



School of Science and the Environment Human Tissue Act Guidance and Procedures

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Introduction

This guidance has been developed to ensure that all staff and students in the School of Science and the Environment (SSE) are complying with the Human Tissue Act (2004). The guidance applies to everyone carrying out research or teaching 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 member of staff of the University of Worcester is found to be in breach of the requirements of the Act.

This guidance should be read alongside the University’s [Ethics Policy](#) and the University’s Guidelines and [Procedures for Good Research Practice](#)

Definition of research

The Human Tissue Act does not provide a definition of research. For the purposes of this guidance, we defer to the definition of research used by the Human Tissue Authority¹:

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.

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>

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 Guidance.

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 [Ethics 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 SSE's Human Tissue Advisor and ethical approval secured via the Ethical Review Procedures and the School Ethics Co-Ordinator. Forms for application are available on Blackboard module sites for undergraduate students and the Ethics and Research Integrity Blackboard site for staff and postgraduate students.

Responsibilities

Responsibility for ensuring that their own research complies with this guidance 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 guidance lies with the University's Director of Research, who is advised by the SSE's Human Tissue Advisor. The Human Tissue Advisor is a member of the SSE Safety Committee and appointed by the committee. A deputy Human Tissue Advisor may also be nominated. Ideally the Deputy will be from a different academic department to the Advisor.

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.

² <https://www.hta.gov.uk/guidance-professionals/hta-legislation>

For further guidance, the HTA has a list on whether specific materials fall within the remit of relevant material under the Human Tissue Act

<https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/material-covered-human-tissue-quality>

Human Tissue Licence

A Human Tissue Licence is required for the storage of human tissue for research purposes. The University does not have a licence, and so researchers are not permitted to store human tissue. More detail on storage 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 licence. The SSE's Human Tissue Advisor will periodically review whether a licence is required and recommend to the Pro Vice Chancellor Research if the University should apply for one.

Exceptions

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 at appendix A).

Exceptions to the licensing 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
- It is being held whilst it is processed with the intention to extract DNA or RNA, or other subcellular components that are not relevant material (i.e. rendering the tissue acellular by day 7). See 5.0 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 [Ethics 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 SSE's Human Tissue Advisor and ethical approval secured from the School Ethics Co-Ordinator and Ethical Review Procedures.

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 tissue should complete this training module. See appendix C for webpage directions

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

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>

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, advice must be sought from the Human Tissue Advisor.

Additional Considerations

Human DNA

Isolated or extracted DNA is not 'relevant material' under the Human Tissue Act and therefore its storage is not subject to HTA research-storage licensing. However, the Act contains specific requirements concerning DNA analysis, including circumstances in which consent is required. DNA analysis of human bodily material is subject to the requirements of section 45 of the Human Tissue Act.

Consent is required, although statutory exceptions apply in certain circumstances, including specified research involving material from living people where the relevant conditions are met. Researchers should consult the Human Tissue Advisor where DNA analysis is proposed.

It is illegal to carry out DNA analysis upon human DNA without the donor's consent (see appendix A: Consent), with only a few 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.

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.

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

Samples from deceased

Appropriate consent from the deceased person, their nominated representative, or, where applicable, a person in a qualifying relationship 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 (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 was collected and stored 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.

If the material is less than 100 years old and is to be stored for 'education or training relating to human health', this would constitute a licensable activity under The Act. In these circumstances, the University would require a HTA licence for the storage of the material.

Use for forensic archaeology and anthropology teaching would not constitute a licensable activity under the legislation.

Storage

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 recognized 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 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 (seven days absolute maximum). 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 requirements 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.

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.

HRA Ethically Approved Projects

As outlined in section 4.1, if a project utilising human tissue has ethical approval from a Health Research Authority (HRA) recognised ethics panel (such as an NHS Research Ethics Committee (REC)), then a human tissue licence is not required. The University Ethical Review Bodies 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 the University of Worcester School Ethics Panels, are not recognised by the HTA and as such approval solely by the University Ethics Panels or Review Bodies cannot replace the need for a human tissue licence. For advice on the HRA approval process, researchers should first consult the NHS HRA Approval pages

<https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/>

As outlined in section 1.3, all research, including projects involving human tissues, require ethical approval through the routes outlined in the University's [Ethics Policy](#)

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 the University of Worcester 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 the SSE 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;

All adverse events will be investigated by the Human Tissue Advisor in the first instance and subsequently reported to Head of School. If necessary, an extraordinary meeting will be set up.

Health and Safety

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

All human tissue activity must operate to the satisfaction of the SSE Health and Safety 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 University Health and Safety Manager and the Head of Health, Safety and Wellbeing. Once the investigation has been completed, a report by the Human Tissue Advisor 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 SSE Senior Management Team.

For example, if someone cuts their hand with a scalpel whilst extracting a buccal swab, this will be reported as an accident on the portal, investigated by the line manager and the HT Advisor and the case closed by the Health, Safety and Wellbeing Manager. The HT Advisor would report any significant findings to the Health and Safety Committee and to Head of School 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 Advisor will consult and liaise with the Biological Safety Advisor as appropriate about Health and Safety practices within the human tissue facilities.

Key People

Pro Vice Chancellor Research Directorate – Professor John-Paul Wilson

Human Tissue Advisor – Dr Allain Bueno (Deputy Anne Sinnott until Spring 2025)

Health, Safety and Wellbeing Manager – Gordon Reeves

Biological Safety Officer – Professor Mahmut Tor

Material considered to be 'relevant material' and material not considered to be 'relevant material'

Material considered to be 'relevant material' #	Material not considered to be 'relevant material' #
• Bile <i>[Considered relevant material as it contains epithelial cells]</i> • Blood (whole) <i>[This includes whole human capillary blood, venous blood, as well as menstrual blood]</i> • Bone marrow • Bones/skeletons <i>[see separate guidance for working with the SSE osteological collection]</i> • Brain • Breast milk <i>[Considered relevant material as it contains epithelial cells, white blood cells and stem cells]</i> • Buccal cells (cheek cells) <i>[For example, those collected via cheek swabs]</i> • Buffy coat layer (interface layer between plasma and blood cells when blood is separated) • CSF (cerebrospinal fluid) <i>[Considered relevant material as it contains white blood cells]</i> • Cystic fluid • Epithelial cells <i>[There is a risk that epithelial cells may be contained in bodily fluids, materials and waste, which is why some samples that do not intentionally contain cells are considered relevant material]</i> • Faeces <i>[Considered relevant material as it will contain epithelial cells and may contain blood cells]</i> • Fluid from cystic lesions • Hair (from deceased person) • Joint aspirates • Material relating to early pregnancy loss or termination • Mucus <i>[e.g. nasal or throat swabs, nasal fluid. Contains epithelial cells]</i> • Nail (from deceased person) • Nasal and bronchial lavage <i>[Rinsing the nasal passages and sinuses, and medical procedure for lungs. Considered relevant material as it contains epithelial cells and may contain blood cells]</i> • Non-blood, derived stem cells (i.e. derived from the body) • Non-foetal products of conception (i.e. the amniotic fluid, umbilical cord, placenta and membranes)	• Antibodies • Breath condensates and exhaled gases • Cell lines • Cells that have divided in culture • DNA • Eggs (ova) • Embryonic stem cells (cells derived from an embryo) • Embryos (created outside the body) • Extracted material from cells e.g. nucleic acids, cytoplasmic fractions, cell lysates, organelles, proteins, carbohydrates and lipids. <i>[As long as no whole cells remain within the sample]</i> • Gametes • Hair <i>[without the follicle], (from living person) [hair follicles are relevant material]</i> • Lysed cells • Nail (from living person) • Plasma (Please note: Depending on how plasma is prepared and processed, it may contain small numbers of platelets and other blood cells. If any of these cells are present, then the plasma must be regarded as relevant material) <i>[If any platelets remain in the plasma, it is considered relevant material]</i> • RNA • Sebum <i>[Oily secretions of the sebaceous glands]</i> • Serum • Sperm cells (spermatozoa) • Sweat

• Organs • Pericardial fluid • Platelets <i>[Plasma samples containing platelets are considered relevant material]</i> • Pleural fluid • Primary cell cultures (whole explant/biopsy present) • Pus • Rectal swab <i>[Considered relevant material as it contains epithelial cells and may contain blood cells]</i> • Saliva <i>[Considered relevant material as it contains buccal cells, other epithelial cells, white blood cells]</i> • Skin • Sputum (or phlegm) <i>[Considered relevant material as it contains epithelial cells and may contain blood cells]</i> • Stomach contents • Teeth • Tumour tissue samples • Umbilical cord blood stem cells • Urine <i>[Considered relevant material as it contains epithelial cells and may contain blood cells]</i> • Vaginal mucus & vaginal swab <i>[Considered relevant material as it contains epithelial cells and may contain blood cells]</i>	
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#a table describing material type, scheduled purpose, and license conditions can be found in Appendix E below, and provides local University interpretation of the table above.

Further Notes and Examples of the Scope of the HTA for Staff and Students

Some of the principal issues of the Human Tissue Act are related to obtaining **appropriate consent** from the donor, or recognised legal representative, for the acquisition and precise use of samples in the proposed research/teaching. **Obtaining appropriate informed consent from sample donors is essential, even for finger puncture samples.** Other issues relate to the retention or storage of human tissue which may require a Human Tissue Licence, the following example is taken from the codes of practice.

A researcher wants to undertake a study looking into immunological responses to breast cancer. To do this clotted blood samples will be spun down to collect the serum. As the blood will be spun down within a matter of days and any residual cells disposed of to leave serum that is not relevant material, the blood does not need to be stored under an HTA licence.

The need for consent and/or a Human Tissue Licence is very much dependent on the nature of the proposed research. It will greatly assist those approving research proposals if details such as nature of samples, who will be sampled, how samples will be used and disposed of, etc. is included in the proposal. Researchers should familiarise themselves with the relevant Human Tissue Act Codes of Practice, which can be found by following the URL below.

<https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation>

Note 1

e-mail from Dr Caroline Kerridge HTA 13.11.17

1) The Human Tissue Act governs the removal (from deceased) and storage (from living and deceased) of relevant material for 'scheduled purposes' set out in the Human Tissue Act in England, Wales and Northern Ireland. The scheduled purposes include: research in connection with disorders, or the functioning, of the human body; public display; and education or training relating to human health. A full list of the scheduled purposes can be found in [Schedule 1 of the Human Tissue Act](#).

2) Blood smears and tissue samples that you mentioned are considered to be 'relevant material' under the Human Tissue Act 2004 (Human Tissue Act). If they are being stored for use for a 'scheduled purpose' then the [consent](#) and [licensing](#) requirements of the Human Tissue Act may apply.

3) If the samples are from living donors and are being stored for use only for the scheduled purpose of education or training relating to human health then the consent and licensing requirements of the Human Tissue Act would not apply. However if the samples were from the deceased then they would need to be stored on licensed premises. If this is the case please see our [website](#) for information about getting a licence.

4) If the samples are being stored for use for the scheduled purpose of research in connection with disorders, or the functioning, of the human body then the consent and licensing requirements of the Human Tissue Act may apply. Further information can be found in [Code of Practice E – Research](#). Again if this is the case please see our [website](#) for information about getting a licence.

5) Information on the consent and licensing requirements of the Human Tissue Act can be found in the [HTA's Codes of Practice](#). In particular, [Code of Practice A – Guiding Principles and the Fundamental Principle of Consent](#) provides information on when consent is required under the Human Tissue Act (summarised in Annex B and C). You may also find the [guidance flowchart](#) on the licensing requirements of the Human Tissue Act useful.

6) With regard to the bones, the Human Tissue Act 2004 governs material used for teaching human health. In this instance, teaching of archaeology and forensics would be outside the remit of the Human Tissue Act and therefore would not need to be stored on licensed premises.

Note 2

The following advice is reproduced from: [E Research Code of Practice and Standards](#)

pg 20-22

84. A licence to store relevant material for research within the scope of the Human Tissue Act is not required in the following circumstances:

a) It is from a person who died prior to 1st September 2006 and at least one hundred years have elapsed since their death.

This exemption from licensing is set out in the Human Tissue Act.

b) It is being held 'incidental to transportation'.

This exemption from licensing is set out in the Human Tissue Act. This term is not defined in the law and the HTA has interpreted this as the temporary holding of material in transit, while it is being conveyed from one place to another. We consider the timeframe for this to be a matter of hours or days and no longer than a week. The intention of the wording of that interpretation is not to 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.

Example Skin biopsies for use in research are collected across a number of sites and batched before being sent to an establishment licensed by HTA for storage for research. The multiple sites collecting the biopsies do not need to be licensed as the storage is pending transportation to a licensed establishment.

c) It is being held whilst it is processed with the intention to extract DNA or RNA, or other subcellular components that are not relevant material (i.e. rendering the tissue acellular).

The HTA views this as analogous to the incidental to transportation exception above. The HTA therefore takes the position that a licence is not required in these circumstances, providing the processing takes a matter of hours or days and no longer than a week. In summary, if there is no intention to use or store human cellular material for research, and the only holding of cellular material is temporary and for the purpose of obtaining material which does not contain cells, then no storage licence is required

Example A researcher wants to undertake a study looking into immunological responses to breast cancer. To do this clotted blood samples will be spun down to collect the serum. As the blood will be spun down within a matter of days and any residual cells disposed of to leave serum that is not relevant material, the blood does not need to be stored under a HTA licence.

d) Further examples where a HTA storage licence would not be required:

Example 1 A whole blood sample is taken and immediately sampled for blood lactate levels in the plasma, then the sample is disposed of about five minutes following the sample being taken. **Conclusion:** No storage of relevant material for research would be taking place.

Example 2 A whole blood sample is taken, immediately processed for various tests that day, some of which includes testing directly on the cells themselves. All samples are disposed of when the tests are complete, later that day. **Conclusion:** No storage of relevant material for research would be taking place.

Example 3 A whole blood sample is taken and made acellular immediately, and only serum is retained for research. **Conclusion:** No storage of relevant material for research would be taking place.

Example 4 An experiment is conducted over a 6-day period. Whole blood samples are provided by volunteers throughout the sample collection period. All the samples are made acellular by day 7, with only serum being stored for research. **Conclusion:** There is no intention to use or store human cellular material for research, and the only holding of cellular material is temporary (a few days) and for the purpose of obtaining research material which does not contain cells. The serum is the material which will be stored for research, and this does not require a HTA licence.

Example 5 A study has received approval from a recognised Research Ethics Committee (REC) where blood samples are taken during a clinical trial. Recognised RECs are those established under and operating to the standards set out in the governance arrangements issued by the UK Health Departments, or those recognised by the UK Ethics Committee Authority (UKECA) for clinical trials. **Conclusion:** No HTA licence is required to store samples for which REC approval has been obtained (see paragraph 86).

e) Example where a HTA storage licence would be required:

Blood samples from healthy volunteers are collected from two groups of participants as part of a research study over a two-day period. After each collection, the samples are stored in a refrigerator and then analysed for research, as a batch, once all have been collected. All samples are used and disposed of within seven days of the first collection. The project involves healthy volunteers and has not been approved by a recognised REC.

Conclusion: Although the storage period is for only 2-3 days, relevant material samples (whole blood) are being stored solely for the purpose of research within the scope of the Act; a HTA storage licence is therefore required. *Please note that even if the research destroys the cells, this does not alter the point that prior licensable storage of relevant material for research would have taken place.*

Note 3

HTA position statement on storage of human material for teaching by schools and colleges

Some schools and colleges store human material for use in teaching. Such specimens could include cells on a microscope slide, specimens preserved in formalin, skulls, and partial or complete skeletons.

Under the Human Tissue Act 2004 ('the Human Tissue Act'), human material which contains cells is called 'relevant material'.

Our view is that:

- human material used for teaching biology in schools is not being stored for a scheduled purpose under the Human Tissue Act. These schools do not require an HTA licence to store human material for teaching.

- colleges providing courses with a specific healthcare focus, which are intended to lead to professional registration, such as nursing or dental nursing, which use human material in teaching, are storing relevant material for the scheduled purpose of 'education or training relating to human health'.

Institutions storing human material removed from the deceased for 'education or training relating to human health' require an HTA licence, unless the material was removed from a person who died before 1 September 2006 and more than one hundred years have passed since their death. An institution wanting to acquire human material for teaching should also follow the guidance in the HTA's Code of practice on Consent.

Note 4

Licensing exemptions – living persons

Under Statutory Instrument 1260, 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:

- determining the cause of death;
- establishing after a person's death the efficacy of any drug or treatment administered to them;
- obtaining information which may be relevant to another person;
- public display;
- clinical audit;
- education or training related to human health;
- performance assessment; (of in vitro devices and diagnostic kits)
- public health monitoring;
- quality assurance; or
- qualifying research (Qualifying research means research which has been ethically approved by a recognised REC.)

Note 5

The definition of relevant material in the Act is: Section 53: Relevant material:

In this Act, "relevant material" means material, other than gametes, which consists of or includes human cells.

In this Act, references to relevant material from a human body do not include embryos outside the human body, or hair and nail from the body of a living person.

The fundamental concept of relevant material is that if a sample is known to contain even a single cell that has come from a human body, then the sample should be classified as relevant material.

Where a **processed material** is generally agreed – as a result of the process – to leave it always either cellular or acellular, then the presumption should be that all examples should be regarded as such. The HTA would rely on an assurance that the process in question had been carried out. Under this category, plastinated tissue and plastinated body parts (where the cellular structure is retained by the plastination process) are considered relevant material; while plasma or serum, for example, will not be regarded as such. Plasma and serum, widely produced from blood taken for diagnostic investigations, are however examples of where ‘normal expectations’ may well need to be applied

The HTA considers **bodily waste** should normally be regarded as relevant material. The Act’s wording is clear and reflects the possibility that even a single cell can be subject to an activity such as research. There will be cases where a person believes that material, intended for a scheduled purpose, is actually acellular. In such cases, the HTA can be approached for advice.

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 or are intended to be representative of whole cells.

Note 6

Temporary storage

Under section 16(7) of the Human Tissue Act, 'storage' does not include storage incidental to transportation.

The HTA defines storage as incidental to transportation if human tissue is held for a matter of hours or days (and no longer than a week) pending transfer to another organisation.

Where this applies, a licence is not required. However, where a researcher holds human tissue for a short period for the purpose of a project to conduct analysis prior to discarding the human tissue, this is storage for a scheduled purpose (i.e. research). Such storage requires either a licence from the HTA or ethical approval for the project.

In the HTA Code of Practice and Standards on Research (Code E) there are several examples where a HTA storage licence would and would not be required ([see paragraphs 84](#)).

Tissue being held prior to processing

If human tissue is being held while it is processed with the intention to extract DNA or RNA, or other subcellular components that are not relevant material (i.e. rendering the tissue acellular), it is viewed as analogous to the incidental to transportation exception. A licence is not required, providing the processing takes a matter of hours or days and no longer than a week. More details can be found here [Licensing exemptions | Human Tissue Authority](#)

Note 7

Relevant material and research from Code E page 7

What is research?

24. The Human Tissue Act does not contain a definition of research, but for the purposes of what falls within the HTA's remit, we endorse the following definition:

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.

25. The HTA also endorses the definition provided by the UK Policy Framework for Health and Social Care Research, which is as follows:

Research can be defined as the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods.

Appendix A: Consent

HTA Consent

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

<https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation>

Introduction

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

<https://content.hta.gov.uk/sites/default/files/2023-06/Code%20A%20-%20Guiding%20principles%20and%20the%20fundamental%20principle%20of%20consent.pdf>

Fundamental principles of consent

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

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 SSE Human Tissue Advisor should be consulted in the first instance.

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.

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 SSE 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.

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.

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”.

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.

Who can obtain consent?

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

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.

How consent will be sought

Each research project will be required to obtain ethical approval from the Ethics Panel. As part of the ethical approval process, the researcher is 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.

Approval of consent forms and participant information sheets

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

Consent requirements

Consent requirements are split in to three

- a) General provisions

- b) Tissue from the deceased
- c) Tissue from the living

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.

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. All researchers are expected to familiarize themselves with the contents of this document and to clarify any concerns with the Human Tissue Advisor.

Further Information

For further information relating to consent requirements, please contact the University Human Tissue Advisor.

See also • [Human Tissue Authority Code A Guiding Principles and the Fundamental Principle of Consent](#)

Appendix B

Disposal of Human Tissue Material

Introduction

The Human Tissue Act (2004) was brought in to regulate the use of human tissue. One of the principal requirements of the Human Tissue Act is 'disposal'. One of the purposes of the Human Tissue Act was to ensure that human tissue is used and treated in accordance with 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 should allow human tissue to be treated with respect, without adding a disproportionate burden on staff and resources. This applies to those involved in the disposal of human tissue.

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. Many samples will be analysed and disposal is part of the process, usually via autoclaving. See 'Guidance for Working Safely with Human Blood, Tissue or Other Specimens' document for further information.

Where there are materials left to be disposed of there are three disposal options allowed under the Human Tissue Act, incineration, cremation, or burial. Given the nature of the expected HT research being carried out in the SSE, cremation or burial options are not currently available. If there is an intention to use human tissue from the deceased for research purposes on University premises, then the Human Tissue Advisor must be informed immediately, so that the appropriate disposal procedures can be implemented.

Incineration

We currently do not have the facilities for incineration on site. Clinical waste is collected and taken offsite for incineration in either sharps bins or yellow clinical waste bags. Should this not be sufficient, then the Human Tissue Advisor must be informed prior to the research starting, so appropriate procedures can be developed.

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.

Existing holdings

Existing holdings are stored human tissue that have been acquired prior to the implementation of the Human Tissue Act (September 2006), but are expected to be disposed of according to the Human Tissue Act.

Appendix C

Accessing Online Training

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 tissue should complete this training module. Follow the following steps:

1 On the website click 'Regulatory Support Centre',

2 Click 'e-

Learning',

Medical Research Council
Regulatory Support Centre

MRC Regulatory Support Centre Learning Management System

[LMS Home](#)

Welcome back, Jessica! 🎉

Welcome

Welcome to the MRC Learning Management System, designed and hosted by the MRC Regulatory Support Centre. The content on this LMS is intended for those working in health research. E-learning modules on the MRC's expectations for good research practice, regulation in health research (e.g. data protection and confidentiality; human tissue), can all be accessed through this site.

Normal office hours are between 8.30am and 5.00pm, Monday to Friday. If you have any queries outside these hours we will get back to you on our next working day.

If your query relates to an account registration issue, please check your spam or junk folder for the activation email. If you are experiencing issues in getting the modules / assessments to run, please ensure you have allowed pop-ups and/or try accessing them in a different browser.

If you would like information about MRC please contact corporate@mrc.ukri.org. If you are submitting a Freedom of Information request, please send your message on to foi@ukri.org.

ORCID - We have added **ORCID ID** to your user profile. While it isn't mandatory to complete this field you and your organisation may find it useful to attach this ID to your account. To do so please visit your profile page (top right) then 'edit profile' and you will find ORCID ID near the bottom under 'Other fields'.

Regulatory Support Centre
Free e-learning and other resources for those whose research involves people as participants, their tissues or data.

Good Research Practice (developed by MRC Head Office)
Free e-learning on the MRC's expectations for good research practice, that should underpin all MRC-funded research.

Medical Research Council
Regulatory Support Centre

Regulatory Support Centre

[LMS Home](#) / [My courses](#) / [Regulatory Support Centre](#)

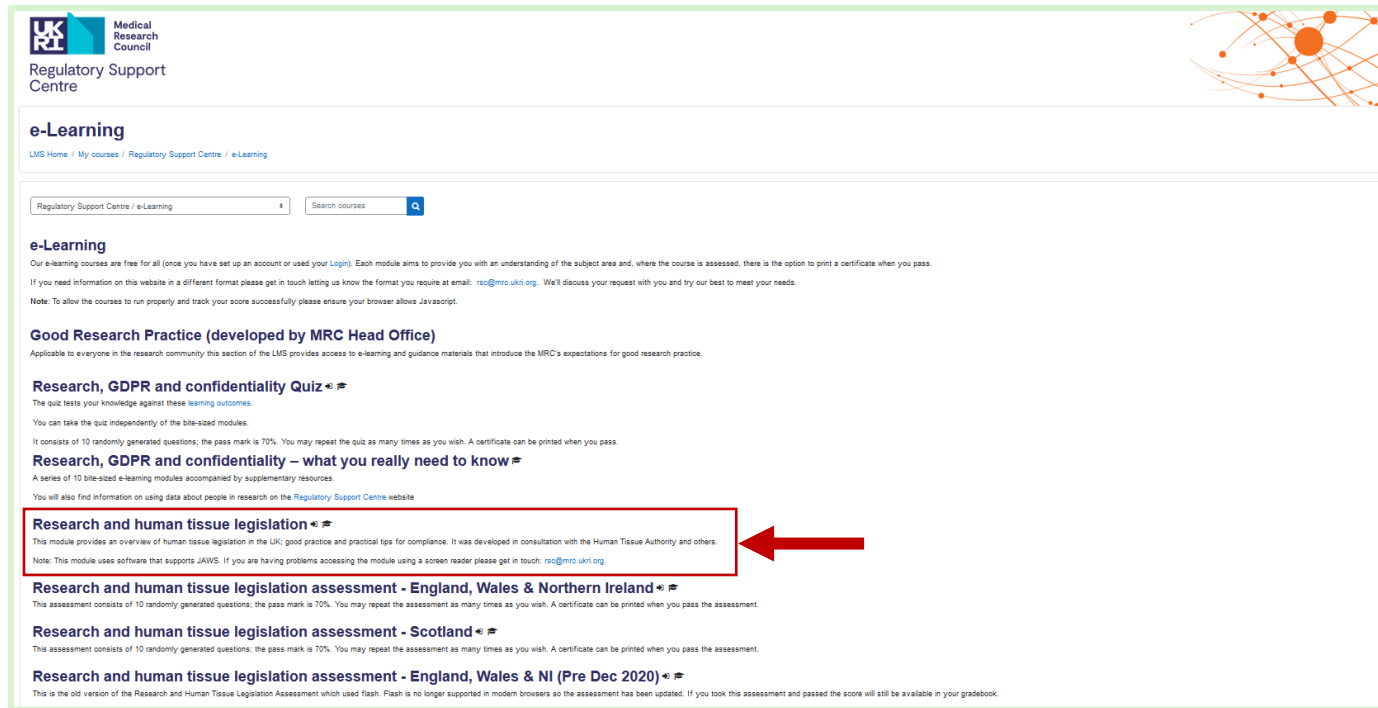
3 Scroll down and click 'Research and human tissue legislation'.

4 You will need account by and instructions.

5 Once you course, Learning and assessment Northern

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have completed the return to the e-page (second page) complete the for England, Wales & Ireland



Medical Research Council
Regulatory Support Centre

e-Learning
LMS Home / My courses / Regulatory Support Centre / e-Learning

Regulatory Support Centre / e-Learning Search courses

e-Learning
Our e-learning courses are free for all (once you have set up an account or used your Login). Each module aims to provide you with an understanding of the subject area and, where the course is assessed, there is the option to print a certificate when you pass.
If you need information on this website in a different format please get in touch letting us know the format you require at email: rsc@mrc.ukri.org. We'll discuss your request with you and try our best to meet your needs.
Note: To allow the courses to run properly and track your score successfully please ensure your browser allows Javascript.

Good Research Practice (developed by MRC Head Office)
Applicable to everyone in the research community this section of the LMS provides access to e-learning and guidance materials that introduce the MRC's expectations for good research practice.

Research, GDPR and confidentiality Quiz
The quiz tests your knowledge against these learning outcomes.
You can take the quiz independently of the bite-sized modules.
It consists of 10 randomly generated questions; the pass mark is 70%. You may repeat the quiz as many times as you wish. A certificate can be printed when you pass.

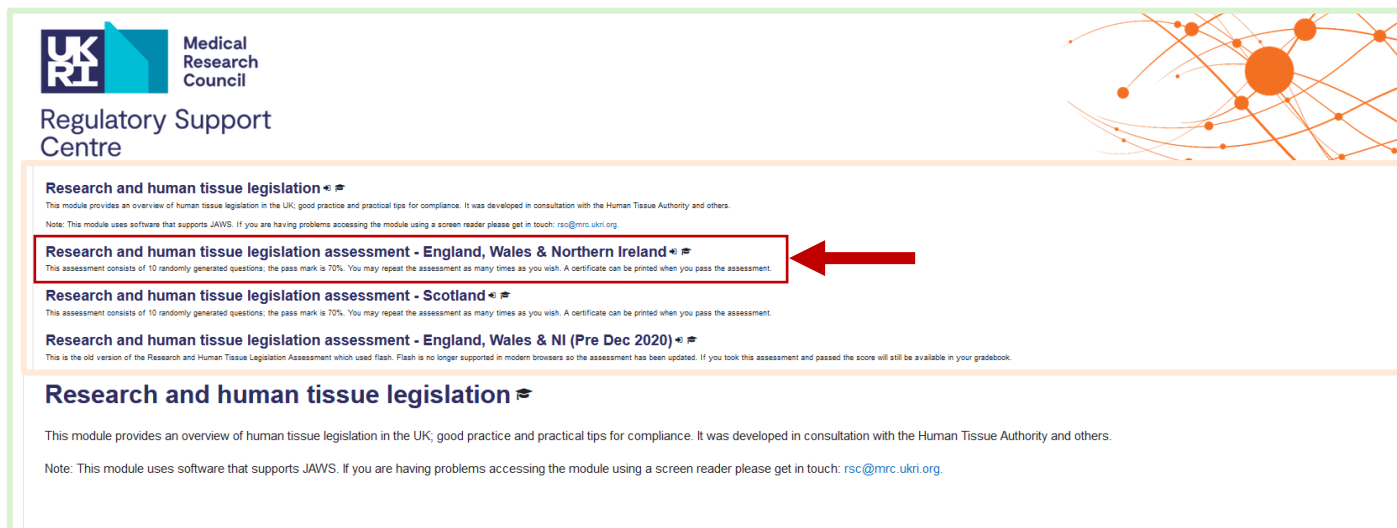
Research, GDPR and confidentiality – what you really need to know
A series of 10 bite-sized e-learning modules accompanied by supplementary resources.
You will also find information on using data about people in research on the Regulatory Support Centre website

Research and human tissue legislation
This module provides an overview of human tissue legislation in the UK; good practice and practical tips for compliance. It was developed in consultation with the Human Tissue Authority and others.
Note: This module uses software that supports JAWS. If you are having problems accessing the module using a screen reader please get in touch: rsc@mrc.ukri.org

Research and human tissue legislation assessment - England, Wales & Northern Ireland
This assessment consists of 10 randomly generated questions; the pass mark is 70%. You may repeat the assessment as many times as you wish. A certificate can be printed when you pass the assessment.

Research and human tissue legislation assessment - Scotland
This assessment consists of 10 randomly generated questions; the pass mark is 70%. You may repeat the assessment as many times as you wish. A certificate can be printed when you pass the assessment.

Research and human tissue legislation assessment - England, Wales & NI (Pre Dec 2020)
This is the old version of the Research and Human Tissue Legislation Assessment which used flash. Flash is no longer supported in modern browsers so the assessment has been updated. If you took this assessment and passed the score will still be available in your gradebook.



Medical Research Council
Regulatory Support Centre

Research and human tissue legislation
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Appendix D

Lists of Materials

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

The list is not intended as exhaustive or exclusive but is intended to provide guidance to stakeholders in respect of materials that might be considered relevant. The HTA will review the list periodically and update it as required.

Where a material is not included within the following list, stakeholders should use the information on our website to make their own assessment about whether it is relevant material, seeking advice from us where necessary.

Materials classified in the following list as relevant material are done so subject to the following general caveat that they are relevant material except where:

- ✓ They have divided or been created outside the human body.
- ✓ They have been treated, processed or lysed through a process intended to render them acellular. This would include the freezing or thawing of cells only where that process is intended to render the material acellular.
- ✓ See also for more information: <https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/material-covered-human-tissue-quality>

Appendix E:

Human Tissue usage in SSE. The table below tries to cover the current uses of human tissue/cells in SSE.

Material Type (see list above)	Description	Is it from a Living or Deceased person?	Relevant material (see list above)	Use or Purpose (Teaching specify course; Research specify type)	Scheduled Purpose	Is Consent required?	Can it be stored without a licence?	Is it being stored?	Would we require a licence?
Human Bone	Full skeleton and individual bones and teeth	Deceased. (See code of practice for acquiring additional bones)	Yes	Education and training relating to human health.	Yes, but exempt as held before 01.09.06 and over 100 years old	No	Yes	yes	No
				Education other than healthcare	no	no	Yes	yes	no
				Research for other purposes (e.g. Forensics)	no	no	Yes	possibly	no
Human tissue	Tissue samples prepared slides e.g. blood smears or tissue sections	Living	yes	Education and training relating to human health and other	Yes, but excepted see note 1:3, note 4	Yes, but excepted see note 1:3, note 4	Yes, due to the exceptions	yes	No
		Living or deceased	yes	Research on the structure, function, or disorders of the human body	yes	Yes	No	No	Yes, but University of Worcester researchers can work under the licence of a body taking the samples or under the approval of a recognised Research Ethics Committee (REC)
Blood	Capillary blood, venous blood, menstrual blood	Living	Yes	Education and training relating to human health	Yes, but excepted see note 1:3, note 4	yes	Yes excepted see note 4	yes	No
				Education other than healthcare	no	yes	No.	Not stored (i.e. used on day taken and disposed of or rendered acellular as part of a batch)	no

Material Type (see list above)	Description	Is it from a Living or Deceased person?	Relevant material (see list above)	Use or Purpose (Teaching specify course; Research specify type)	Scheduled Purpose	Is Consent required?	Can it be stored without a licence?	Is it being stored?	Would we require a licence?
								asap or within a max of 7 days#)	
				Research on the structure, function, or disorders of the human body (see definition below)	yes	Yes however exceptions may apply to research approved by a recognised Research Ethics Committee (REC). The UW Ethics Committee is not a recognised REC.	No.	Not stored (i.e. used on day taken and disposed of or rendered acellular as part of a batch asap or within a max of 7 days#)	No
								If there's a requirement to store then 	Yes. But University of Worcester researchers can work under the licence of a body taking the samples or under the approval of a REC
				Research for other purposes	no	yes	No	Not stored (i.e. used on day taken and disposed of or rendered acellular as part of a batch asap or within a max of 7 days#)	no
Blood serum	Serum separated from blood asap and no greater than 7 days, remaining material disposed of immediately	Living	No	Education or research	Yes (note2: d3)	yes	Yes	yes	No
Blood plasma	Plasma separated from blood and rendered acellular asap and no greater than 7 days, remaining material disposed of immediately	Living	No	Education or research	Yes (note 2: d3)	yes	Yes	yes	No
Lysed cells	Cells lysed from blood or other tissue asap or no greater than 7 days of sampling	living	No	Education or research	Yes	yes	Yes	yes	No

Material Type (see list above)	Description	Is it from a Living or Deceased person?	Relevant material (see list above)	Use or Purpose (Teaching specify course; Research specify type)	Scheduled Purpose	Is Consent required?	Can it be stored without a licence?	Is it being stored?	Would we require a licence?
Urine, Saliva, Cheek swabs Vaginal swabs Spit/sputum Faeces Breast milk Mucus	Participant samples	Living (if from deceased they would need a licence)	Yes	Education and training relating to human health	yes	yes	No.	Not stored (i.e. used on day taken and disposed of or rendered acellular as part of a batch asap or within a max of 7 days#)	no
				Education other than healthcare	no	Yes	No	Not stored (i.e. used on day taken and disposed of or rendered acellular as part of a batch asap or within a max of 7 days#)	no
				Research on the structure, function, or disorders of the human body	yes	Yes (also see REC note above)	No	Not stored (i.e. used on day taken and disposed of or rendered acellular as part of a batch asap or within a max of 7 days#)	No
				Research for other purposes (e.g. Forensics)	no	yes	No	Not stored (i.e. used on day taken and disposed of or rendered acellular as part of a batch asap or within a max of 7 days#)	no
Teeth See above under bones									

Material Type (see list above)	Description	Is it from a Living or Deceased person?	Relevant material (see list above)	Use or Purpose (Teaching specify course; Research specify type)	Scheduled Purpose	Is Consent required?	Can it be stored without a licence?	Is it being stored?	Would we require a licence?
Hair samples without follicle	Samples on slides or in containers	Living	No	Education or research	No	possibly	Yes	yes	No
Spermatozoa	Prepared slides	Living	no	Education Forensic	No	yes	Yes	yes	No
Semen	Semen sample that may contain cells other than spermatozoa	Living	Yes	Education Forensic	No	yes	No	Not stored (i.e. used on day taken and disposed of or rendered acellular as part of a batch asap or within a max of 7 days#).	No
Cell lines			No				Yes	yes	No

as soon as reasonably practicable; where material is being held temporarily while processing renders it acellular, this should normally be completed within hours or days and no longer than one week.

Appendix F: Guidance for Students

Human Tissue Research | What you must know before you start

IMPORTANT If your research involves human tissue, you must follow the University's Human Tissue Act Guidance and Procedures. Do not start collecting, acquiring, storing or using human tissue until the required approvals, advice and training are in place.

1. Does my project involve human tissue?

Human tissue (or relevant material) means material from a human body that consists of, or includes, human cells. The guidance stresses that even a single human cell can make material relevant.

Examples include blood, bone, saliva, skin/cells, urine, breast milk, organs, buccal cells, CSF, faeces, mucus/swabs, primary cell cultures and tumour tissue.

Some processed materials may not be relevant material if they are genuinely acellular, such as serum or extracted cellular components, but this depends on how the material has been processed.

If you are unsure whether your material is relevant material, ask your supervisor and the SSE Human Tissue Advisor before doing anything with it.

2. Before you commence: the non-negotiable checks

Ethical approval: Your research must have ethical approval before it starts. Human-tissue projects must follow the University's Ethics Policy and the required School ethical review route.

Human Tissue Advisor: Before any research that may involve human tissue—even if you think the material is 'excepted'—advice and approval must firstly be obtained from your supervisor, or the SSE Human Tissue Advisor if a referral is made by the supervisor.

Supervisor: You are responsible, together with your supervisor, for ensuring that your research complies with the guidance. Do not make assumptions about licensing, consent or storage.

Training: Researchers undertaking human tissue research should complete the Human Tissue Research training identified in the guidance. Human Tissue consent training is also required before sample collection/acquisition.

Consent documents: Your project must explain how consent will be obtained. Consent forms and Participant Information Sheets require ethical approval and must comply with the Consent Codes of Practice.

Risk assessment & safety: The participant must understand relevant activity and risks; risk assessments should be available to them. All human tissue work must comply with Health and Safety requirements.

3. Consent: what you must understand

Consent is a legal requirement for the relevant human-tissue activities covered by the guidance. Written consent is required by SSE for each sample provided.

Consent must be voluntary, informed and given by someone with capacity. The donor must understand what the activity involves, the risks and the intended purpose.

The person giving consent must be able to ask questions and seek further information. Refusing consent must not disadvantage or advantage them—for example, consent to provide a sample must not be a condition of receiving a student project.

For research, the guidance advises that consent should be 'generic and enduring'. Participants must be told that consent can be withdrawn.

Withdrawal may not be effective once a sample has already been analysed. Participants must be told that withdrawal means the sample will be destroyed/disposed of and will not be returned.

Samples from colleagues, staff, fellow students or other people within the University are not automatically exempt from consent or ethical requirements.

4. Human tissue storage: a critical rule

DO NOT STORE HUMAN TISSUE WITHOUT CHECKING FIRST The guidance states that the University does not currently have a Human Tissue Licence for research storage. Therefore, you must not assume that you can keep human tissue in a laboratory, refrigerator, freezer or other location. Some licensing exceptions exist, but these must be established for the particular activity/project. Speak to your supervisor and the SSE Human Tissue Advisor before storing any material.

Temporary holding is not a general 'seven-day licence'

Material being held while it is processed to remove cellular material may fall within an exception when processing takes hours or days and no longer than seven days. The guidance emphasises that this is not a seven-day exemption period: material should be held for as short a time as possible.

Examples of storage include batching samples before bulk processing, waiting for extraction reagents, or creating a biobank. If material needs to be stored longer, or taken off the premises, consult the Human Tissue Advisor before work begins.

Research with HRA-recognised ethical approval may be exempt from licensing requirements in the circumstances described in the guidance. University/School ethical approval alone does not replace an HTA licence.

5. Working safely and responsibly

Follow the approved research protocol, risk assessment, laboratory procedures and Health and Safety requirements at all times.

Treat human tissue respectfully and ensure it is used only for the purpose covered by the approved project and consent.

Do not use a sample for a new purpose, transfer it, or change how it is stored or disposed of without checking the implications with your supervisor and Human Tissue Advisor.

Any Health and Safety incident occurring where human tissue research is carried out must also be reported to the Human Tissue Advisor as an adverse event.

6. What counts as an adverse event?

An adverse event is an incident that could breach, or lead to a breach of, the Human Tissue Act or relevant requirements.

Examples include theft or loss of a sample, inadvertent destruction of a sample because of a storage/environmental failure, or analysing samples outside the scope of consent.

Report all adverse events to the Human Tissue Advisor immediately. Do not wait until you have established exactly what happened.

7. Disposal of human tissue

Human tissue must be disposed of respectfully and in accordance with the project arrangements and consent.

Many research samples are disposed of as part of the process, usually via autoclaving, following the relevant University guidance for working safely with human blood, tissue or other specimens.

Where human tissue remains for disposal, the Human Tissue Act identifies incineration, cremation or burial as disposal options. The SSE guidance states that cremation or burial are not currently available for its expected research.

Each research group or human-tissue laboratory must have a documented disposal procedure covering the type and volume of waste, storage before disposal, frequency and disposal method. Follow the procedure applicable to your project.

8. Your 'ready to start' checklist

- ☐ I know whether my project involves human tissue/relevant material.
- ☐ My project has received the required ethical approval.
- ☐ I have discussed the human-tissue aspects of my project with my supervisor.
- ☐ The SSE Human Tissue Advisor has provided the required advice/approval.
- ☐ I have completed the required Human Tissue Research training and consent training where applicable.
- ☐ The consent process, consent form and Participant Information Sheet have been approved.
- ☐ I know exactly what samples I may collect/use, for what purpose and under what consent.
- ☐ I know where samples may be held and have confirmed that storage is permitted.
- ☐ I know the approved disposal route for my samples and waste.
- ☐ I know how and who to contact if something goes wrong.

KEY CONTACT	ALSO SPEAK TO
SSE Human Tissue Advisor Dr Allain Bueno	Your research supervisor / relevant module or course leader before commencing work.

This two-page guide is a student-facing summary of the School of Science and the Environment Human Tissue Act Guidance and Procedures. It does not replace the full guidance. When in doubt, stop and ask your supervisor and the SSE Human Tissue Advisor.