Human Tissue and Data Protection:
 a guide for researchers

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Overview

HUMAN TISSUE

• Brief background to the Human Tissue Act
• The Act in Practice
  – Ethics Approval
  – Consent
  – Record Keeping
  – Inspections

DATA PROTECTION

• Guidance
• In practice
Background to HT Act

- Alder Hey Children’s Hospital
  - Between 1988-1995 unconsented removal and retention of body parts
  - Redfern report published in 2001
- NHS audit of stored tissue
- Cash for tissues row
- Stolen body parts
- 1st prosecution under HT Act
Human Tissue Act 2004 - Recap

• HT Act implemented 1\textsuperscript{st} April 2006:
  – *Regulates removal, storage and use of tissue and organs from the deceased, and the storage and use of tissue from the living*

• ‘Relevant Material’
  – *Material from human body consisting of/including human cells*

• HT Act does not apply if 100 years have passed since date of donor’s death
Relevant Material – Current situation 2008

RELEVANT*
• Sputum
• Tears
• Foetus
• Bile
• Mucus
• Nasal lavage
• Breast Milk
• Organs

Body parts
• Blood
• Urine
• Tissue Arrays
• Faeces
• Saliva
• Brains

NOT RELEVANT*
• Hair
• Plasma
• Nails
• Serum

• DNA
• Cell lines
• Embryos

* lists not exhaustive
Other relevant regulations

- Human Fertilisation and Embryology Act (1990)
  - Governs storage and use of gametes and embryos
  - Regulated by HFEA

  - Transposed into UK law as the Blood Safety and Quality Regulations 2005
  - Regulated by MHRA
  - Covers blood banks and transfusion

  - Quality & Safety of human tissues and cells for human application
  - Includes stem cells and cord blood, excludes organs
  - Covers: Donation, Procurement, Testing, Processing, Preservation, Storage & Distribution
Human Tissue Authority

- The Act and EUTCD overseen by HTA
  - Public Body to inform Public and Parliament on issues within their remit

- Codes of Practice:
  - Consent
  - Donation of organs
  - Post-Mortem
  - Anatomy
  - Disposal
  - Donation of bone marrow
  - Public display
  - Import and export
  - Research

- www.hta.gov.uk/guidance/codes_of_practice.cfm
Licensable Activities

Under HTA, certain activities must be licensed:

– Anatomical examination
– Post-mortem examination
– Removal of relevant material from a deceased person
– Storage of relevant material from a deceased person (other than for a specific ethically approved project)
– Storage of anatomical specimens
– Storage of relevant material from a living person for research (other than for a specific ethically approved project)
– Public display of a body or material from a deceased person
Excepted purposes for licences

- The ‘excepted’ purposes:
  - Medical diagnosis Coroners purposes
  - Prevention/detection of crime or prosecution
  - National security
  - Court / Tribunal
  - Clinical audit, education, training, performance assessment
Designated Individuals

• DI responsible for:
  – Ensuring suitable practices are used to undertake licensed activity
  – Checking those working under licence suitably qualified
  – Certifying licence conditions are complied with
Local Designated Individuals

- Chelsea & Westminster
  - Professor Mervyn Maze, Anaesthetics

- Imperial College Healthcare NHS Trust
  - HH/CXH: Dr Timothy Ryder, Histopathology Department
  - St Mary’s: Dr Graham Taylor, Infectious Diseases Department

- NWLH
  - Michael Burke, Medical Director

- Royal Brompton & Harefield
  - Professor Tim Evans, Medical Director and Deputy Chief Exec

- Specific sites within IC
  - Mr Gary Roper, IC Research Governance Manager
Local research licences

• Chelsea & Westminster
  – No licence

• Imperial College Healthcare NHS Trust
  – Research licence

• NWLH
  – Research licence

• Royal Brompton & Harefield
  – Research licence

• South Kensington
  – No licence (but RBH satellite sites from their licence)

In addition:
- all sites have pathology licences
- some departments have anatomy licences
HT Act Offences

• Removing/Storing tissue without consent
• Using tissue stored for one purpose for another
• Tissue trafficking for transplantation
• Carrying out licensable activities without a licence
• DNA theft (analysis without consent)
Are you storing organs, tissue or cells (relevant material) for research purposes (from living or deceased person)?

- Is the material you are storing created outside of the human body e.g. a cell line?
  - No licence required

Are you storing material for a specific research project with ethical approval?

- No licence required

Are you storing organs, tissues or cells for distribution to other researchers?

- Needs to come under research licence

Are you storing organs, tissues or cells for a future undefined project?

- Needs to come under research licence
Ethics – Approvals for Tissue Work

• Requirement for all tissue research to be ethically approved by a recognised committee – NRES
• Ethics approval = exempt from licensing requirement
• BUT, if licence in place, does NOT exempt you from ethics requirement for research with human tissue
Consent process for retaining tissue

Ethics approval → End of ethically approved research → Consent for future use?

- Yes: Stored under research licence until new ethics approval granted
- No: Cannot use or store tissue until consent sought
INFORMED CONSENT
Informed Consent – the living

• Required:
  – Obtaining scientific or medical information which may be relevant to any other person, now or in the future
  – Research in connection with disorders, or the functioning, of the human body
  – Public display
  – Transplantation

• Not required:
  – Clinical audit
  – Education or training relating to human health
  – Performance assessment
  – Public health monitoring
  – Quality assurance

• Exceptions to obtaining consent in research:
  – Ethical approval
  – Anonymised samples
Informed Consent – the deceased

• Required:
  – After post mortem, continued storage or use of material no longer required to be kept for coroner’s purposes
  – Removal, storage and use for:
    • Anatomical examination
    • Determining cause of death
    • Establishing, after death, efficacy of any drug administered to patient
    • Obtaining scientific or medical information relevant to any future person
    • Public display
    • Research in connection with disorders, or the functioning, of the human body
    • Clinical audit
    • Education or training relating to human health
    • Performance assessment
    • Public health monitoring
    • Quality assurance
Informed Consent – the deceased

• Not required:
  – Carrying out investigation into cause of death
  – Keeping material after a post mortem under the authority of a coroner
  – Keeping material in connection with a criminal investigation
Appropriate consent - genetics

• Offence to have any bodily material with intent to analyse the DNA in it without *qualifying* consent

• Offence does not apply if results are to be used for one of the ‘excepted’ purposes:
  – Medical diagnosis or treatment of that person
  – Coroner purposes
  – Prevention / detection of crime or prosecution
  – National security
  – Court / tribunal
  – Clinical audit, education, training, performance assessment, etc
  – Anonymised tissue
Record Keeping

• *Systems* to maintain records and documentation for all tissues and organs (acquired and passed to others)

• Tissue must be tracked for health and safety
  – eg in case of infection
  – record should start at site of tissue removal from body
Record Keeping

Records should include:

1. Details of who gave consent
2. Exactly what the consent related to; any restrictions on use imposed
3. Processes applied to the tissue
4. If tissue is transferred; when and to whom
5. When and where disposal is undertaken (if relevant)
Material Transfer Agreement

Should be in place for all studies where tissue is being transferred in or out of College

• Tissue coming in
  – Managed by Research Office (not CRGO)

• Tissue going out
  – Managed by Research Services

• Further information:
  – http://www3.imperial.ac.uk/researchservices/mta
Inspections

HTA must be satisfied that:

– The DI is suitable to supervise activities authorised by the licence
– That those carrying out licensed activities are suitable to carry out such activities
– That suitable practices are used to carry out activities
– That the conditions of the licence are complied with
What should I have in place?

1. Consent
   - Consent must be obtained as set out in the HTA Code of Practice on Consent

2. Governance and quality systems
   - Systems to ensure the provision of safe tissue with reliable quality

3. Premises, facilities and equipment
   - Premises, facilities and equipment must be suitable for the licensed activity undertaken

4. Disposal
   - Establishments should develop a clear and sensitive disposal policy
Data Protection
Principles of the Data Protection Act 1998

Personal information must be:

1. Fairly and lawfully processed
2. Processed for limited purposes
3. Adequate, relevant and not excessive
4. Accurate and up to date
5. Not kept for longer than is necessary
6. Processed in line with participant’s rights
7. Secure
8. Not transferred to other countries without adequate protection
In practice

- Act refers to personal data about a living, identifiable individual
- No patient identifiable information can be held on College-networked computers
  - Coding / pseudoanonymisation
  - Key held separately
  - Limit variables to max two (beware of being able to deduce identities)
- Consent required to review notes for research purposes
- If consent not possible, submission to PIAG
  - With approval from Trust Caldicott Guardian
Further Guidance

- Data Protection Act 1998
- Health and Social Care Act 2001
- Caldicott Report 1997
- Human Rights Act 1998
- Freedom of Information Act 2000
- Research Governance Framework for Health and Social Care 2005
Summary

In summary:

• Ethically approved research does NOT need to come under a licence for tissue storage
• Appropriate consent must be in place
• Confidentiality of patient data paramount

If in doubt – check with Joint Research Office
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