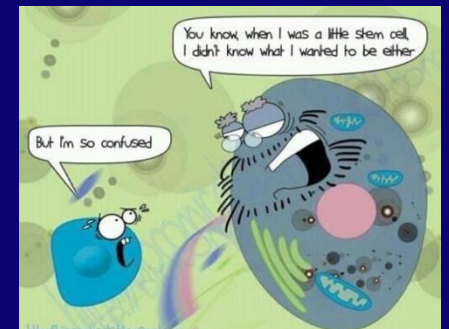


# Human Tissue Act

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# What is the Human Tissue Act?

- **The Human Tissue Act (2004)** is an Act of Parliament which created the Human Tissue Authority (HTA) to regulate the:

- **removal**
- **storage**
- **use**
- **disposal**

of human bodies, organs and tissue

- Came into force on 1<sup>st</sup> September 2006
- Essentially the Act is in place to ensure that we are not removing and storing human tissue without CONSENT (of the living donors or the relatives of deceased donors)

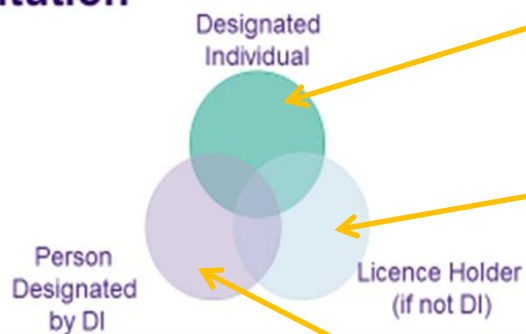
# What does this mean in practical terms?

- Every institution storing licensable human tissue is required to hold a HTA licence
- The University currently holds a licence that covers activity on the St Luke's and Streatham Campuses
- Our licence allows us to store samples for **research** *i.e. for a study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body*
- Our licence also allows us to store human material for teaching
- The HTA inspect periodically to ensure that the terms of the Act are being complied with

# How does the Human Tissue Act work in practice in a licensed institution?

The Human Tissue Act framework in any premises operates around three key roles, as outlined in the HT Act

## HTA framework - based on governance of institution



Other people working on licensed premises and carrying out licensed activities do so **under the direction of** the Designated Individual or a Person Designated by the DI

**Supervises the activities being carried out (J Whatmore)**

**Oversees the licence (G Seymour, UoE Research Ethics and Governance Manager)**

**Authorised by the Designated Individual (DI) to undertake activities performed under the Licence. In practice – the PI on a study or someone nominated by the PI to act for them**

## Role of the Designated Individual (DI)

- Implement the requirements of the HT Act. i.e. the consent, collection, storage, use and disposal of licensable human tissue
- Authorised by the HTA to supervise the licensed activity
- Has legal responsibility under Section 18 of the Human Tissue Act to ensure:
  - that suitable practices are used in undertaking the licensed activity
  - that other persons working under the licence are suitable
  - that the conditions of the licence are complied with

Failure to undertake the responsibilities expected of the DI could lead to prosecution and/or the revocation of the licence

## What is covered by the Act?

- Material from a human body which consists of, or includes, human cells with intact / undisrupted cell membranes (e.g. blood, tissue slices/biopsies, bone, skin, sputum etc.)
- Even the possible presence of a **single** intact human cell means that the sample is covered by the Act
- The HT Act does not cover:
  - embryo's outside the human body
  - hair and nail from the body of a living person
  - cell lines or primary cells that have divided in culture
  - any other human material created outside the human body
  - serum
  - DNA and RNA
  - Samples that have been treated, processed or lysed through a process intended to render them acellular e.g. plasma that has been centrifuged to ensure removal of all cells, even platelets

# A couple of definitions

## **Relevant material:**

All cellular human samples are referred to by the HT Act as “relevant” material

## **Licensable material:**

Relevant material that is regulated by our HT Authority licence and subject to audit and inspection by the HTA

In practical terms – under the HT Act all licensable human samples that we store must have a unique ID code and be fully traceable and documented through from collection, storage, use and disposal. New samples can only be collected with fully documented informed consent of the donor (or a relative if the donor is deceased)

**Compliance with the legislation is NOT optional**

## What if I want to store human samples at the University of Exeter?

- It is essential that the DI keeps a record of any stored human samples so that relevant and licensable material can be recognised and the Act implemented
- Therefore, the DI should be informed of ANY human sample/tissue that is being brought to the University for storage
- An “Application to store human tissue” must be completed. This provides information on: the type of samples; storage location; study ID, relevant ethical approval
- Supporting documentation will be required i.e. copy of any ethics approval, confirmation of end dates of current ethics, copies of any Material Transfer Agreements if samples were collected elsewhere.
- If you hold licensable material then every quarter you will be required to report the number of licensable samples you hold.



### Application to store human samples for research

The Human Tissue Act (2004) requires us to govern all human tissue collected and stored for research purposes. In order to ensure that we are complying with the Act please complete one of these forms for ALL human research samples that you want to store on University premises. If you wish to store samples for less than 48 hours you may do so without completing this form, but please inform the Designated Individual (see below).

Samples collected with ethical approval from a NHS Research Ethics Committee are not licensable under the Act, but it is essential that the Designated Individual is still aware of the samples. University Research Ethics Committees are not recognised by the Act and so all samples collected with approval of these committees are licensable.

<b>Contact Details</b>			
1. Person Designated on study			
2. Name of person(s) responsible for samples *			
3. Contact telephone number of person(s) responsible			
<b>Study Details</b>			
4. Brief name of study (including CRF code if applicable) *			
5. Unique study code (assigned by Researcher) *			
6. Sample collection start date			
7. Study end date			
<b>Sample Details</b>			
8. What kind of samples are you storing e.g. plasma, blood, urine, tissue, histology slides, etc.			
9. Where will the samples be stored:		Building	Room No
		Freezer <input type="checkbox"/>	Fridge <input type="checkbox"/>
		Room Temperature <input type="checkbox"/> (check box)	
10. Do these samples contain cellular material? <i>If no, provide protocol used to render tissue acellular.</i>			
11. Were the samples collected before 1 September 2006?			
12. How many samples (approximately in total) are you storing?			
13. Were the samples collected in Exeter? If no, provide a copy of the MTA			
<b>Ethics Details</b>			
14. Ethics number of this study (University of Exeter/ NHS)			
15. Was collection of your samples approved by an NHS Research Ethics Committee? If yes, please provide a copy of the Ethics?			
16. When does your ethical approval to store these samples expire?			
17. Do you want to keep the samples after the ethics expires?			

APPLICATIONS TO STORE HUMAN TISSUE CAN ONLY BE PROCESSED IF THIS FORM IS COMPLETED AND RETURNED TO THE HUMAN TISSUE AUTHORITY DESIGNATED INDIVIDUAL (DI)  
(DR J WHATMORE, [J.L.WHATMORE@EXETER.AC.UK](mailto:J.L.WHATMORE@EXETER.AC.UK)).

If you wish to store cellular human samples then please provide:

- (1) a copy of the ethical approval letter for this study
- (2) documented evidence that the ethics is current
- (3) a copy of the MTA if the samples were collected elsewhere

Details marked with \* must be recorded on sample box and/or freezer door plan



Name of Study		Person Responsible	
Are samples licensable under the HTA? Yes <input type="checkbox"/> No <input type="checkbox"/>	Is ethics in place? Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>		
NHS ethical approval confirmed? Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	Dates covered by NHS LREC approval confirmed: Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>		
Evidence of MTA – are samples collected elsewhere? Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>	Date application received by DI		

# What if I have licensable human samples?

Then procedures must be in place to ensure that:

1. All new samples are collected with informed consent of donors. Collection, use and storage of human tissue without consent is an offence
2. Sample consent, collection, storage, use and disposal have appropriate standard operating procedures (SOPs), risk assessments etc. in place
3. Samples have a unique sample code and are logged on a database recording date of collection, storage location, date of use and disposal

Continued.....

4. Premises, facilities and equipment are suitable. Storage provisions should be secure, and where appropriate (e.g. freezers) have documented regular maintenance/servicing and monitoring and back-up systems

5. A clear and sensitive disposal policy is in place e.g. human samples can go to clinical waste but should be bagged separately to other waste

**The DI will carry out regular audits to ensure that these practices are in place AND the HTA inspect periodically.**

Human samples to be stored at the University of Exeter (St Luke's or Streatham)

Inform DI and complete an "Application to store form" providing supporting documentation i.e. proof of Ethics, protocol for producing acellular plasma etc.

DI will determine whether samples constitute licensable material

If samples are licensable ensure that all documentation i.e. SOPs, RAs etc are in place for consent, collection, storage, use and disposal of samples

Complete quarterly return detailing any licensable material to DI

DI will complete an audit of any licensable material

If samples are not licensable material store in designated freezer (s) as described on the "Application to store"

# A few specific questions

## 1. Are cell lines defined as relevant material?

**NO** Primary human tissue and cells i.e. tissues and cells removed directly from a person ARE relevant material under the HT Act

But... cell lines resulting from expansion of primary cell cultures are not relevant material, as all the original cells have divided and so have been created outside the human body. The storage of cell lines for research does not require a HTA licence

## 2. Are cell deposits / tissue sections on microscope slides relevant material?

**YES** In general cell deposits or tissue sections on microscope slides are considered to constitute relevant material. This is because such deposits or sections are likely to contain whole cells

## A few specific questions ....

### **3. What if I have samples collected before the Act came into force – 1<sup>st</sup> September 2006?**

- There is no exemption for cellular material collected prior to the Act coming into force. This material is still relevant, and may be licensable. However, you are not required to provide evidence of consent for its storage, use or disposal

So.... an “Application to Store Form” must be completed

### **4. What if my samples were collected overseas?**

- The consent provisions of the HT Act do not apply to imported material. However, the licensing provisions of the Act do; thus this material will be relevant and licensable. A Material Transfer Agreement must be in place authorising transfer of the samples

*N.B. Although the consent provisions of the Act do not apply to imported material, the HTA still require documented evidence that the samples were donated for the purpose for which they are being used in the UK.*

## A few specific questions ....

### **5. Is plasma classed as relevant material?**

**NO** – as long as it has been rendered acellular i.e. it has been centrifuged sufficiently to pellet any platelets.

Similarly, urine, sputum, synovial fluid etc. samples will not be classed as relevant material if they have been processed to remove ALL cells.

**The DI will need details of the protocol used to produce acellular material in order to confirm to the HTA that your stored human samples are cell free.**

## A few specific questions ....

**6. Do I need to fill in an “Application to Store Human Tissue” form if my samples do not contain cells e.g. processed plasma, urine etc.**

**Yes** – the DI needs to be aware of **all** human samples on site and their location even if they are acellular

**This is because:**

- the DI needs to be satisfied that the samples are not relevant and licensable
- the DI needs to demonstrate a robust system that can identify HT Act relevant material
- all human samples in storage areas need to be identifiable and accountable should we be inspected

**Material that has been confirmed to be not licensable under the HT Act will not subject to regular audit**



## A few specific questions ....

### **7. What if I wish to store material in Exeter that was collected elsewhere in the UK?**

- This material can be stored in Exeter, but the DI will need documentary evidence to satisfy the HTA that the samples were collected
  - a) with ethical approval and
  - b) that the original consent covered transport to a different location
- Copy of a Material Transfer Agreement or Transport document confirming transfer/transport of the samples between the two institutions will be required

## A few specific questions ....

**8. Do I need to fill out an Application to Store form for samples that I am receiving and analysing immediately?**

**NO** – the HT Act regulates stored samples. If you receive cellular human samples and then immediately process or analyse them in such a way that all cells are lysed or removed then the samples do not need to be reported to the DI at this site

# A couple of local case studies ....

**Human bones or skeletons donated to the University prior to the Act i.e. 1<sup>st</sup> September 2006**

**DI asked the HTA if these are licensable**

*Answer – yes. Since it is impossible to prove that the bones have no intact cells they are subject to the licencing provisions of the Act, but not the consent provisions (since they were collected prior to the Act)*

To be licensable a human sample only has to only possibly contain a single cell with an intact membrane - doesn't matter if cell is not viable

# A couple of local case studies ....

**DI asked the HTA if cellular human material from a commercial supplier is licensable and if so what is required in terms of confirming consent**

*Answer – Yes the tissue is licensable. When purchasing human tissue from a commercial supplier, you do have a responsibility to ensure that the tissue supplied has been consented appropriately. The supplier should adhere to local requirements for seeking such consent*

So... if storing commercially purchased human cellular tissue then you must complete an “Application to Store” form and request written confirmation from the supplier that the tissue was collected with full consent of the donors

# Summary

- **Any human samples/tissue stored on the St Luke's or Streatham Campuses MUST be reported to the DI via an "Application to Store" form**
- ALL cellular human samples/tissue MUST be reported to the University Designated Individual
- The Designated Individual will ensure that all HTA regulatory requirements are met
- Compliance with the law is NOT optional
- Consent MUST be obtained for use of all human tissue collected in the UK after 1<sup>st</sup> September 2006. Up to 3 years imprisonment for failure to obtain/misuse 'appropriate' consent
- Failure to adhere to our HT Authority licence requirements could lead to prosecution and/or the revocation of the licence

# Where do I find more information

Designated Individual

Dr Jacqueline Whatmore  
St Lukes' Campus  
01392 722944  
j.l.whatmore@exeter.ac.uk

HTA Administrator/  
Person Designated

Susan Westoby  
St Luke's Campus  
01392 722940  
s.westoby@exeter.ac.uk

Shared drive

\\isad.isadroot.ex.ac.uk\uoer\research\UEMS\HTA\

UoE website

<http://www.exeter.ac.uk/research/toolkit/throughout/ethics/humantissue>

HTA website

<http://www.hta.gov.uk/>

Your Person Designated