

Research and Information Governance at Cambridge

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Research Policy Framework

- Research in the Clinical School is governed by the **UK Policy Framework for Health and Social Care Research**

Legal Considerations

- Human Tissue Act 2004
- Data Protection Act 2018
- Mental Capacity Act 2005
- EU Clinical Trials Directive/Regulations
- Medical Devices Directives/Regulations

Human Tissue Act 2004

- Regulates the removal, storage and use of human tissue
- TISSUE - anything that contains a cell - blood, urine, saliva etc
- Consent is the fundamental issue
- Storage requires HTA licence or NRES ethics approval

Mental Capacity Act 2005

Supports and protects people who may be unable to
make some decisions

Mental Health

Emergency medicine

Intensive Care Units

Data Protection Act 2018

- Establishes a framework of rights and duties which are designed to safeguard personal data
- Consent
- Storage

What is Data

Electronic data

Paper files

Imaging

Ensuring the right consent

How do you intend to use the data?

Do you want to share data with other researchers

in the UK?

overseas?

in the commercial sector?

Storage of data

- All identifiable data MUST be stored in the Clinical School secure data storage area or area with equivalent security
- Never take identifiable data home or place on personal laptops

Identifiable data

Names and addresses

Date of Birth

Post code

NHS number

Any data that allows the researcher to identify the participant

Pseudo-anonymisation and anonymisation

Anonymisation – All identifying factors have been removed and no-one has the information to identify the participant

Pseudo-anonymisation – Anonymous data linked to a code which can de-identify the data

Breaches

All breaches must be reported to the head of department and the research governance officer as soon as possible

If patient data involved the relevant NHS Trust R&D office needs to be informed

Research Contracts

- Participating Site Agreements
- Collaboration Agreements
- Material Transfer Agreements (MTAs)
- Data Transfer Agreements (DTAs)

Useful weblinks

Research governance

- Clinical School Research Governance page
<http://www.medschl.cam.ac.uk/research/research-governance-information/>
- University Cambridge Psychology Research Ethics Committee <http://www.bio.cam.ac.uk/sbs/psyres/>
- University Human Biology Research Ethics Committee
<http://www.bio.cam.ac.uk/sbs/hbrec/>

Useful weblinks

Information Governance

- <http://www.medschl.cam.ac.uk/research/information-governance/>
- <https://ico.org.uk/for-organisations/guide-to-data-protection/anonymisation/>

Useful contacts

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