincoln
- Ethical reviews at Lincoln


Rules and Regulations
Rules of Conduct
Values
Ethics
Ethical Practices
Research
Moral Principles

Research Ethics - key dates

- Tuskegee Syphilis experiments (1932)
- World Medical Association (1945)
- Safe guarding participants: the 1946-1948 U.S. Public Health Service Sexually Transmitted Diseases (STD) Inoculation Study in Guatemala
- Nuremburg Doctors' Trial led to Nuremburg Code 1947
- Declaration of Helsinki (1964) now version 7.0 (2013)
- Belmont report (1979)
- Alder Hey (1999)
- Human Tissue Act (2004)
- Data Protection Act 1998 now Data Protection Act 2018

Principles for ethics and integrity

- Declaration of Helsinki (1964) – now 7th revision 2013
- Research funder ethics codes (e.g. ESRC)
- Standardising international practice
  - Singapore Statement for Research Integrity 2010
  - ICH GCP
- Intergovernmental and governmental bodies
  - UNESCO, WHO, ORI,
  - National guidelines – REF
- Professional Codes of Practice
  - E.g. BPS, BSA, PSA, SRA, GPhC, BMS
- Institutional Policies (relating to Research)
  - Code of Practice for Research, Research Ethics Policy, Procedure for Research Misconduct (UKRIO), Research Data Management Policy.
  - Secretariat – Academic Policies

The University of Lincoln - Research Ethics Policy

is intended to support good conduct in research, in order to encourage research of the highest quality.

It provides general principles and standards for good ethical practice in research, for the individual researcher (staff member or student) and the institution as a whole.

Good research ethics applies to all researchers who conduct research for the University of Lincoln – regardless of whether the research is funded or unfunded, who it is funded by and where the research is conducted.

Source: UoL - Research Ethics Policy (2018)

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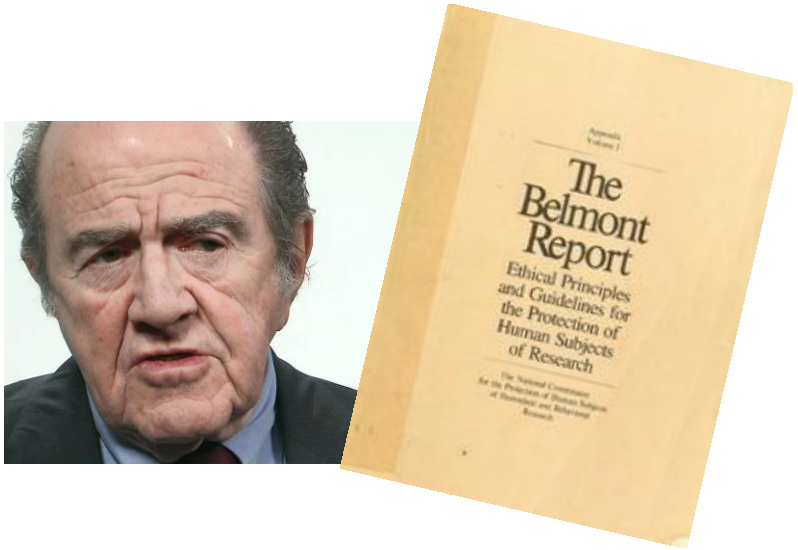
ETHICAL PRINCIPLES FOR RESEARCH WITH HUMAN PARTICIPANTS AND PERSONAL DATA

Belmont Principles

- Respect for persons dignity, rights and welfare (and their autonomy)
- Beneficence
- Non-Maleficence
- Distributive justice



Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

Belmont Principles

The principle of **respect:**

- Acknowledges the dignity and autonomy (when possible) of individuals, and requires that people with diminished autonomy be provided with special protection;
- Ensures that certain participant populations including (but not limited to) children, prisoners, the mentally disabled and people with severe illnesses are appropriately protected;
- Requires that participants (and third parties – which may include family members, carers, or the wider community) are fully informed about the purpose and intended possible uses of the research, what their participation involves and details of any risks (unless the ethics committee explicitly approves otherwise because, for example, the research involves the deception of participants in the research project);
- Ensures that participants freely and voluntarily provide their consent to participate in such research and can choose to withdraw without adverse consequences (or, for those with diminished autonomy, consent is sought from an appropriate representative);
- Requires researchers to observe the confidentiality of information provided by participants and, where appropriate, respect their anonymity.

Belmont Principles

The principle of **beneficence**:

- Requires that any risk of adverse effect on people, either directly or indirectly as a result of participation in the research project, is outweighed by the benefits.

The principle of **non-maleficence**:

- Makes it necessary to examine carefully (through risk assessment) the design of the study and its risks and benefits including, in some cases, identifying alternative ways of obtaining the benefits sought from the research.

The principle of **justice**:

- Requires that we treat participants fairly. Participants should be carefully and equitably chosen to ensure that certain individuals or classes of individuals – such as prisoners, elderly people, or financially impoverished people – are not systematically selected or excluded, unless there are academically or ethically valid reasons for doing so;
- Requires that unless there is careful justification for an exception, research should also not involve persons from groups that are unlikely to benefit from subsequent applications of the research.

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GDPR IN RESEARCH

Consent

Research participants should have confidence that their personal information is being handled fairly and securely. Any use of personal data must have a clear, specified purpose and not be kept for longer than necessary.

The GDPR also allows for personal data collected for one purpose to be re-used for research purposes, as long as certain conditions and safeguards are met. If the same aims can be met without identifying individuals then the data should be anonymised before re-use.

Legal basis for using personal data in research

As with the DPA, before personal data are collected or used, the purpose and legal basis (or condition) for processing must be identified. Data collection and use should be limited to only that which is necessary to meet the purpose.

Legal Basis

The most likely legal bases for research purposes are:

Consent

This must be a **specific**, **informed**, and **genuine choice** and can be **withdrawn at any time**. An individual has to understand what they have signed up for and to have made a positive indication of their choice.

Note: Pre-ticked boxes, asking someone to ‘untick’ if they do not wish their information to be used in a certain way, are not allowed.

Public interest / exercising official authority

Public authorities may need to conduct research to perform a task in the public interest or exercise official authority. Any ‘public task’ must have a basis in UK or EU (until 2019) law. This basis will determine the purpose for the processing. This condition allows for collaboration between public and private institutions if the research is in the public interest.

Legitimate interests

Researchers may use personal data if it is in the organisation’s, or a third party’s, legitimate interests, but this condition can only be relied upon if the individual subject’s own information rights do not override those interests. This condition cannot be relied upon if the use of data relates to a public authority’s ‘public task’.

Source: https://lncn.ac/gdpr_r

Sensitive or special category data

Sensitive or special categories of personal data are racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, health or sex life and sexual orientation, genetic data, and biometric data. It is likely that, to follow the DPA, the UK will also classify criminal allegations or proceedings as special category data.

There is a different set of conditions for processing special category data; the most likely for research are:

Medical purposes

- It is necessary for medical purposes (carried out by a medical professional or someone with an equivalent duty of confidentiality) – specifically includes occupational health and determining capacity to work.

Public Health

- It is necessary for public health, such as serious cross-border threats to health and ensuring high standards of health care and medicinal products.

Archiving, research and statistics

- It is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. The processing must respect data protection and people's rights. Consider if we can do the job without keeping identifiable information

Source: https://lncn.ac/gdpr_r

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ETHICAL PRINCIPLES FOR NON-HUMAN RELATED RESEARCH

The 3Rs

National Centre for the Replacement Refinement & Reduction of Animals in Research

	Standard	Contemporary
Replacement	Methods which avoid or replace the use of animals	Accelerating the development and use of models and tools, based on the latest science and technologies, to address important scientific questions without the use of animals
Reduction	Methods which minimise the number of animals used per experiment	Appropriately designed and analysed animal experiments that are robust and reproducible, and truly add to the knowledge base
Refinement	Methods which minimise animal suffering and improve welfare	Advancing research into animal welfare by exploiting the latest *in vivo* technologies and by improving understanding of the impact of welfare on scientific outcomes

https://nc3rs.org.uk

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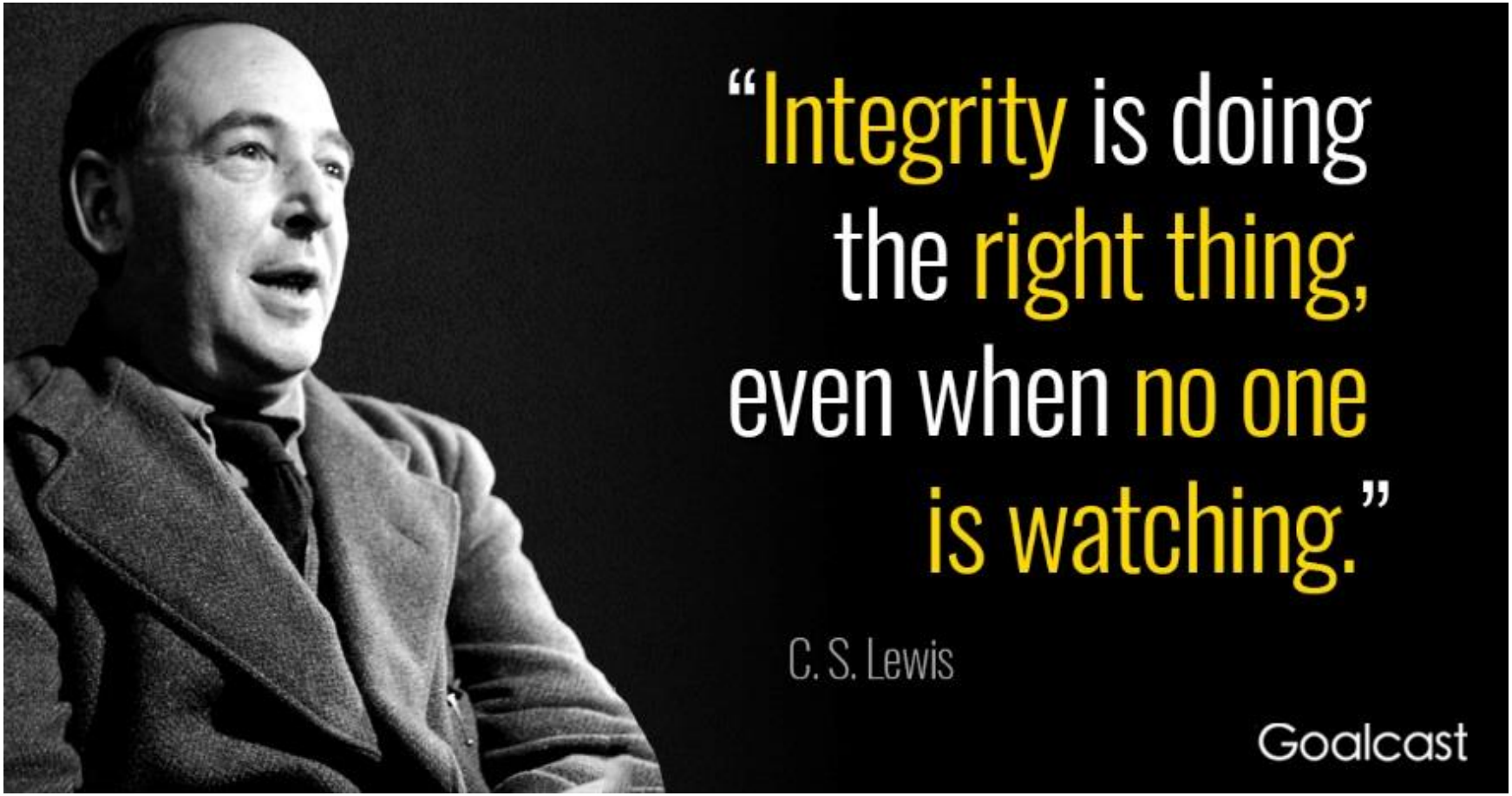
RESEARCH GOVERNANCE & RESEARCH INTEGRITY

Research Governance

Research governance is essentially about ensuring high standards in research - including (but not only) standards of research ethics.

These standards are ensured through regulation and assurance - in other words, through checks such as ethics and governance review.


"Integrity is doing the right thing, even when no one is watching."
C. S. Lewis
Goalcast

Research Integrity

Responsible conduct of research

- the use of honest and verifiable methods in proposing, performing and valuating research
- reporting research results with particular attention to adherence to rules, regulations, guidelines
- following commonly accepted professional codes or norms.

Research Integrity

- Singapore Statement (2010)
- Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations (2013)
- European Code of Conduct for Research Integrity
- UUK Concordat to Support Research Integrity
- **University of Lincoln – Code of Practice for Research (revised 2018)**
- House of Commons Science and Technology Committee report: Research Integrity (2018)
- House of Commons Science and Technology Committee's report: Clinical Trial Transparency (Oct 18)
- Retraction Watch

UKRIO UK Research Integrity Office

ORI THE OFFICE OF RESEARCH INTEGRITY

COPE

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RESEARCH MISCONDUCT

Research Misconduct

UKRIO defines misconduct in research as including, but not limited to:

a) Fabrication

b) Falsification

c) Misrepresentation of data and/or interests and/or involvement

d) Plagiarism

e) Failure to follow accepted procedures or to exercise due care in carrying out responsibilities for:

i) Avoiding unreasonable risk or harm to:

- humans
- animals used in research
- the environment

ii) The proper handling of privileged or private information on individuals collected during the research

University policy relating to research misconduct follows the UKRIO procedure

Procedure for the Investigation of Misconduct in Research (UKRIO)

Consequences of research misconduct

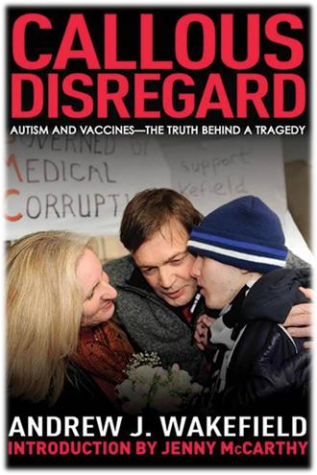
- Sanctions by institutions and professional bodies
  - Fines / Dismissal
- Imprisonment
- Adverse effects on reputation of institutions and staff
- Waste of research money (from GO/NGOs)
- Retraction of publication(s)
- Health related

Infamous Misconduct Cases

Andrew Wakefield

(Former physician)

MMR vaccine & autism



Jon Sudbo

(Norwegian dentist & former physician)

Fabricated cancer studies

Retraction—Non-steroidal anti-inflammatory drugs and the risk of oral cancer: a nested case-control study

We have received confirmation from Prof Anders Ekbom, who chairs the investigating commission appointed by the University of Oslo and Rikshospitalet, that the paper published by Jon Sudbø and colleagues in *The Lancet*[1] contains fabricated data. This information supersedes our earlier expression of concern[2] and we now retract this article in full.

Richard Horton
The Lancet, London NW1 7BY, UK

1 Sudbø J, Lee JJ, Lippman SM, et al. Non-steroidal anti-inflammatory drugs and the risk of oral cancer: a nested case-control study. *Lancet* 2005; **366**: 1359–66.
2 Horton R. Expression of concern: non-steroidal anti-inflammatory drugs and the risk of oral cancer. *Lancet* 2006; **367**: 196.

[ORI Case Summaries](#)

THE OFFICE OF RESEARCH INTEGRITY

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RESEARCH MISCONDUCT

Human Tissue

Do you plan to work with human tissue?

If so:

All staff and students are required to register, undertake specific human tissue training and maintain a Research Training Portfolio (RTP) in addition to laboratory specific induction and Lab Code of Conduct and Guidelines which must be completed before a researcher may work in any University of Lincoln laboratory.

The dates of the next training sessions are available here

HTOG@Lincoln.ac.uk

HTA
Human Tissue Authority
Licensed establishment

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ETHICS APPLICATIONS

Ethics applications

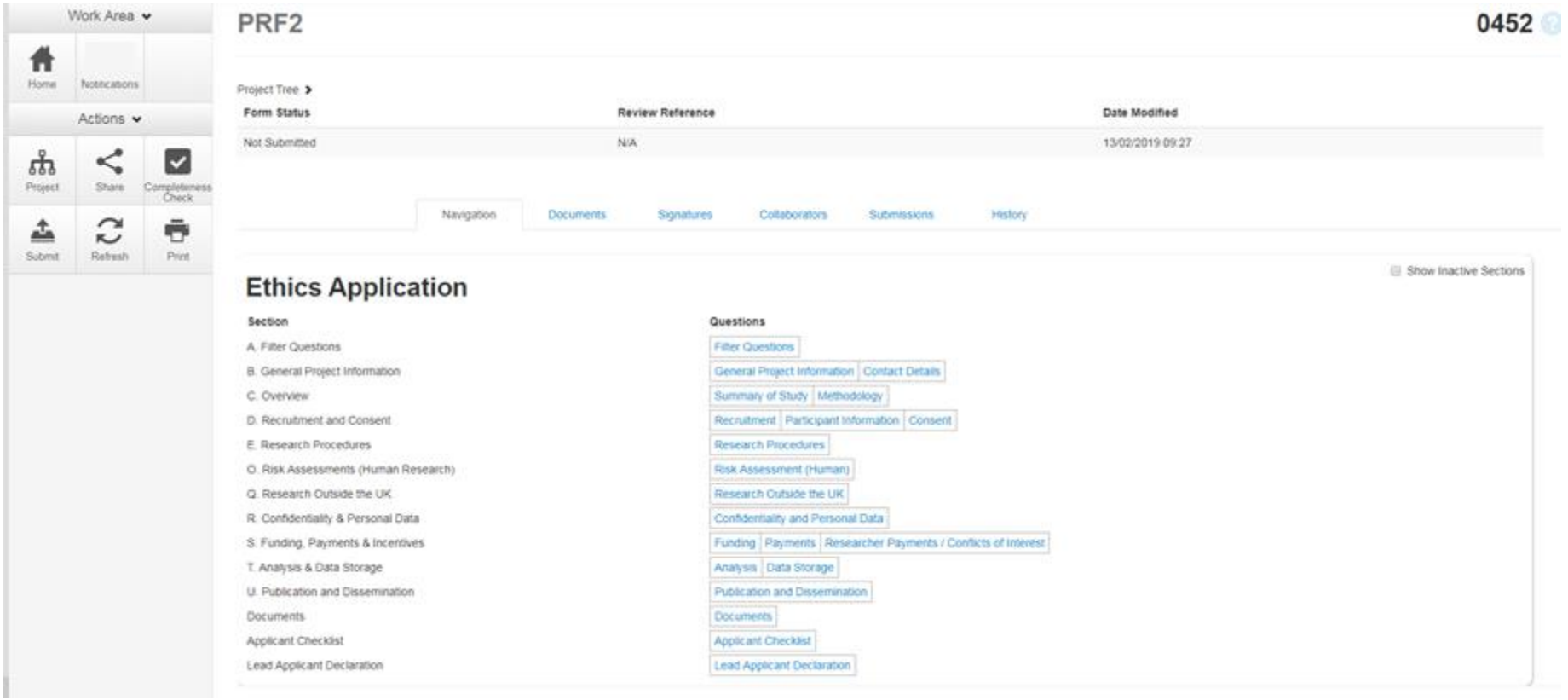
PGR applications > **L**incoln **E**thics **A**pplication **S**ystem (LEAS)

https://ethicsapply.lincoln.ac.uk

Must be reviewed and discussed with Academic supervisor prior to sign off

Comprehensive question set – populated dependent on study type

Applicants


Work Area
Home
Notifications
Actions
Project
Share
Completeness Check
Submit
Refresh
Print
PRF2
0452
Project Tree
Form Status
Review Reference
Date Modified
Not Submitted
N/A
13/02/2019 09:27
Navigation
Documents
Signatures
Collaborators
Submissions
History
Ethics Application
Show Inactive Sections
Section
Questions
A. Filter Questions
Filter Questions
B. General Project Information
General Project Information
Contact Details
C. Overview
Summary of Study
Methodology
D. Recruitment and Consent
Recruitment
Participant Information
Consent
E. Research Procedures
Research Procedures
O. Risk Assessments (Human Research)
Risk Assessment (Human)
Q. Research Outside the UK
Research Outside the UK
R. Confidentiality & Personal Data
Confidentiality and Personal Data
S. Funding, Payments & Incentives
Funding
Payments
Researcher Payments / Conflicts of Interest
T. Analysis & Data Storage
Analysis
Data Storage
U. Publication and Dissemination
Publication and Dissemination
Documents
Documents
Applicant Checklist
Applicant Checklist
Lead Applicant Declaration
Lead Applicant Declaration

Top Tips

- **Proof read** the application especially any outward facing documents.
- Keep your project summary in **lay terms** and include enough detail to give a **full overview** of your project including: **background, justification and methodology**
- Be aware of the difference between **personal data** and **research data**:
  - **Personal data** is information such as names, email addresses (work/personal), phone numbers and addresses and any information that could identify a participant
  - **Research data** is all other data collected during the course of the project
- Don't forget to **submit your application** or re-submit after changes
- Read the guidance information provided in the  button
- **Supervisors** should provide guidance and comments before submission
- Ethics system email come from donotreply@Infonetica.net – **please do not ignore these**

Ethical review

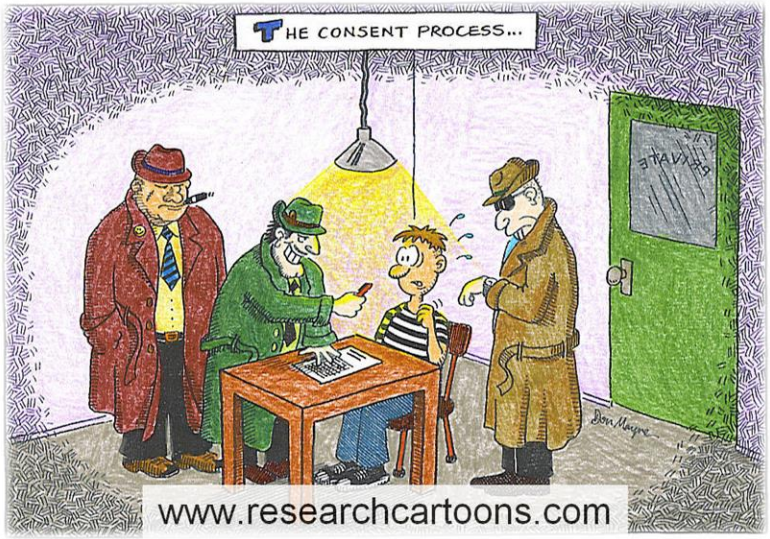
What are reviewers looking for?

- Has the applicant summarised any ethical concerns?
- Has the research been adequately planned so it will be carried out in a timely manner? Does it fit the time frame given?
- Is there a balance of the potential benefits - whether for science, society or participants themselves - against the potential risks and burdens of the study?
- Does the research involve vulnerable groups? Is it necessary for these groups to be included in the study? Has the applicant provided adequate justification?
- Is it clear who is and isn't eligible? Does this match with the objectives of the study?
- Have data protection and security been addressed adequately?
- Have risks been adequately addressed?
- Are there any conflicts of interest?
- How research data will be managed and published

Summary

Ethics and integrity are **integral** to good research practice and not an option or regulatory burden

Obtaining ethics approval is not a hurdle



Ongoing process throughout whole project