

University arrangements for compliance with the Human Tissue Act

What do I need to know about licences and consent?

Definition of Relevant Material

The definition of relevant material in the Human Tissue Act 2004 (excluding human application) is:

Section 53: Relevant Material

1. In this Act, "relevant material" means material, other than gametes, which consists of or includes human cells.
2. In this Act, references to relevant material from a human body do not include:
 - (a) embryos outside the human body, or
 - (b) hair and nail from the body of a living person.

The Human Tissue Authority (HTA) has produced a list to provide stakeholders with guidance on whether specific materials fall within the definition of relevant material under the Human Tissue Act 2004 (HT Act). Please see the supplementary list of materials for the purposes of the HT Act.

<https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004>

Consent

Consent is the fundamental principle of the HT Act and must be obtained for the removal, storage and use of human tissue for certain scheduled purposes, including research. Further information is available via the HTA Code of Practice (Consent)

<https://www.hta.gov.uk/hta-codes-practice-and-standards-0>

Licence arrangements at the University of Birmingham

The University of Birmingham (UoB) is the corporate Licence Holder for the HTA Licences in the University. The PVC Research and Knowledge Transfer is the corporate point of contact.

Premises where tissue collections are held must be licensed, not the collections themselves. All collections stored at these premises must be collected and held in accordance with the Quality Manual for the University and the facility.

Each licence has a Designated Individual (DI) who has a set of specific legal responsibilities for compliance with the HT Act on their premises. The following table summarises the Licences that are currently held and the DI associated with each

licence.

Licence	No	DI	Link to HTA information
Anatomy	12236	Prof Eric Jenkinson	https://www.hta.gov.uk/establishments/university-birmingham-12236
Dental School incl. Research Tissue Bank	12313	Dr Phillip Tomson	https://www.hta.gov.uk/establishments/birmingham-dental-hospital-and-school-dentistry-12313
College of Medical & Dental Sciences incl. Research Tissue Bank (HBRC) https://www.birmingham.ac.uk/facilities/hbrc/index.aspx	12358	Prof Christopher McCabe	https://www.hta.gov.uk/establishments/college-medical-and-dental-sciences-12358
Human Application Licence	22672	Prof Philip Newsome	https://www.hta.gov.uk/establishments/university-birmingham-22672

HTA regulatory alerts

Regulatory alerts received by the Licence Holder from the HTA will be sent to the Head of Research Governance and Integrity who will circulate to all DIs. These alerts can be found on the HTA website.

Working under a HTA Licence exemption

According to guidance from the HTA, tissue stored for research purposes is exempt from the licensing requirement if the tissue is:

- held for a specific research project approved by a NHS Research Ethics Committee;
- from a person who died over 100 years ago;
- stored pending transfer elsewhere, providing it is held for a matter of hours or days and certainly no longer than a week and no research activity is undertaken.
- held whilst it is processed with the intention to render the tissue acellular providing the processing takes a matter of hours or days and certainly no longer than a week and no research activity is undertaken.
- created outside the human body and which does not involve any application of tissues or cells into humans.

Human Tissue Oversight Committee

The University has established the Human Tissue Oversight Committee (HTOC) to oversee the University's compliance with the Human Tissue Act (HT Act), EU Tissue and Cells Directive, licensing processes and auditing of licensed activities. It is also an expert advisory group, sharing best practice in all aspects of the HTA licensing requirements and HT Act compliance. In addition it functions as a forum for HT Act related consultations on behalf of the University. The Committee meets 4 times per year. Please contact CRCT colleagues for the Terms of Reference.

<https://intranet.birmingham.ac.uk/hr/wellbeing/worksafe/biological/index.aspx>

What do I need to know if I want to use human tissue in my research?

Support for researchers wishing to use human tissue in their research is available

- the Clinical Research Compliance Team (CRCT)
<https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx>
- the Research Governance Team (RGT)
<https://intranet.birmingham.ac.uk/finance/rss/research-support-group/integrity-ethics-governance/research-governance/index.aspx>

What do I need to do to work in line with a Licence exemption?

Research that involves the storage, collection, use and/or import of human tissue requires an ethical review by a NHS Research Ethics Committee (NHS REC) to ensure HTA Licence exemption.

Researchers should familiarise themselves with requirements for human tissue research and the following MRC information and e-learning has been developed for the research community

<https://mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/human-tissue/>

This includes research involving healthy volunteers on non-NHS premises. University ethics committees are not recognised under the HT Act. Research that involves Relevant Material should be registered with the Research Governance Team by completing a Self-Assessment Form (SAF).

<https://intranet.birmingham.ac.uk/finance/rss/research-support-group/integrity-ethics-governance/research-ethics/index.aspx>

- A specific study involving human tissue and taking place in the NHS will need to apply for HRA Approval (which will include NHS REC review) and seek confirmation of capacity and capability from participating NHS organisations.
- A specific study involving human tissue that is taking place at non-NHS sites will need to apply for NHS REC review without the need for HRA Approval.
- If research involves the procurement of material and subsequent transplantation then a HTA Application Licence might be required and you must contact the RGT.
- Research that involves tissue from a Research Tissue Bank
 - A Research Tissue Bank (RTB) is 'a collection of human tissue or other biological material, which is stored for potential research use. If you plan to obtain human tissue from a RTB, you should check the ethical arrangements of the RTB to determine whether:
 - you need to make your own project-specific ethics application to a NHS REC; or

- your study will be covered by the NHS REC ethics approval held by the RTB.
- Research that involves imported tissue
Human tissue samples received from outside of England, Wales and Northern Ireland are considered an import. Storage of imported samples for research is a licensable activity under the HT Act and will either need to be stored under a Human Tissue Authority Licence or with a favourable opinion from a NHS REC. Imported material should be procured, used, handled, stored, transported and disposed of in accordance with the consent given by the donor. Further guidance can be obtained from the HTA Codes of Practice (Research)
<https://www.hta.gov.uk/hta-codes-practice-and-standards-0>

Please note

If you have been presented with a research related agreement or material transfer agreement for signature please, contact the University's Research Contracts Team.

What to do when the ethical approval expires

If you do not want to dispose of the samples collected during your specific study when the ethical approval expires, there are a number of options available:

- extend the ethical approval by advising the NHS REC in a progress report
- make a new ethics application to a NHS REC
- apply to deposit the samples into a RTB
- apply for short-term storage in a biorepository, for example via the NIHR National Biosample Centre in Milton Keynes <https://www.ukbiocentre.com/>
- transfer the samples to a HTA licensed facility, with the agreement of the appropriate Designated Individual

Disposal of samples should be in accordance with the HT Act and as described in the ethics application.

Health and Safety Requirements

When working with human tissue it is necessary to consider the types of pathogens that may be present in the material, taking into account the distribution of specific pathogens within the body, and the likelihood that they will be present given the source (be it a donor, patient group, or general population).

A risk assessment of the proposed work with human tissue must be undertaken and, depending on the risks identified, approval in line with H+S processes may be required before work can commence.

<https://intranet.birmingham.ac.uk/hr/wellbeing/worksafe/biological/index.aspx>