University of Staffordshire Human Tissue Policy

Contents

1.0 Introduction

1.1 Introduction

This policy has been developed to ensure that all staff and students at University of Staffordshire are complying with the Human Tissue Act (2004). The policy applies to everyone carrying out research which is covered by the Act, including but not limited to undergraduate and postgraduate students; staff members; visiting researchers; and individuals holding honorary posts.

The Human Tissue Act was created in response to a number of high-profile incidents in the UK where human tissue was removed, stored, used and disposed of without consent of the individual or their close relatives. Following an inquiry, the Human Tissue Act (2004) was created which, amongst other things, led to the creation of the Human Tissue Authority (HTA). The HTA is the regulating authority for matters relating to human tissue. The Act came into force on 1st September 2006.

The purpose of the Act and the HTA is to regulate the "removal, storage, use, and disposal of human bodies, organs and tissues". The HTA Codes of Practice and Standards can be accessed at www.hta.gov.uk/guidance-professionals/codes-practice

Failure to comply with the requirements of the Act may lead to substantial fines and potentially a custodial sentence for the researcher(s) involved, or potentially for officers of the University. This may also lead to disciplinary action if a University of Staffordshire member of staff is found to be in breach of the requirements of the Act.

This policy should be read alongside the University's Research Ethical Review Policy and the University's Code of Practice for Research.

1.2 Definition of research

The Human Tissues Act does not provide a definition of research. For the purposes of this policy, we defer to the definition of research used by the Human Tissue Authority[1]:

> *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. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications or new knowledge.*

The HTA also endorses the definition provided by the Department of Health and the Welsh Assembly Government, which is as follows:

> *Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.*

As such, any proposed activities that meet these definitions will be considered as research and must be undertaken in accordance with the Human Tissue Act, the Human Tissue Authority Code of Practice and Standards, and this Human Tissue Policy.

[1] Human Tissue Authority Code of Practice and Standards (E: Research), page 7, paragraphs 24-25 https://content.hta.gov.uk/sites/default/files/2020-11/Code%20E.pdf

1.3 Ethical approval

All research undertaken at the university, or in its name, must receive ethical approval before any research commences, in accordance with the university's Research Ethical Approval Policy. This includes any research involving human tissues. Before any research which may involve human tissue (regardless of whether it is believed to be 'excepted' or not) is undertaken, advice and approval must be obtained from the University's Human Tissue Advisor and ethical approval secured from the University Research Ethics Committee.

Any application for ethical approval of research which involves human tissues must have approval from the Human Tissue Advisor as part of the ethical approval process, as outlined in the Research Ethical Approval Policy.

1.4 Responsibilities

Responsibility for ensuring that their own research complies with this policy lies with the individual researcher and, in the case of a student, with their supervisor. Responsibility for ensuring that all research at the University which involves human tissue complies with this policy lies with the University's Director of Research, who is advised by the University's Human Tissue Advisor (humantissue@staffs.ac.uk). The Human Tissue Advisor is nominated by the Director of Researcher. A deputy Human Tissue Advisor may also be nominated. Ideally the Deputy will be from a different academic school and/ or academic discipline to the Advisor.

2.0 Definition of human tissue

Human tissue is defined as "material that has come from a human body and consists of, or includes, human cells" [2]. This includes, but not limited to blood, bones, saliva, semen, hair, skin cells, urine, breast milk, organs, and corpses. The Human Tissue Act makes no distinction between a single human cell and a human body. For further guidance, the HTA has a list on whether specific materials fall within the remit of relevant material under the Human Tissue Act www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004/list-materials

3.0 Human Tissue Licence

A Human Tissue Licence is required for the storage of human tissue for research purposes. The University does not have a license and so researchers are not permitted to store human tissue. More detail on storge is outlined in section 5, below.

Researchers should speak to the Human Tissue Advisor in the first instance if they think their research is being hampered by the absence of a license. The University's Human Tissue Advisor will periodically review whether a licence is required and recommend to the Research and Innovation Committee if the University should apply for one.

4.0 Exceptions

4.1 Exceptions to the Human Tissue Act licensing requirements

According to guidance from the Human Tissue Authority, tissue stored for research purposes is exempt from the licensing requirements in certain circumstances, as outlined below. Please note, in all instances, informed consent to use relevant material for the intended purpose must be sought (see Consent Policy at appendix A).

[2] https://www.hta.gov.uk/guidance-professionals/hta-legislation

Exemptions to the licencing requirements include:

- Human Tissue held for a specific research project that has received HRA approval, (i.e., approved by an NHS Research Ethics Committee)
- Human tissue collected and stored prior to 1st September 2006 does not require a licence. However, it is expected that such samples are subjected to good practice as laid down by the HTA (and indicated in their Codes of Practice).
- Human tissue from individuals who have been deceased for over 100 years does not require a human tissue licence. However, it is expected that such samples are treated respectfully and are stored in a secure and safe fashion. The university will require reasonable reassurance that such individuals have been deceased for over 100 years.
- Fingernails and cut hair may be stored without a licence. However, care must be taken as 'plucked/pulled' hair cannot be stored as this may contain root sheath material/follicular material/skin cells, which is not excepted.
- Relevant material intended to be used for education and training relating to human health, see section 4.2 below

As outlined in section 1.3 above, all research undertaken at the university, or in its name, must receive ethical approval before any research commences, in accordance with the university's Research Ethical Approval Policy. Before any research which may involve human tissue (regardless of whether it is believed to be 'excepted' or not) is undertaken, advice and approval must be obtained from the University's Human Tissue Advisor and ethical approval secured from the University Research Ethics Committee.

If, following discussions with the Human Tissue Advisor, it is believed by the Advisor and the researcher that the proposed activities do not require a human tissue licence, this should be stated clearly within the application for ethical approval. This will enable the University to demonstrate clearly that it is operating within the requirements of the Act

If any researcher has any questions in relation to the Act, they should consult with the Human Tissue Advisor.

Training into Human Tissue Research is available from the Medical Research Council at the following link - https://byglearning.com/mrcrsc-lms/. Researchers intending to undertake any research involving Human Tissues should complete this training module.

4.2 Education and training relating to human health

There is an exception under the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 to the requirement to hold a licence under the Human Tissue Act where relevant material is being stored for use in the scheduled purposes of education or training relating to human health. This is outlined in section 3 subsection 2(a) of the legislation;

> *(2) Storage of relevant material which has come from the body of a living person is excepted where the person storing it is intending to use it for—*
>
> > *(a) any purpose specified in paragraphs 2 to 5 or 8 to 12 of Part 1 of Schedule 1 to the Act (determining the cause of death, establishing after a person's death the efficacy of any drug or treatment administered to him, obtaining information which may be relevant to another*

person, public display, clinical audit, ***education or training relating to human health,*** *performance assessment, public health monitoring, quality assurance)* [3]

It is the responsibility of the module leader, in consultation with the course leader to ensure that any teaching activity they propose to deliver or be delivered using human tissues on their module and course is covered under this exception. Advice and approval must be sought from the Human Tissue Advisor in advance of the teaching activity being undertaken.

Consent is a legal requirement under the Human Tissue Act and informed consent to store and use relevant material for this purpose must be sought. In addition, the module and course leader must assure themselves that the proposed use of the human samples is in accordance with the informed consent given by the donors who donated the samples. If in any doubt, advise must be sought from the Human Tissue Advisor.

4.3 Additional Considerations

4.3.1 Human DNA

Isolated/extracted DNA is excepted material and as such does not require a licence for storage.

However, it is illegal to carry out DNA analysis upon human DNA without the donor's consent (see appendix A: Consent Policy). There are exceptions to this (for example as part of a criminal investigation), but it is not envisaged that such exceptions would apply to research activities at the University.

4.3.2 Forensic Genetics

Forensic genetics research is **not** exempt from the Act under the 'criminal investigation provisions'. Where sample analysis is being carried out as part of a criminal case (under instruction from the prosecution or the defence), consent is not required. A written copy of the instructions will need to be provided to satisfy this (an email will suffice). This should be forwarded to the University Human Tissue Advisor (humantissue@staffs.ac.uk).

However, every other aspect of the Human Tissue Act requirements are expected to be complied with, including secure storage and disposal.

4.3.3 Samples from deceased

Consent from the family of the deceased **must** be obtained for the use of any tissue for the purpose of research. Whilst consent of the family is not required for autopsy purposes, once the purpose of the activity becomes research (as defined by the HTA in section 1.2), then informed consent must be sought from the family. Please see Consent Policy (appendix A).

As outlined in section 4.1, a licence to store relevant material for research within the scope of the Human Tissue Act is not required where it is from a person who died prior to 1st September 2006. Human tissue from individuals who have been deceased for over 100 years does not require a human tissue licence.

5.0 Storage Policy

5.1 Storage to remove the cellular component of a 'relevant material'

It is a breach of the Human Tissue Act to store any relevant material for a 'period of time' for the purpose of research without a licence. It is recognised that researchers will need a short time period to remove the cellular component of a 'relevant material' (which may include using the batching principle – i.e., waiting

[3] The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 - http://www.legislation.gov.uk/uksi/2006/1260/made/data.pdf

for samples to accumulate before mass processing). However, this should be done in as short a period as possible. The HTA consider the timeframe for this to be a matter of hours or days, and no longer than a week. The HTA Code of Practice and Standards makes clear that this wording does not designate a seven-day exemption period, but rather to indicate that the material should be held for as short a period as possible. The focus is on hours or days, rather than one week. If there are any requirement to store the samples for longer or to remove samples off the premises, then the Human Tissue Advisor must be consulted prior to any work being carried out

5.2 Examples of storage

Examples of storage include, but are not limited to:

1. Batching of samples prior to bulk processing
2. Storing of samples waiting for extraction reagents to arrive
3. Creation of a biobank for collaborative partners.

If undertaking any of the above, researchers should ensure this is done for as short a period as possible, as outlined in section 5.1, above. If stored for longer, all the above would be in breach of the Human Tissue Act. If the sample is being processed or is under experimental conditions (e.g., decomposition studies), then this is not classed as storage by the HTA.

6.0 HRA Ethically Approved Projects

As outlined in section 4.1, if a project utilising human tissue has ethical approval from a Heath Research Authority (HRA) recognised ethics panel (such as an NHS Research Ethics Committee (REC)), then a human tissue licence is not required. The University Research Ethics Committee will require assurance that such activities are in receipt of all relevant external ethical approval. It is usual that the requirements of the HRA recognised Ethics Panels are commensurate with the requirements of the HTA.

University Ethics Panels, including University of Staffordshire's University Research Ethics Committee, are not recognised by the HTA and as such approval solely by the University Research Ethics Committee cannot replace the need for a human tissue licence. For advice on the HRA approval process, researchers should contact the University's IPR (Independent Peer Review) co-ordinator. As outlined in section 1.3, all research, including projects involving human tissues, require ethical approval through the routes outlined in the University's Research Ethical Review Policy (which can be found here)

7.0 Adverse Events

An adverse event (AE) is an incident that could be in breach or lead to a breach of the Act, or licence conditions. As University of Staffordshire does not currently have a licence, we do not have any licence conditions to breach, but we must remain compliant with the Human Tissue Act.

All adverse events must be reported to the Human Tissue Advisor immediately.

A serious adverse event (SAE), serious adverse reaction (SAR), or HTA reportable incident (HTARI) will need to be reported to the Human Tissue Authority. However, this only applies where the human tissue is provided for human applications, post-mortem sector, or organ donation and transplantation and it is not expected that University of Staffordshire will be carrying out such activities.

An example of an adverse event is loss of a sample, by:

- Theft;

- Inadvertent destruction of sample, through environmental failure of the storage facility;
- Analysis of samples outside remit of consent; and

All adverse events will be investigated by the Human Tissue Advisor in the first instance and subsequently reported to the next Research and Innovation Committee. If necessary, an extraordinary meeting will be set up.

8.0 Health and Safety

Health, safety and wellbeing is governed by the Health, Safety and Wellbeing Committee.

All human tissue activity must operate to the satisfaction of the Health, Safety and Wellbeing Committee and in compliance with Health and Safety legislation.

Any Health and Safety incidents occurring in a location where human tissue research is carried out must also be reported to the Human Tissue Advisor as an adverse event. The incident must be investigated by the Human Tissue Advisor or to the satisfaction of the Research and Innovation Committee and the Head of Health, Safety and Wellbeing. Once the investigation has been completed, a report by the Human Tissue Adviser will be presented to the Health, Safety and Wellbeing Committee as appropriate to discharge their governance duties. The wider implications of this will be discussed by the Research and Innovation Committee.

For example, if someone cuts their hand with a scalpel whilst extracting a buccal swab, this will be reported as an accident, investigated by the line manager and the HT Adviser and the case closed by the Head of Health, Safety and Wellbeing. The HT Adviser would report any significant findings to the Health, Safety and Wellbeing Committee and to the Research and Innovation Committee as appropriate. The Human Tissue Advisor will consider the wider ramifications, such as contamination of the sample with blood from the injured party; or inadvertent loss of the sample.

The HT Adviser will consult and liaise with the Biological Safety Adviser as appropriate about Health and Safety practices within the human tissue facilities.

9.0 Key People

Director of Research – currently vacant
Human Tissue Advisor – Sarahjane Jones
Health and Safety – Sue Emery
Biological Safety Officer – Dr Arthur Hosie

Appendix A: Consent Policy

HTA Consent

This document must be read in conjunction with the University of Staffordshire Human Tissue Policy Document and with the Human Tissue Authority's relevant code of practice:

https://www.hta.gov.uk/sites/default/files/HTA%20Code%20of%20Practice%20A%20-%20Guiding%20principles%20and%20the%20fundamental%20principle%20of%20consent%201.pdf

1. Introduction

The Human Tissue Act (2004) was brought in to regulate the use of human tissue. At the core of the requirements of the HT Act is 'consent'. Consent is a statutory requirement of the HT Act. Guidance relating to Consent can be found within the HTA Code of Practice 1.

2. Fundamental principles of consent

According to the Code of Practice relating to consent, there are six issues to be considered.

2.1 Is consent required?

Consent is required to:

a) Store and use dead bodies;
b) Remove, store, and use relevant material from dead bodies; and
c) Store and use relevant material from the living.

At this time, it is not expected that storage and use of dead bodies will be required.

Anyone removing, storing or using material in such circumstances must be satisfied that consent is in place.

There are exceptions to these provisions for Coroners and Criminal Justice purposes. At this stage, it is not expected that such situations should arise. However, should such a situation arise, then the University Human Tissue Advisor should be consulted in the first instance.

2.2 Appropriate consent

This is a key part of the Act and is defined as to who can give consent. In the case of the living, this is the person concerned (i.e., the donor), or their nominated representative.

At this stage, it is not expected that human tissue from the deceased will be obtained. If such a situation should arise; then the Human Tissue Advisor should be consulted in the first instance.

2.3 Valid consent

For consent to be valid, it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Consent is a positive act, in that the absence of refusal to provide consent must not be considered as giving consent.

For consent to be valid, the person should understand what the activity involves and what the risk involves. Risk Assessments for the activity should be made available to the person. The consent should also be appropriate for the intended purpose.

For the consent to be legally valid, it must be shown that consent has been given. Although, legally, the consent needs not be written, the University of Staffordshire requires written consent for each sample provided.

All persons (including their family) must be allowed to ask questions or seek further information before providing consent. The person seeking consent must be co-operative and forthcoming in this situation.

Any refusal or agreement relating to consent must not result in that person being advantaged or disadvantaged. For example, a condition of being allocated a student project is that the student must consent to providing samples.

2.4 Scope of Consent

Consent can be specific or generic. However, if the purpose of seeking samples is for research, then the consent should be generic. This avoids the need to seek further consent in the future. However, the consent must still be valid.

2.5 Duration of Consent

Consent may be enduring, or it may be time limited. For research, it is advised that such consent should be enduring. This should be clearly indicated to the person. Enduring consent means that it is in force until the person withdraws their consent.

Consequently, any consent required for samples for the purpose of research should be “Generic and enduring”.

2.6 Withdrawal of Consent

Consent may be withdrawn at any time. This must be clearly indicated to the person at the point of requesting consent. The practicalities of withdrawing consent must also be considered – for example, withdrawal of consent is not effective if the sample has already been analysed.

The person must also be informed that withdrawal of consent means that the sample will be destroyed or disposed of and that the sample will not be returned to them.

2.7 Who can obtain consent?

All staff seeking consent, regardless of whether the tissue is under licenced, under REC approval, or otherwise, must undergo consent training provided by the University Human Tissue Advisor. Exceptions may be applied where individual can demonstrate they had received recent (within 2 years) consent training elsewhere – documentary evidence will be required.

2.8 Seeking consent from colleagues or members of staff

Acquiring samples from within the University, School, Department or research groups does not remove the need to obtain appropriate consent by trained individuals. In addition, such samples are not exempt from ethical considerations.

2.9 How consent will be sought

Each research group will be required to obtain ethical approval from the Ethics Committee. As part of the ethical approval process, they are required to indicate how they intend to obtain consent. If the sample in question relates to human tissue, then they need to demonstrate compliance with the Consent Codes of Practice.

No standard protocol will be ratified at committee level, given the diverse range of research topics undertaken within the University.

2.10 Approval of consent forms and participant information sheets

All consent forms and participant information sheets (PIS) require ethical approval via the Ethics Committee. If the samples collected relate to HT, then they need to demonstrate compliance with the Consent Codes of Practice.

3. Consent requirements

Consent requirements are split in to three

a) General provisions
b) Tissue from the deceased
c) Tissue from the living

3.1 General Provisions

Before the removal, storage, or use of human tissue for scheduled purposes, the following should be considered

a) Does the activity require consent? If the donor is deceased, then consent is required for all scheduled purposes. Where the tissue is from a living person then consent is required unless the researcher is not in possession, and not likely to come into possession of information that identifies the person from whom it has come AND that the material is used for a research project that has HRA recognised ethical approval.

4. Consent **training**

All HT researchers will be required to undergo Consent training, as part of their Human Tissue induction and/or training prior to starting their sample collection/acquisition

5. Further Information

For further information relating to consent requirement, please contact the University Human Tissue Advisor (email: humantissue@staffs.ac.uk)

Appendix B

Disposal of Human Tissue Material

1. Introduction

The Human Tissue Act (2004) was brought in to regulate the use of human tissue. One of the principal requirements of the HT Act is 'disposal'. One of the purposes of the HT Act was to ensure that human tissue is used and treated in accordance to the wishes of the donors or their relatives. This includes sensitive and respectful disposal, in recognition of the feelings of the donors. There is also a need for clarity when providing information.

The guidance in this policy should allow human tissue to be treated with respect, without adding a disproportionate burden on staff and resources. This policy applies to those involved in the disposal of human tissue.

2. Disposal options

If a donor has provided consent to the use of their samples, they should also be offered the option of allowing the University to dispose of the material after its examination and use. Researchers should strongly encourage the donors to make use of this facility.

There are three disposal options allowed under the HT Act, incineration, cremation, or burial. Given the nature of the expected HT research being carried out at the University, none of these are an option currently available. If there is an intention to use human tissue from the deceased for research purposes on university premises, then the University Human Tissue Advisor must be informed immediately, so that the appropriate disposal procedures can be implemented.

2.1. Incineration

We currently do not have the facilities for incineration. Should this be required, then the University Human Tissue Advisor must be informed prior to the research starting, so appropriate procedures can be developed.

3. Disposal procedure

It is recognised that each research group will have different procedures and techniques for HT. As such, one central disposal procedure would not be fit for purpose. Consequently, it is necessary for each research group or HT laboratory to have a documented disposal procedure. Such documented procedures should clearly indicate the nature of the waste, the volume of expected waste, how it is stored prior to disposal, frequency of disposal, and method of disposal. Such disposal streams should be respectful of the nature of the human tissue sample and should not be disposed of through the same processes as animal clinical waste. For example, excess human tissue disposed of as clinical waste and placed in the same disposal bags as clinical waste from pigs or other animals considered as "unclean" by some religions.

4. Existing holdings

Existing holdings are stored human tissue that have been acquired prior to the implementation of the HT Act (September 2006). Although a licence is not required for the storage of these tissues, they are expected to be disposed of according to the HT Act.