Human Tissue Act Overview

Using Human Material in Research
Dr. Janet Risk j.m.risk@liv.ac.uk

14th November 2016
Overview

- The Human Tissue Act
- The Human Tissue Authority – Licencing
- Relevant Material
- Ethical Approval & Sponsorship
- Staying Compliant
  - Consent
  - Storage
  - Disposal
  - SOPs
- Contacts
What do all of these have in common?

They are all RELEVANT HUMAN MATERIAL. Collections of these materials, regardless of where they originate, should be registered and a summary of holdings returned annually.
Relevant Material

- Intentionally broad definition
- Any human material, other than gametes, that is composed of, or containing, human cells
- Includes tissue and fluids such as saliva & faeces
- Includes material collected in order to isolate infectious agents
- Can be a section or portion as in slides
- Embryos outside of the body and hair and nails are not considered relevant material
- Material containing cells which is processed to remove those cells within ‘normal expectations’ (for example serum or plasma) will not be considered relevant as long as it is processed and the cells are disposed of within a week

The Human Tissue Act

- The HT Act was created as a response to ‘scandals’ being highlighted in the media
- One of the most notable being at Alder Hey
- It was created in 2004 to replace all other acts/regulations in place at the time
- It regulates the removal, storage, use, and disposal of human material, including tissue and fluids
- The Human Tissue Authority was set up to implement the HT Act and has created several Codes of Practice – revised 2017
- The HTA’s role is to support users and to provide public confidence in the process of using human material in research
Human Tissue Authority licencing

- HTA offers 5 types of licence: anatomy, research, transplant, post-mortem and display
- University holds research and anatomy licences
- Research Licence
  - physical licence
  - pertains to storage of relevant material for research in university-owned facilities
  - responsibility lies with the Designated Individual (DI)
  - delegation to Persons Designated (PDs) at satellite sites and Human Material Officers (HMOs) in Research Institutes
- Anatomy licence – ICS
- NHS holds transplant and post-mortem
Person Designate (PD)
- Works under supervision of the DI to fulfil the same role as the DI
- Responsibility is delegated by the DI to PDs
- Often located at a geographically distinct site or in an area with increased activity involving human material

Designated Individual
Dr. Janet Risk

Central PD
Dr. Jen Blaylock

PDs
- Liverpool Women’s Hospital
- Institute in the Park at Alder Hey Hospital
- Aintree University Hospital
- Leahurst campus

CIs and Custodians

CIs and PIs on projects involving relevant human material

Biobank managers
Person Designate (PD)
- Works under supervision of the DI to fulfil the same role as the DI
- Responsibility is delegated by the DI to PDs
- Often located at a geographically distinct site or in an area with increased activity involving human material

Human Material Officer (HMO)
- Local contact with knowledge of human material issues
- Advice on local and HTA procedures & requirements
- Support with reporting, documentation
- Training & audit

Designated Individual
Dr. Janet Risk
Liverpool Women’s Hospital
Institute in the Park at Alder Hey Hospital
Aintree University Hospital
Leahurst campus

Biobank managers
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Central PD
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Liverpool Women’s Hospital
Institute in the Park at Alder Hey Hospital
Aintree University Hospital
Leahurst campus

HMOs
FoHLS Institute of Translational Medicine
FoHLS Institute of Integrative Biology
FoHLS Institute of Infection and Global Health
FoHLS Institute Psychology Health & Society
FoHLS Institutes of Learning & Teaching
Faculty of Science and Engineering
Faculty of Humanities & Social Sciences

CIs and Custodians

Faculty of Science and Engineering
Faculty of Humanities & Social Sciences
UoL HTA research licence allows storage of human material, **but not its collection or use in research**

Ethical approval is required for all research undertaken by any staff or student that involves human participants, including the collection, storage, and use of relevant material.

Project–specific ethical approval is granted via a REC and relates to one protocol and a defined endpoint:

- Health Research Authority (HRA) – national research ethics network (NRES)
- Local eg. UoL REC [https://www.liv.ac.uk/intranet/research-support-office/research-ethics/ethics-application-submission/](https://www.liv.ac.uk/intranet/research-support-office/research-ethics/ethics-application-submission/)
- Conferred by a tissue bank
Ethical Approval

- Tissue banks have ethical approval to collect tissue for future research, rather than for a specific project.
- Tissue banks may have an associated REC that can give approval for projects requesting material.
Liverpool Bio Innovation Hub (LBIH) Biobank

- Research Tissue Bank on campus
- Offering a variety of samples including bespoke sampling, IHC, H&E, embedding, TMAs
- Able to confer ethical approval for projects
- Speak to Rhiannon Clarke on 0151 794 9103 or at rhugh@liverpool.ac.uk for more information

http://www.liv.ac.uk/lbih
Twitter @LBIH_Biobank
Ethical Approval

- Tissue banks have ethical approval to collect tissue for future research, rather than for a specific project.

- Tissue banks *may* have an associated REC that can give approval for projects requesting material.

- Projects using any relevant material, including that from healthy volunteers, must be approved by a REC, registered with your Institute’s HMO and included in the Human Material annual return.

- Don’t know which ethical approval route to use?

  [https://forms.liverpool.ac.uk/ActivityForm/Index](https://forms.liverpool.ac.uk/ActivityForm/Index)
The sponsor is an organisation which takes responsibility for the quality and conduct of a research project.

Sponsorship **must** be obtained for projects involving NHS patients. [https://www.liv.ac.uk/intranet/research-support-office/crg/](https://www.liv.ac.uk/intranet/research-support-office/crg/)

The Liverpool Bio Innovation Hub (LBIH) Biobank can confer both ethical approval and research sponsorship to projects that are approved by its REC.
As an institution, we are required to implement certain procedures and policies to ensure compliance in the following areas:

- Consent
- Governance (including records of tissue acquisition, storage, usage, disposal)
- Premises, Facilities and Equipment (PFE)
- Disposal
- Training and support for all staff
- Annual return of holdings
Consent

- First “Code of Practice” implemented by the HTA and is a legal requirement
- Donors should be asked for relevant and fully informed consent
- Include stipulations for use in genetic testing, non-human models, and commercial collaboration if these are part of the planned use
- Consider asking for consent for future studies
- Jen or your HMO can supply you with a template consent form to use
Existing Holdings

- We were given until 1 Sept 2006 to ‘catch up’ with regulations.
- Samples collected before then are considered ‘existing holdings’ and may not be subject to consent stipulations.
- In all cases, it is best to obtain consent, but where the sample is classified as ‘existing holdings’ and it is impossible to obtain consent, the tissue may be used, provided ethical approval has been obtained.
Bringing Human Material from Other Institutions

• Bringing Human Material from other institutions, for example a previous post, may require a Material Transfer Agreement (MTA)

• As previously, stated, ALL Human Material brought onto campus, whether for current projects or past work, MUST be registered with your HMO
Storage

- Must be stored and **catalogued appropriately**
  - labelled boxes – best practice in a multi-user and/or multi-project storage site with is to store all samples from a single study together
  - logged in and out of the storage facility – i.e. sample tracking

- Any facility storing/using identifiable information must have a linked system to ensure that only permitted individuals are allowed access to it

- In the case of ‘existing holdings’ labelled with identifiable information, that information must be removed; if this is not possible, these samples must be stored using additional security
Disposal

- Disposal
  - Routine, post-analysis
  - Storage anomaly e.g. freezer failure,
  - Consent withdrawn,
  - Unusable sample e.g. haemolysed blood

- The donor has the right to request a specific means of disposal (although this is rare) and this should be recorded on the consent form and highlighted in any sample database

- Disposal should be made in a respectful manner – separately bagged and tagged

- Disposal should be recorded
SOPs

- Good practice is to ensure that there are Standard Operating Procedures for collection (including taking consent), storage, disposal and keeping records.

- A Human Material web site, including guidance documents, is under development

- Key overarching documents (University human material policy, overarching risk assessment, summary of documentation required) are available on request from your HMO, Dr. Jen Blaylock (rsojb486@liverpool.ac.uk) or Dr. Janet Risk (j.m риск@liverpool.ac.uk)
Your PDs/HMOs are

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Questions?