



# HTA

Human Tissue Authority



## Licensing of Research Tissue Banks

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# Overview

- HTA's structure and regulatory aim
- Legislative framework
- Risk based approach to regulation
- Licensing of RTBs
- Research Issues



# HTA

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## **Regulatory aim**

“To create an effective regulatory framework for the removal, retention, use and disposal of human tissue and organs in which the public and professionals have confidence.”

# How we work

- Independent statutory regulator
- Human Tissue Authority – members
  - Lay chair
  - Professional representatives
- Human Tissue Authority – staff
  - 42
  - Four directorates – regulation, policy, communications and resources

# A wider regulatory remit than storage for research

- **Human application (EUTCD)**
- **Research (HT Act 2004)**
- Post mortem services
- Anatomy
- Public display
- Organ transplantation

# Research: licensable activities

- Storage
  - Removal from the deceased (pathology)
- 

# Human application: licensable activities

- Procurement, processing, testing, storage, distribution, import/export
- Embryonic stem cells – pre – clinical trials (heart, pancreas)
- Cell lines – clinical trials – chondrocyte cultures

# Human tissue and its use in research

- Research is essential for continuing improvement in the quality of healthcare in the UK
- The public supports research and donates large sums of money to medical research charities
- The use of human tissue in research is essential for the understanding of disease mechanisms, and the prevention, diagnosis and treatment of disease
- HTA recognises the importance of research and the need to allow this work to continue and flourish in the future

# Working with researchers

- Meetings
  - Cancer Research, Medical Research Council, Wellcome, Bio Industry Association, NPSA (COREC) etc
- Liaising with MRC, UKCRC etc.
- Advice and guidance
  - Telephone, email, face to face
- DI training workshops
  - 7 multi disciplinary training events in 2006/07
  - 2 Research training events
  - [di@hta.gov.uk](mailto:di@hta.gov.uk)





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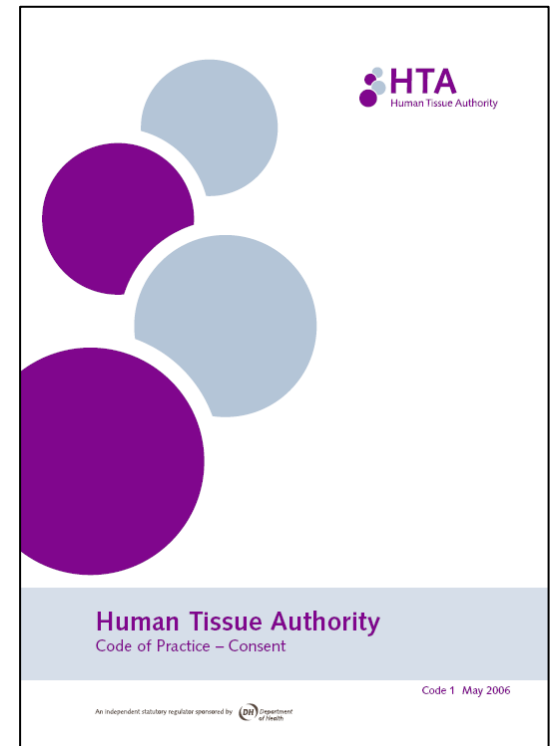
**Legislative framework**

# Current legislative framework

- Human Tissue Act 2004
- Human Tissue (Scotland) Act 2006
- Commencement Orders
- 2006 Regulations (include exemptions to licensing)
- The Human Tissue (Quality and Safety for Human Application) Regulations 2007

# Codes of Practice

- One of the HTA's statutory functions is to issue codes of practice
- Practical guidance to those carrying out activities which lie within the HTA's remit
- Lay down the standards expected
- Failure to follow this guidance may be taken into account by the HTA when carrying out its responsibilities in respect of licensing





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**Risk based approach to regulation**

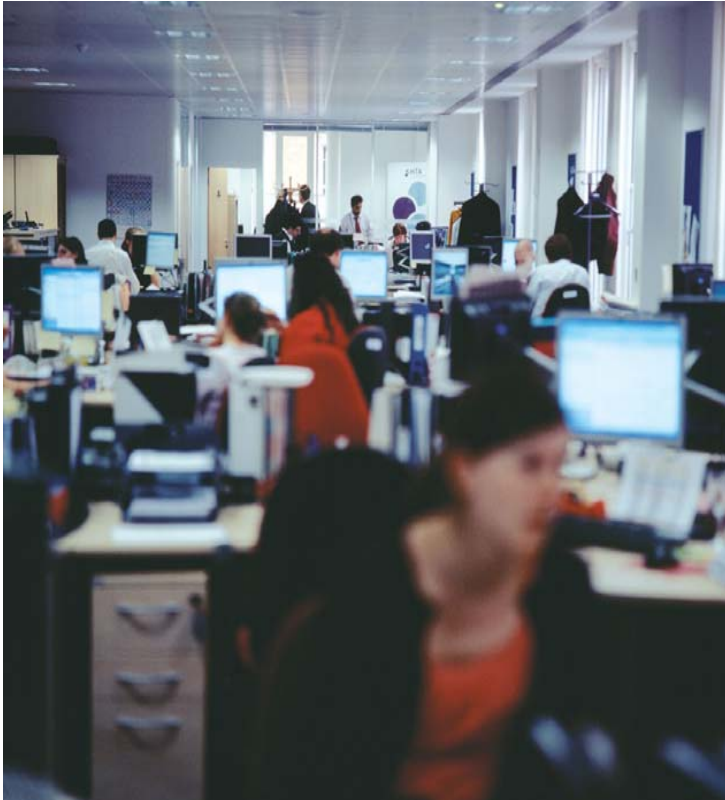
# Risk based approach



# Schedule site visits based on risk

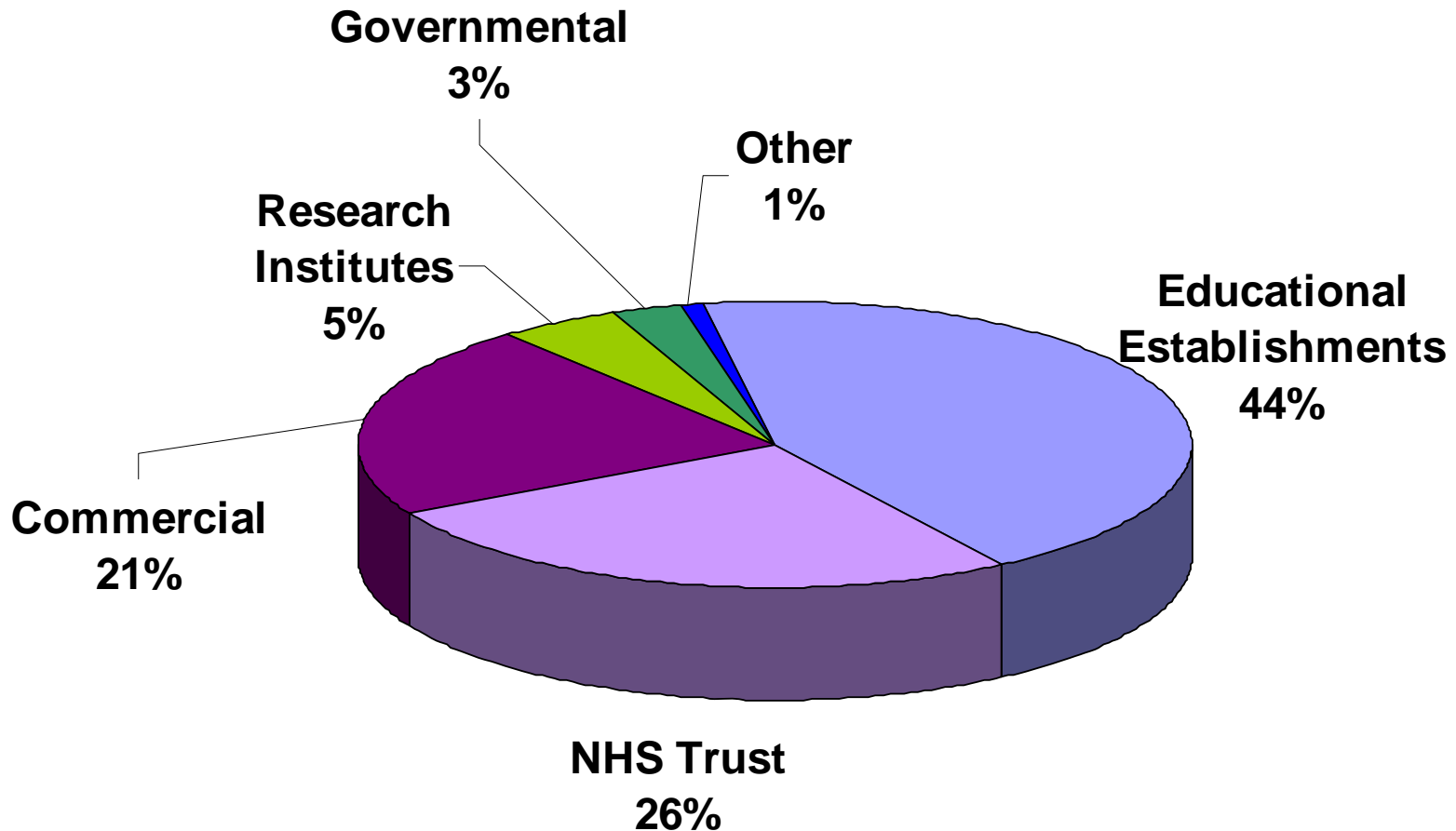
- Phase 1 inspection - desk based
  - All establishments
  - Evaluation of self assessed compliance report
  - Licence issued with licence specific conditions
- Phase 2 inspection - site visit
  - Risk based schedule
  - High risk and sample of low risk
- Assessing high risk
  - Additional conditions
  - Complexity of service
  - Legislative requirements
  - New and emerging information

# Phase one and two inspections so far



- 535 phase one (desk based) inspections
  - Research 174
  - Human Application 213
- 92 risk based phase two (site visit) inspections
- 4 Special Directions issued

# Applications by type of research establishment



# Compliance Report: The standards

- **Consent**
  - Fully informed consent taken by trained individuals
- **Governance & Quality Systems**
  - Traceability of material
  - Quality Management System (proportionate to the size of the undertaking)
  - Policies and procedures for all licensed activities
- **Premises, Facilities & Equipment**
  - Appropriate storage, regularly monitored
  - Contingency plans
- **Disposal**
  - Different requirements for tissue from living and deceased

# Research licences

- Lines of accountability not always clear
- Additional conditions
  - Most relate to lack of compliance with standards for Governance and Quality Systems. Specifically, the requirement for a documented system of quality management and audit and procedures for distribution of body parts, tissues or cells.
- Inadequate level of governance and quality systems at about 60% of research establishments



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**Licensing Research Tissue Banks**

# RTBs and the HTA

- Very few licences relate specifically to Research Tissue Banks
- Most RTB are licensed as part of other establishments
- Few conditions on licences for dedicated banks
- Comparatively well developed QM systems

# Licensing RTBs and Research Ethics Approval

- RTBs can apply for approval to REC
- Will still need to have HTA licence
  - contrast project specific REC approval: licensing exemption
- Researchers receiving material from a REC approved RTB can store this material without a licence
- Normally expect MTAs with researchers receiving material

# Diagnostic Archives

- Primary purpose of storage?

Diagnosis → Not licensable

Research → Licensable

Diagnostic material when used for research needs to be stored under a licence or be used subject to REC approval



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**FAQs from the research sector**

# What is Relevant Material?

- Material taken from the human body that consists of / includes cells
- Guidance by HTA on website

Material includes:

- 'Waste products' (urine, faeces)
- Cellular material (viable and non viable): CSF, ascites

# What is not Relevant Material?

- Material which has been processed to remove cells – plasma, serum
- Cell lines (unless grown for human application)
- Genetically modified cells
- DNA/RNA ('genetic material')
- Proteins/Lipids/Carbohydrates, etc
- Hair and nails from the living (but 'bodily material' in terms of DNA analysis)

# Consent: Storage and Use

- Existing Holdings: Material stored before 1 September 2006
  - From the living or the deceased
  - Consent provisions do not apply
- Material acquired after 1 September 2006
  - Consent required
- Exemptions:
  - Not required for anonymised, ethically approved research
    - Good practice to obtain consent

# Licensing for Storage

- License the storage of relevant material for a scheduled purpose –
  - Research in connection with the disorders, or the functioning, of the human body
- Licence required unless current / pending ethically approval
- Existing holdings not exempt
- No exceptions for short term storage

# Import and Export of material

- HTA import and export Code of Practice:
  - Good practice
- Legal provisions apply within UK only
- Ethics Committees defined by statute
- Storing under licence as alternative

# Contacts :

[www.hta.gov.uk](http://www.hta.gov.uk)

## Research:

- **Advice and guidance** – [enquiries@hta.gov.uk](mailto:enquiries@hta.gov.uk)
- **Kristi Collins** – Strategic lead for research, Head of Regulation  
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- **Dr. Christiane Niederlaender** – lead for research, Regulation Manager  
[christiane.niederlaender@hta.gov.uk](mailto:christiane.niederlaender@hta.gov.uk)

## Heads of Regulation by geographical patch:

- Scotland, East of England, North East of England and South East of England.  
**Caroline Browne** - [caroline.browne@hta.gov.uk](mailto:caroline.browne@hta.gov.uk)
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