ULSTER UNIVERSITY

RESEACH GOVERNANCE

Policy on Research using Human Tissue

Policy on Research using Human Tissue

1. Background

The Human Tissue Act 2004 ('the Act') became law on 1 September 2006. It applies to England, Wales and Northern Ireland (only part of the Act applies in Scotland). The Act regulates the procurement, use and storage of human tissue for a range of "Scheduled Purposes". These include anatomy, public display and – of primary concern to the University, its staff and students – research. Research activities covered by the Act are:

- Research in connection with disorders, or the functioning, of the human body.

- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person).

In order to fulfil its obligations under the Act, the University is required to hold a licence from the Human Tissue Authority (HTA) https://www.hta.gov.uk/ and to adhere to a series of terms and conditions relating to ethics, consent, record-keeping and the appropriate use and disposal of tissue.

It is an offence under the Act and also against the policy of the University to procure, store or use tissue for the purposes of research unless the provisions of the Act have been and will continue to be complied with. The Act makes the following activities offences:

- Removing, storing or using human tissue for Scheduled Purposes without appropriate consent.

- Storing or using human tissue donated for a Scheduled Purpose for any other purpose.

- Trafficking in human tissue for transplantation purposes.

- Carrying out licensable activities without holding a licence from the HTA (with lower penalties for related lesser offences such as failing to produce records or obstructing the HTA in carrying out its power or responsibilities).

- Having human tissue, including hair, nail, and gametes (i.e. cells connected with sexual reproduction), with the intention of its DNA being analysed without the consent of the person from whom the tissue came or of those close to them if they have died. (Medical diagnosis and treatment, criminal investigations, etc., are excluded.)

The procurement, use, storage and disposal of human tissue as set out in sections 6 to 9 below are subject to the University's standard operating procedures (Appendix 1).

2. Definition of Human Tissue

For the purposes of the Act, human tissue is any material from a living human being that is likely to contain a human cell.

This is labelled "relevant material" which in turn is defined as:

Material other than gametes which consists of or includes human cells.

This includes obvious examples such as blood, muscle, lung, bowel, brain, bone, skin etc. It also includes urine and faecal matter, other bodily waste or excretions and preserved and fixed samples.

In the 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

It does not include hair or nails unless the purpose of procurement is DNA analysis. Reproductive cells are also excluded as they are regulated by a separate act and authority.

The use of tissue from deceased individuals is also regulated by the Act. This includes, for example, skeletal remains that are less than 100 years old and also post mortem material.

More detailed lists of relevant and non-relevant material are provided under 10 (below).

3. The University's Position

At this time, the University holds a single licence for the purposes of research. The licence permits the University to operate a tissue bank of existing and future holdings. These holdings will largely be stored in appropriate refrigeration facilities, mainly within the premises of the Faculty of Life and Health Sciences at the Coleraine campus, but also at other permitted locations including the Ulster Sports Academy at the Jordanstown campus, and the C-TRIC facility at Altnagelvin Hospital, Londonderry.

All locations that hold or wish to hold human tissue must apply to the University to do so. This requirement is absolute because of the terms of the licence and the positions in law of the University as a licence holder and of the Designated Individual.

All research activities conducted by University staff or students should also comply with other University polices, such as in relation to Health and Safety, Data Protection and the Code of Practice for Professional Integrity in the Conduct of Research:

- http://www.ulster.ac.uk/hr/healthandsafety/Procedures/university_health_and_safety_policy.pdf
- http://www.ulster.ac.uk/secretary/policyimplementation/dataprotection/data_protection_policy__august_2015.pdf
- https://www.ulster.ac.uk/__data/assets/pdf_file/0005/59837/conduct-of-research.pdf

4. The Designated Individual

The Designated Individual (DI) is the member of staff of the University who oversees the implementation and maintenance of the provisions of the Act. The DI carries

responsibility in law for ensuring that the University and its staff and students comply with the Act.

The DI is supported in this position by the University and by appropriate policies and procedures.

There can be only one DI per licence. However, with the knowledge and approval of the DI, the University can also appoint Persons Designated (PDs) at individual locations in which human tissue is stored.

5. Persons Designated

As the appointment of Persons Designated is linked to the locations of individual storage facilities (see under 3 above), their identities, positions and qualifications must be registered as part of the licensing process. The position of PD is formal under the Act. All PDs are responsible to the DI for matters related to or regulated by the Act.

6. Tissue from the Living

6.1 Procurement of Tissue from the Living

It is anticipated that the requirements of most researchers at the University will be met by the procurement or use of tissue from the living.

Under the Act, the principles of the procurement of such tissue are governed by requirements relating to consent.

6.2 Consent

It is a requirement that those donating tissue for the purposes of research are made aware of and agree to the uses to which their tissue will be put. This is **informed consent** and is fundamental to the Act. Researchers should bear in mind that different procedures apply in respect of obtaining consent from adults (particularly vulnerable adults), children, and people with learning disabilities. Studies that involve researchers working alone with vulnerable adults or children require the individual researchers to be assessed under the Protection of Children and Vulnerable Adults (NI) Order 2003.

https://www.ulster.ac.uk/__data/assets/pdf_file/0010/75637/HumanParticipantsPolicy.pdf

It is incumbent upon researchers to retain a full set of signed consent forms for all samples. The samples and the consent forms must be cross-referenced (or appropriately coded) to ensure that they can be matched for the purposes of audit and inspection.

If it is the researcher's intention to retain the tissue beyond the duration of the study for possible use in future, as yet undefined, studies, then the information and consent process must reflect this. The Act permits what is known as *enduring consent* but only if the basis for it is explicit and ethical.

All samples that are retained with enduring consent must be stored appropriately and in full compliance with the University's licence from the Human Tissue Authority.

The Human Tissue Authority has issued a Code of Practice in respect of consent:

https://www.hta.gov.uk/code-practice-1-consent

Researchers must note that as the Act has made consent the fundamental requirement upon which access to and use of human tissue is based, it is likely that any review or audit conducted by the Human Tissue Authority will focus upon the procedures used in obtaining consent and the retention of all documentation relating to it.

It is therefore incumbent upon researchers to retain in an appropriate manner and to make available for inspection all consent forms and associated documentation.

To ensure equality of opportunity in accessing information researchers should take into account in the consent process that information may need to be made available on request in accessible formats (for example; large print, computer disc, audiocassette, Braille or other) and in minority languages to meet the needs of those who are not fluent in English. Specific consideration should also be given to how best to communicate information to young people and those with learning disabilities.

6.3 Ethical Review and Approval

The Human Tissue Authority has indicated that consideration and approval of research proposals by a research ethics committee is not required by law except in specific circumstances (i.e., where there is no licence for the storage of tissue for research and/or where the researcher does not intend to obtain the consent of the tissue donor for the proposed research):

> *"There is no legal requirement by the Human Tissue Authority for researchers to obtain approval by an approved ethics committee"*
> (Human Tissue Authority, 21 September 2006, e-mail response to query on the position of ethical review under the Act)

However, it is the University's position that all research projects that include the procurement and use of tissue from the living must be reviewed by an appropriate ethics committee. Such studies will fall either into research category C (research involving patients of the NHS/HSC and requiring consideration by a statutory ethics committee) or category D (research involving the use of tissue from healthy volunteers).

6.3.1 Category C studies that involve human tissue

The role of a statutory ethics authority can only be fulfilled by an ethics committee appointed by the Health Research Authority (England), with equivalent arrangements in Scotland and Wales, and by the Health and Social Care Business Services Organisation in Northern Ireland. As no university ethics committees are currently recognised by any of the responsible authorities, this means that all human tissue studies in category C must be submitted to the relevant HSC/NHS ethics committee (for example, Office of Research Ethics Committees NI (ORECNI)) using the national (Integrated Research Approval System (IRAS)) application form.

As with other studies that are submitted to HSC/NHS ethics committees by staff or students of the University, these must first be subjected to peer review and consideration by a filter committee. As the University is required to confirm that indemnity and

sponsorship are in place and that the research is compliant with the Act, all such studies must also be made known to the Research Governance section prior to final submission via IRAS.

6.3.2 Category D studies

On the basis of the guidance received and quoted in 6.3 above, it is the University's position that all category D studies must be reviewed by the University Research Ethics Committee (UREC). Forms RG1 should be used (including RG1d, the supplemental form for human tissue studies). As with other categories of study, these forms must be reviewed through the peer review and filter committee process prior to submission to the UREC.

6.4 Storage of Tissue from the Living

All tissue from living persons must be stored appropriately and in compliance with the University's licence from the Human Tissue Authority. In general terms, this means that samples must be:

- labelled and recorded appropriately and cross-referenced with consent forms (see 6.2 above);
- stored in appropriate and recognized facilities within the University or elsewhere (for example, secure and monitored refrigerators or freezers, access to which is controlled by the DI or a PD); and
- recorded in and out of the storage facility on each occasion.

Samples must NOT be:

- removed from University premises unless the appropriate authorization has been granted;
- used for any purpose other than that which has been recorded and for which consent is in place; or
- stored inappropriately.

6.5 Disposal of Tissue from the Living

The Act requires that human tissue must be disposed of appropriately. For blood and similar material, the required method of disposal is incineration. The University has an agreement in place with an appropriate contractor for this service.

Individual research participants must be made aware of how and when their tissue will be disposed of as part of the informed consent process (see 6.2 above).

All samples must be disposed of as required by the University's procedures and the agreement with the contractor.

7. Tissue from Deceased Persons

7.1 Procurement of Tissue from Deceased Persons

There might be occasions upon which researchers require access to post-mortem material, although it is expected that this will be comparatively rare.

As with tissue from the living, access to tissue from deceased persons is subject to receipt of appropriate consent, either obtained prior to the death of the individual concerned or from a nominated representative or qualifying individual after death or in the event of incapacity.

Qualifying individuals are normally family members (spouse, parent, son/daughter).

7.2 Consent

It is a requirement that those agreeing to the donation of tissue for the purposes of research are made aware of and agree to the uses to which the tissue will be put. This is informed consent and is fundamental to the Act.

It is incumbent upon researchers to retain a full set of signed consent forms for all samples. The samples and the consent forms must be cross-referenced (or appropriately coded) to ensure that they can be matched for the purposes of audit and inspection.

If it is the researcher's intention to retain the tissue beyond the duration of the study for possible use in future, as yet undefined, studies, then the information and consent process must reflect this. The Act permits what is known as *enduring consent* but only if the basis for it is explicit and ethical.

All samples that are retained with enduring consent must be stored appropriately and in full compliance with the University's licence from the Human Tissue Authority.

To ensure equality of opportunity in accessing information researchers should take into account in the consent process that information may need to be made available on request in accessible formats (for example; large print, computer disc, audiocassette, Braille or other) and in minority languages to meet the needs of those who are not fluent in English. Specific consideration should also be given to how best to communicate information to young people and those with learning disabilities.

7.3 Storage of Tissue from Deceased Persons

All tissue from deceased persons must be stored appropriately and in compliance with the University's licence from the Human Tissue Authority. In general terms, this means that samples must be:

- labelled and recorded appropriately and cross-referenced with consent forms (see 7.2 above);

- stored in appropriate and recognized facilities within the University or elsewhere (for example, secure and monitored refrigerators or freezers, access to which is controlled by the DI or a PD); and

- recorded in and out of the storage facility on each occasion.

Samples must NOT be:

- removed from University premises unless the appropriate authorization has been granted;
- used for any purpose other than that which has been recorded and for which consent is in place; or
- stored inappropriately.

Skeletal remains that are less than 100 years old must be stored (e.g. boxed and kept in a known location) and labelled appropriately.

7.4 Disposal of Tissue from Deceased Persons

The Act requires that human tissue must be disposed of appropriately. For blood and similar material, the required method of disposal is incineration. The University has an agreement in place with an appropriate contractor for this service.

The person giving consent must be made aware of how and when the tissue will be disposed of as part of the consent process (see 7.2 above).

All samples must be disposed of as required by the University's procedures and the agreement with the contractor.

8. The import of human tissue

8.1 The University requires that the import of material (the act of bringing material into the University from any external source) is formally managed and documented by the use of a material transfer agreement or similar. Evidence of appropriate consent for the material must also be furnished by the providing organisation.

8.2 All imported material must be stored in compliance with the University's standard operating procedures and must only be used as defined in the accompanying agreement.

9. The export of human issue

9.1 The University requires that the export of material (the act of sending material from the University to any external organisation) is formally managed and documented by the use of a material transfer agreement.

9.2 It is a requirement that the receiving organisation will store all such material appropriately and use it only as defined in the accompanying agreement.

10. Relevant and non-relevant material

10.1 Relevant material

The following types of human material are “relevant material” for the purposes of the Act:

- Any body parts or organs
- Whole blood
- Separated red blood cells
- Separated white blood cells
- Buccal swabs
- Tissue blocks
- Microscope slides
- Embryonic stem cells
- Biopsies
- Any human bodily fluid or waste product that might contain cells including:
  - Saliva
  - Tears
  - Milk
  - Faeces
  - Urine
  - Sputum
  - Plasma
  - Serum

- Human cell lines that have not undergone a mitotic division outside of the host.

  NB. After these cells have undergone mitotic division the Human Tissue Authority under the European Union Cell and Tissue Directive regulates them.

10.2 Non-relevant material

The following types of human material are “non-relevant material” for the purposes of the Act:

- All Quality Assurance material
- Gametes – Human Fertilisation and Embryology Authority Licence required
- Embryos and foetal tissue outside the human body – Human Fertilisation and Embryology Authority Licence required
- Hair and nail from a living person – unless you are extracting DNA
- Stomach contents
- Platelets
- Proteins
- Peptides
- Extracted DNA
- Extracted RNA

10.3 Review of relevant and non-relevant material

It should be noted that the University's position on relevant and non-relevant material is subject to change as aspects of the Human Tissue Act are clarified or are tested by law.

10.4 Genetic testing

Both consent and a licence are needed to store any tissue or cells for the purpose of genetic testing – to protect family members. A licence is not required to store DNA.

11. Human Tissue studies not regulated by the Human Tissue Act

It should be noted that studies involving human tissue by University staff or students or collaborations with other institutions outside the UK and therefore not regulated by the Human Tissue Act require the same standard of consent (i.e. fully informed consent) as those studies regulated by the Act irrespective of whether or not the samples will be imported to the University facilities.

Appendix I

SOPs

There is a suite of twenty SOPs relating to the use of human material.

These are accessible via the University Portal.