2024

Human Tissue Research Quality Manual

1. Introduction

The Human Tissue Act (2004) (HT Act) which covers England, Wales and Northern Ireland, came into force on 1st September 2006 to regulate the removal, storage, use and disposal of human bodies, organs and tissue for several Scheduled Purposes (requiring consent) such as research, transplantation, human application and public display.

Human tissue is widely used in research studies across Swansea University (SU). Human tissue that falls under the Human Tissue Authority (HTA) definition of relevant material (defined in section 5.2) must only be stored with Health Research Authority (HRA) & NHS Research Ethics Committee (REC) approval or under a HTA licence.

The HTA have a set of Standards and Codes or Practice for the storage of relevant material for research purposes. Establishments are required to meet these Standards and Codes of Practice to gain and hold a HTA licence.

All staff or students of licenced establishments who work with human tissues must understand and respect the Standards and Codes of Practice.

This Quality Manual has been produced as part of a quality management system to provide a guide for the legal storage of human samples for research at SU.

2. Contents Table

3. Quality Policy

Human tissue donated for research should be considered a valuable gift and treated with the utmost respect. It is paramount that all human samples are collected, stored, handled, used and disposed of responsibly and legally and used only for high-quality research.

SU requires that all researchers working with relevant material from the living or deceased strictly abide by the procedures and standards set out in this quality manual and the referenced Standard Operating Procedures (SOPs).

The objectives of the quality manual are:

A. To maintain an effective Quality Management System in compliance with the HT Act 2004 and the standards and guidance issued by the HTA.
B. To provide a practical framework for staff and students to ensure compliance with the licensing requirements of the HTA.
C. To ensure the delivery of standalone and collaborative research is conducted to the highest quality and ethical standards.
D. To safeguard continued public confidence in the ethics of scientific research to secure ongoing sample donations.

4. Quality Management System Scope

This quality manual and associated Core HTA SOPs provide researchers with a clear set of procedures and management processes to govern, organise, conduct, and document all research studies and tissue collections that must comply with the HT Act regulations and HTA licencing standards.

This quality manual will lay out the quality management activities to be undertaken by Swansea University (SU) research staff and students concerning human tissue collections and studies, including personnel roles and responsibilities, training, quality assurance and audits, document management, record retention and reporting and corrective and preventative actions.

All individuals working under the licence are accountable for the material involved in their research and must abide by this manual and associated Core HTA SOPs. All activities taking place under the HTA licence must comply with the HTA standards and will be subject to internal audit by the Human Tissue Governance Officer (HTGO) and external inspection by the HTA.

This quality manual, and appropriate training, will be made available to all staff and students working with relevant material under the HTA licence.

5. Legislation and Regulation of Human Tissue Research

5.1 What is the Human Tissue Act 2004?

The HT Act (2004) established by the HTA is a legal framework that regulates the removal, storage, use and disposal of human tissue, particularly tissue considered 'Relevant Material'.

There are many different types of human tissue and cells, including skin, body parts, organs and bone. Any sample derived from a human body that contains even a single cell is deemed to be 'Relevant Material'.

The Act has consent as its fundamental underlying principle (though there are exemptions) and aims to ensure that all relevant material is managed ethically and sensitively.

5.2 What does the HT Act consider Relevant Material?

Human tissue as defined in the HT Act, is not restricted to human organs. A HTA licence is required for the storage of any human sample which is deemed to be Relevant Material under Section 53 of The Act, defined as:

1. ***"Relevant material" means material, other than gametes, which consists of or includes human cells.***

2. ***"Relevant material" from a human body does not include embryos outside the human body, or hair and nail from the body of a living person.***

If a sample is known to contain even a single cell that has come from a human body the sample should be classified as relevant material. For a broad list of relevant materials and examples of non-relevant materials refer to the HTA Website.

5.3 Is DNA covered by the HT Act?

DNA is not considered to be relevant material under the HT Act and can be stored for research without the need for a HTA Licence.

However, the HT Act does make it an offence to be in possession of bodily material with the intention of analysing its DNA without consent to do so.

A definition of a bodily material is provided below:

1. ***Bodily material is all material that comes from a human body and contains at least one cell, including gametes and nail and hair from a living person.***

2. ***Extracted DNA and RNA (where no whole cells remain) is not classed as bodily material.***

Anyone holding 'bodily material' without the qualifying consent of the person/s concerned, intending to analyse the DNA and use the results, is breaking the law.

It is an offence to analyse DNA without qualifying consent unless it is for an excepted purpose. The offence attracts a fine, a term of imprisonment of up to three years, or both. Although the HT Act does not generally apply to establishments in Scotland, the offence of non-consensual analysis of DNA applies to the whole of the UK, including Scotland. This also applies to RNA analysis where it is to be used to provide information about DNA.

An exception to this rule is DNA analysis can be used for research without consent, providing the bodily material from which the DNA is extracted meets all of the following 3 conditions:

a) is from a living person; and
b) 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
c) the material is used for a specific research project which has received ethical approval from a recognised REC.

Or, where the bodily material is from the body of a living person and is being used for education or training relating to human health.

Although no offence will be committed in these two situations, the HTA recommends that consent be sought where it is practical to do so.

5.4 What is the Human Tissue Authority (HTA)?

The HTA was established to act as an independent government watchdog to ensure that clear standards are in place for the use of human tissue and to provide researchers with guidance on best practice.

The HTA has created several 'Codes of Practice' and 'Standards' to provide practical guidance to professionals carrying out activities within the scope of the HTA's remit. These are listed in Table 1 and can be accessed from the HTA website:

Table 1- HTA Codes of Practice

Code	Activity
Code A -	Guiding principles and the fundamental principle of consent
Code B -	Post-mortem examination
Code C -	Anatomical examination
Code D -	Public Display
Code E -	Research

Code F -	Part 1: Living Organ Donation and Part 2: Deceased Organ and Tissue Donation
Code G -	Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation
Wales -	Code of Practice on the Human Transplantation (Wales) Act 2013

SU researchers and students working with human tissue for research applications should familiarise themselves with:

- **Code A - Guiding principles and the fundamental principle of consent.**
- **Code E - Research.**

5.5 What is a HTA Research Licence?

The HTA licenses and inspects several different sectors:

- Research
- Anatomy
- Public Display
- Human application
- Postmortem
- Organ Donation and Transplantation

For all sectors (with the exception of the Human Application sector), the Human Tissue Authority offers licences under the Human Tissue Act (2004).

A HTA licence is required for the removal and storage of relevant material for scheduled purposes such as research. A scheduled purpose is defined as an activity relating to the removal, storage and use of human organs and other tissue that legally require consent.

The removal of human tissue from the living or the deceased requires consent for research purposes under the HT Act, with a few exceptions.

This quality manual relates specifically to SU's HTA Research Sector Licence only and the activities that can be conducted under its remit. A HTA licence is only required to store relevant material.

The fundamental principle 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.

5.5.1 Licenced research activities:

- Storage of relevant material, that was previously collected under an approved HRA REC study and **has consent** for storage for future ethically approved studies or use in education.
- Storage of any relevant material collected under **SU ethical approval** and storage on SU premises.

- Storage of relevant material obtained from a **tissue bank** with HRA REC tissue bank approval.
- Storage of relevant material **imported** from **outside** of England, Wales and Northern Ireland including from Scotland.
- Preservation of biological tissues through any means of **fixation** (where the cellular structure is retained) is to be regarded as relevant material and must be stored under a HTA licence.
- The temporary storage **for any period** of relevant material **prior to analysis** is not an exemption from the licensing requirements. Relevant material stored to conduct research with it's cellular material can only be stored legally under a HTA licence or approval by a recognised REC.
- Additionally, relevant material stored for **longer than 7** days before rendering it acellular in preparation for analysis of the acellular components, still requires storage under a HTA licence or approval by a recognised REC.

Any researcher with concerns that a HTA licence is required for storage of their human material should contact the HTGO.

5.5.2 Activities a licence is not needed for?

There are a few **exemptions** in which a HTA licence is **not required** to store relevant material:

a) If the material is to be rendered acellular within 7 days.

Note: *This applies when, there is no intention to research the cellular component, and the cells are removed or disrupted through a process (lysed/rendered acellular) within 7 days, a HTA licence is not required for storage of the material before processing.*

Additionally, the processes applied to render the material acellular must be documented (local SOP) as the HTA may seek assurance that appropriate processing has been carried out. This is particularly important for plasma and urine storage.

b) A HTA licence is not required to store relevant material for up to 7 days pending transfer to another HTA-licensed premises. (No analysis of material can be conducted during this period).
c) If a study has HRA REC approval in place to store the material.
d) If the material has come from a person who died at least 100 years previously.
e) If the material has come from a HTA licensed, HRA REC-approved Research Tissue Bank (RTB) where there is permission in place to use the material.

5.6 Non-compliance with HTA Licence

It is a licence requirement that no person shall conduct a licensed activity other than under the authority of the licence granted.

The offences recognised under The HT Act are summarised as follows:

a. Removal, storage or use of relevant material for scheduled purposes without appropriate consent.
b. Storage or use of relevant material donated for a Scheduled Purpose but used for another purpose.
c. Trafficking of human tissue for transplantation purposes.
d. Carrying out licensable activities without holding a licence from the HTA.
e. DNA theft i.e. having human tissue, including hair, nail and gametes with the intention of its DNA being analysed without the consent of the person from whom the tissue came, or of those close to them if they have died.

The penalties for failure to comply with The HT Act are a fine, up to three years imprisonment or both.

Non-compliance with the Act has the following implications for researchers and the University:

- May invalidate any research conducted using the tissue.
- Risk to the research and ethical reputation of SU.
- May affect public confidence in the ethics of medical research, limiting the provision of future samples.
- Risks the revocation of the licence and therefore the ability to store human tissue for use in research, with significant consequences to research at SU.

6. Swansea University's License

SU Medical School is the Corporate Licence Holder for a Research Sector HTA licence (12651) to license the removal and storage of human organs, tissues and cells for research purposes other than for a specific HRA REC-approved research project.

6.1 Licenced Premises

The HTA licenses premises in three ways:

a. Standalone premises
b. Hub premises
c. Satellite premises

Standalone premises are where a HTA licence covers a single premise only.

Where licensable activities are conducted at different locations, such as two physically separated university campuses, one location can become the hub premises and the second location can become a satellite of the satellite.

Satellite premises must be governed under the same quality management system as the hub premises, including supervision by the Designated Individual (DI). The DI is responsible for ensuring that suitable practices are carried out at any licensed premises under their governance, and for ensuring compliance with the HTA's licensing conditions and standards.

SU hold a Standalone premise licence that covers research activities in three buildings on SU's Singleton Campus:

1. Institute of Life Science 1 (ILS1)
2. Institute of Life Science 2 (ILS1) / Centre for NanoHealth (CNH)
3. Grove building

The address is provided below:

Swansea University Medical School
Institute of Life Science 1
Singleton Park
Swansea
SA2 8PP

Named individual (DI) for correspondence: Professor Cathy Thornton (c.a.thornton@swansea.ac.uk)

All human tissue research on SU's Bay Campus must gain a HRA REC-approved research project before storage of human tissue can commence.

6.2 Roles and responsibilities under a HTA licence

The HTA prescribe that three key roles are required under The Act. These are:

1. **Licence Holder (LH):**
   - A corporate body, or named person, is responsible for applying for the licence.
   - May apply to change the licence and substitute the Designated Individual

2. **Designated Individual (DI):**
   - Named on the licence as the person under whose supervision the licensed activity is authorised. The DI's role is to ensure that activities are conducted properly by people who are qualified and that all the requirements are complied with. They are legal responsibility, under Section 18 of the HT Act, for ensuring:

⇒ that suitable practices are used in undertaking the licensed activity.
⇒ that other persons working under the licence are competent.
⇒ that the conditions of the licence are complied with.
⇒ oversight of all relevant material stored within licenced buildings; including material stored under HRA REC-approved research and collections stored under the HTA licence.

3. **Persons Designate (PD):**
    - A person to whom the licence applies and who is named on the licence.
    - Assists the DI in supervising licensable activities within their groups.
    - May be located within a central hub, or at a satellite site covered by the same licence.
    - Multiple PDs may exist under the same licence.
    - The PD role imposes no legal responsibility, however, it is a licence requirement that the DI has documented evidence of the PD's acceptance of the PD role.

4. **HT Act Coordinator:**
    - A PD may choose to appoint one or more Human Tissue Act Coordinators to help support them within their local environment. These persons may be chosen at the discretion of the PD.

To support compliance with the HT Act, SU has implemented the additional role of:

5. **Human Tissue Governance Officer (HTGO)** – to conduct internal audits, training and develop and maintain the quality management system. To liaise with the DI, PDs and researchers on all HTA issues.

As required by the HT Act, SU has assigned a named LH and DI to oversee the licence, and several PDs to assist the DI in supervising licensable activities. An organogram is provided in **Figure 1.**

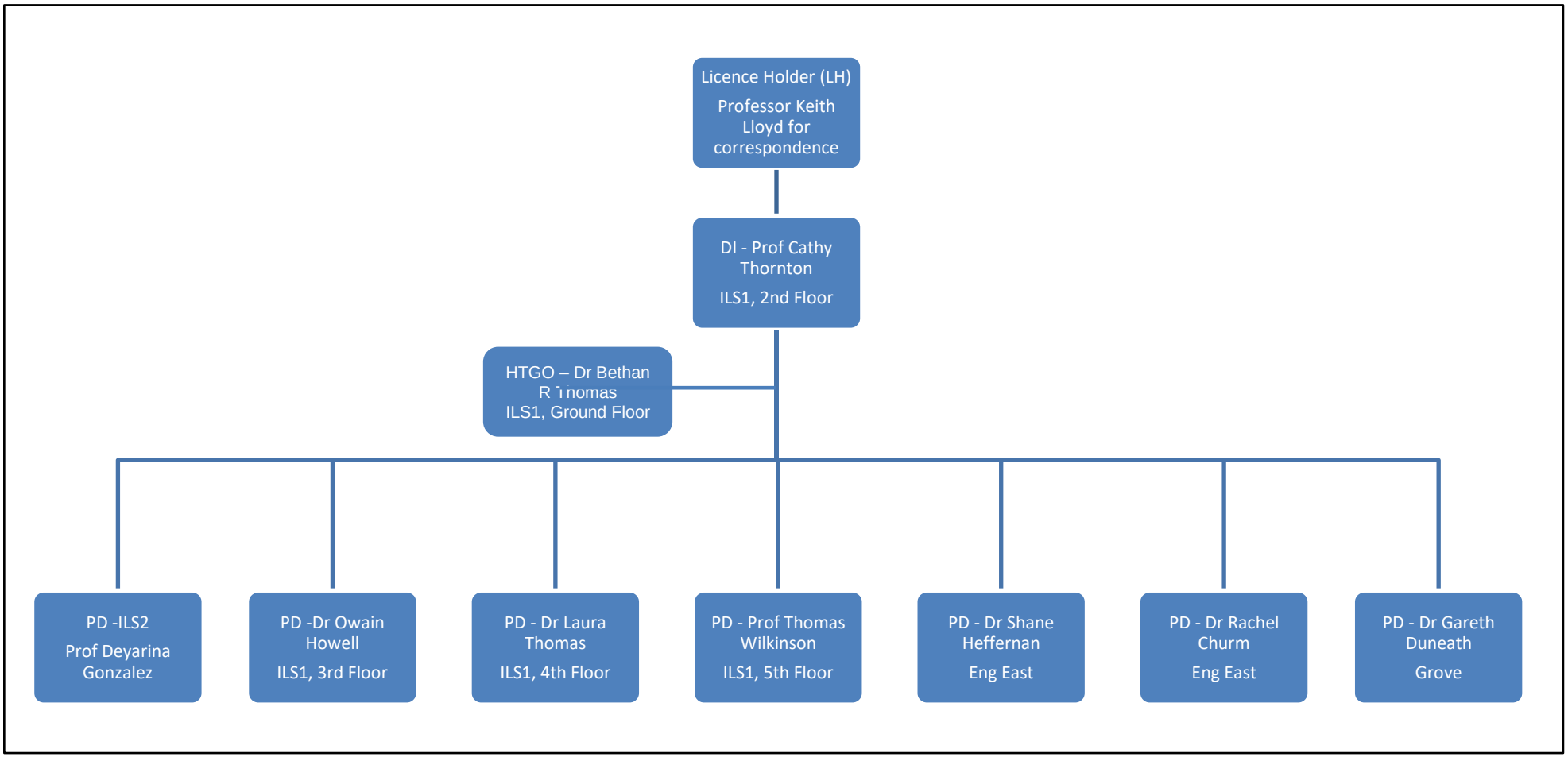

Figure 1- Organisational Chart of SU HTA Research Licence (Owain's square is missing the 1 after ILS.

Contact details for the key personnel under the University's research sector HTA licence are provided in Table 1. Should a Person Designate wish to be removed from the HTA licence, they should contact the HTGO or DI. A new PD should then be appointed, where required.

Table 1- Contact details of key personnel on the SU research sector HTA licence

Role	Name	Contact Details
Named contact for Licence Holder (LH)	Professor Keith Lloyd for correspondence	Institute of Life Science 2 Singleton Park Swansea SA2 8PP Email: K.R.Lloyd@swansea.ac.uk
Designated Individual (DI)	Professor Catherine Thornton	2nd Floor, Institute of Life Science1 Singleton Park Swansea SA2 8PP Email: C.A.Thornton@swansea.ac.uk
Human Tissue Governance Officer	Dr Bethan R Thomas	Ground Floor, Institute of Life Science 1 Singleton Park Swansea SA2 8PP Email: B.R.Thomas@swansea.ac.uk
Person Designate	Prof. Deyarina Gonzalez	Ground Floor, Institute of Life Science 2 Singleton Park Swansea SA2 8PP Email: D.Gonzalez@swansea.ac.uk
Person Designate	Dr Owain Howell	3rd Floor, Institute of Life Science 1 Singleton Park Swansea SA2 8PP Email: o.w.howell@swansea.ac.uk
Person Designate	Prof. Thomas Wilkinson	5th Floor, Institute of Life Science 1 Singleton Park Swansea SA2 8PP Email: t.s.wilkinson@swansea.ac.uk
Person Designate	Dr Laura Thomas ILS1, 4th Floor	4th Floor, Institute of Life Science 1 Singleton Park Swansea SA2 8PP Email: laura.e.thomas@swansea.ac.uk
Person Designate	Dr Gareth Dunseath Grove	Grove building Singleton Park Swansea SA2 8PP Email: g.j.dunseath@swansea.ac.uk
Person Designate	Dr Shane Heffernan Eng East	Eng East Fabian Way Crymlyn Burrows Skewen Swansea

Role	Name	Contact Details
		SA1 8EN Email: s.m.heffernan@swansea.ac.uk
Person Designate	Dr Rachel Churm	Eng East Fabian Way Crymlyn Burrows Skewen Swansea SA1 8EN Email: r.churm@swansea.ac.uk

6.3 Responsibilities of Researchers

In addition to these formal roles, it is the responsibility of all staff and students operating under the University's HTA licence to know their responsibilities under the HT Act, to treat donated material with dignity and respect, and to protect the privacy of donors and maintain data confidentiality.

All researchers storing human tissue under the HTA research licence have a responsibility to know and abide by the HT Act and HTA regulations. All researchers should comply with the management system described herein and all SU HTA Core SOPs.

Researchers should be aware of cases in which material has to be stored under the licence and must disclose this material to the HTGO and DI.

7. Human Tissue Management System

All staff involved in research projects intending to use human tissue considered relevant material under the HT Act, must observe the systems, processes and SOPs detailed herein.

7.1 Read and Understand the Manual & Core SOPs

As part of SU's quality management system, it is expected that all researchers working with human tissue are knowledgeable and familiar with this manual, Core SOPs and the HTA Code of Practice.

Any researcher intending to use human tissue in research at SU must read and understand this manual first and then all the Core SOPs published online. All researchers must also read and understand the HTA Code of Practice for Consent and Research.

Below is a list of all Core SOPs listed in suggested reading order:

1	HTA-CORE-SOP-	Human Tissue Training
2	HTA-CORE-SOP-	Management of Records
3	HTA-CORE-SOP-	Consent
4	HTA-CORE-SOP-	Storage
5	HTA-CORE-SOP-	Disposal
6	HTA-CORE-SOP-	Transportation
7	HTA-CORE-SOP-	Chain of Custody
8	HTA-CORE-SOP-	Maintenance & Monitoring of Cold Storage
9	HTA-CORE-SOP-	Equipment Management
10	HTA-CORE-SOP-	Risk Management
11	HTA-CORE-SOP-	Adverse Event Reporting
12	HTA-CORE-SOP-	Internal Audit
13	HTA-CORE-SOP-	Acceptance of Sample Collection
14	HTA-CORE-SOP-	Standard Operating Procedure
15	HTA-SOP-	QR Code Labels (Not a Core SOP but useful)

All SU HTA Core SOPs and the standards set out HTA Code of Practice must be abided by all staff and students involved in human tissue research.

7.2 Training Requirements for Human Tissue Research

All researchers must undertake appropriate training if they are involved in research projects intending to use human tissue and storage of human tissue at SU, including material that is not considered relevant under the HT Act, human DNA and RNA, acellular human biological fluid, and human-derived cell lines.

Please refer to HTA-CORE-SOP-Human Tissue Training.

7.3 Obtain Ethical Approval

There are a few pathways available for researchers to obtain tissues:

1. Collect new material.
2. Obtaining pre-existing tissue from a Research Tissue Bank (RTB) (biobank).
3. Commercial supplier – *collect material on your behave.*

All researchers have a responsibility to ensure that all human tissue is obtained ethically, and the researcher must be satisfied that appropriate consent is in place for the samples that have been obtained, even if not obtaining consent personally. The consent requirements under the HT Act are set out in SU's HTA-CORE-SOP-Consent.

Regardless of how you will obtain the tissue you must submit an ethical application for approval.

NHS Ethics	**NHS Ethics** is needed if the relevant material originates in the NHS, participants are recruited through the NHS or data is collected from the NHS. NHS ethics may also be needed where previously collected *identifiable* material will be re-used in a new project. To help you decide, please use the HRA Toolkit: "Do I need NHS REC review?"
Swansea University Ethics	**SU Ethics** can be used if relevant material is to be collected from volunteers and the project has no involvement with the NHS or when SU is not the lead organisation but an SU staff or student is receiving human tissue through a collaboration. SU applications involving human tissue must be submitted through SU's online Ethics application.
No Ethics	Ethical approval may not be needed if the relevant material is obtained from a Research Tissue Bank (unless otherwise stated by the tissue bank) or has already been collected under ethical approval and consent that is appropriate for future use; contact HTGO for further information.

When developing consent documentation for SU sponsorship for NHS REC approval or if submitting to SU internal ethics, it is strongly advised to use the templates provided by the Research Governance team for:

- Study Protocol
- Patient Information Sheet (PIS)
- Consent form

Note: If you do intend to store human tissue that was obtained under NHS REC approval beyond the NHS REC expiry date, you should consider this when creating your consent form. You must ensure there is a statement of consent for future storage of samples.

7.4 Material Transfer Agreements

A material transfer agreement (MTA) is always required when transferring relevant material into or out of SU to another organisation, including where material is sourced in the NHS.

The MTA is a legal document, it is the researcher's responsibility to read, understand and adhere to the obligations outlined in the MTA.

Material Transfer Agreement (MTA)	Transfer of material from one organisation to another. An MTA should warrant: • Material was collected/will be used with ethical approval. • Appropriate consent is in place for transfer and intended use. • What samples are to be transferred and permitted use of samples. • Responsibilities for disposal/future use. • Duration of use - start and expiry dates for agreement. • Any risks associated with the material.
Organisation Information Document (OID)	Collaborative project with active NHS REC approval. An OID will detail responsibilities for all participating organisations, including consent, material custodianship, responsibility for material following completion of project etc. There may be cases when OID on its own does not suffice and an additional MTA should be sought.

MTA can be obtained from the REIS Contracts Team, who have templates for both transfer of relevant and non-relevant material.

Samples **must not be transferred** before a signed MTA is in place.

All MTAs will be reviewed by the HTGO via the RESI contracts team before **authorised personnel** from the contracts team can provide a signature.

Researchers cannot sign an MTA on behalf of SU.

7.5 Local SOPs and Risk Assessment and Contingency

The PI must ensure local SOPs and risk assessments are in place for relevant activities and managed through document version control, regular review and updates.

Local SOPs should be in line with all Core SOPs but should be specific to the study, they should clearly identify individual researchers' roles and responsibilities within the research group. It is suggested that you create project-specific / lab-specific SOPs for the following process:

- Receipt of specimens (if applicable)
- Specimen collection, preparation/preservation, labelling, storage and disposal.
- Transport arrangements
- Maintenance, cleaning and decontamination

A more extensive list of local SOPs is available in HTA-CORE-SOP-Management of Records.

The PI must also ensure a study-specific Human Tissue Risk Assessment (RA) is completed, refer to HTA-CORE-Risk Management for guidance on how to complete this. The RA will likely include the development of a contingency plan for key equipment (e.g. fridges/freezers), this is to mitigate risk to the human tissue.

Additional health and safety RAs that should be available if requested would relate to any laboratory activities undertaken in the delivery of the study.

7.6 Human Tissue Study Checklists

Forms and Templates have been developed to assist researchers ensure their work is compliant with the HT Act. All of this documentation is available on SU's Human Tissue Act webpage.

7.6.1 Before Study Commences

Before commencing a study ensure you have completed the appropriate training, gained ethical approval, initiated required MTAs, undertaken a human tissue RA and compiled all local SOPs; as explained in previous sections 7.1 to 7.5.

PIs and all researchers involved can then make use of the HTA-FORM-Before Study Checklist to ensure that they have prepared all mandatory documentation for compliance with the HT Act.

All staff and students directly involved in the delivery of the study utilising human tissue samples should read and understand their local study-specific and laboratory-specific:

- SOPs
- Risk Assessments
- Contingency plans

7.6.2 During Study

Ensure all HTA compliance data and documentation are captured and maintained, see HTA-CORE-SOP-Management of Records.	☐
If the study is HRA-approved, complete and submit yearly reports.	☐
Report any Adverse Events by completing the Adverse Events Form and sending it to the HTGO within 7 days of discovering the event.	☐
Carry out regular Self-Audits and notify the HTGO of any shortfalls.	☐
Regularly challenge storage alarm systems to ensure the system is working. See HTA-CORE-SOP-Maintenance and Monitoring of Cold Storage.	☐
Follow the above MTA process and complete the Transfer of Relevant Material process (Section 6.3) if any human tissue is to be transferred in or out of SU during the study.	☐

7.6.3 Study Closure

If tissue samples remain at the end of the study and you do not wish to retain them for future work or have no consent to do so Complete and submit a HTA-FORM-Human Tissue Disposal Log to the HTGO at the end of the study.	☐
If tissue samples remain at the end of the study and you do wish to retain them for future work and have consent to do so: 2 months before the end of the study, complete the HTA-FORM-Licence Storage Application together with the documentation listed in the HTA-CORE-SOP-Acceptance of Sample Collection and submit all to the HTGO.	☐
Securely archive study documents for 10 years.	☐

If you do intend to store human tissue collected under an NHS REC-approval after its expiry date you should have considered this when creating consent forms. If there is no statement of future storage you will not be able to store the samples under the SU HTA research licence.

You may wish to store the tissue samples to create a Research Tissue Biobank.

This again would require completion of the HTA-FORM-Licence Storage Application together with the documentation listed in the HTA-CORE-SOP-Acceptance of Sample Collection and submission to the HTGO.

7.7 Research Tissue Biobanks

A Research Tissue Biobank (RTB) is defined as a collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending. It can contain many different types of biological

samples (e.g. tissue samples, DNA and blood) and information (e.g. health records, diet and lifestyle information, and family history of disease, gender, age, and ethnicity).

RTBs which store relevant material must only do so on premises which hold a HTA licence for storage for a scheduled purpose.

RTBs may be granted generic HRA REC tissue bank approval for a broad range of future research to be carried out by the establishment responsible for the bank and/or by other researchers to whom tissue is released by the bank within the conditions of the ethical approval. As a condition of approval, RTBs must create access policies that document the procedures for processing applications to use the bank, the conditions of access and any governance requirements. Researchers must then apply to use the bank; requests will be reviewed by an access committee in line with the bank access policy.

A significant advantage of gaining REC approval as a RTB is that this negates the need for researchers to obtain separate REC approval for research they wish to conduct using relevant material, providing that the research to be conducted falls within the scope of the ethical approval that has been granted to the RTB and the consent given by the donors.

Applications for RTBs to obtain REC approval is not a legal requirement, however, it may have benefits by facilitating programmes of research without a need for individual project-based ethical approval.

REC approval of RTBs is given for a period of up to five years and may be renewed.

7.8 Document Management

To comply with HTA standards on Governance and Good Clinical Practice all research groups and biobanks working under a HTA research licence should establish and maintain a procedure to control all documents that form part of their QMS (e.g. local SOPs, policies, training records, RAs). Change control should be in place for the implementation of new or revised operational procedures. Documentation should be managed in line with HTA-CORE-SOP-Management of Records. Standard operating procedures should be created and managed following HTA-CORE-SOP-SOPs.

Compliance with these standards will be assessed by the HTGO during internal audits.

Research group-specific quality documents (e.g. SOPs, policies, training records, RAs) may be stored in hard copy or digital on the SU OneDrive, provided that document management complies with the HTA quality standard.

7.9 Adverse events

An adverse event is any occurrence that threatens, or has the potential to threaten, the integrity of samples, and/or associated data, the safety of staff, or undermines good practice.

Adverse events, or near misses, will be categorised, recorded and managed according to HTA-CORE-SOP-Adverse Events.

All corrective and preventative actions must be managed promptly to maintain the integrity of samples, protect participant data and ensure staff safety.

For any further advice should an adverse event occur, please contact the HTGO.

7.10 Audit

Official inspections reviewing compliance with the HT Act are conducted on a regular basis. These audits may be either:

Internal audits	• Conducted by the HTGO, PD and/or DI. • Self-inspection audits within groups
External audits	• Licence standard compliance inspections conducted by the HTA

The format of internal audits, and what researchers can expect, is set out in HTA-CORE-SOP-Internal Audit. Audit frequency will be conducted based on a risk analysis. All internal HTA audit reports will be stored electronically by the HTGO and can be provided to regulators on request.

7.11 Governance

To ensure compliance with the HT Act, the DI has ultimate responsibility for the implementation and management of the overarching QMS and oversight of relevant material held under the licence.

The HTGO is responsible for maintaining and supporting the QMS by monitoring regulatory and legal requirements and changes and managing the processes described in the QMS documentation.

Regular meetings of the SU HTA Sub-Committee will be held to review Adverse Events and Audits.

7.12 Complaints

Complaints relating to SU's research sector HTA licence received either internally or externally (from a Health Board, participant, patient, visitors or other organisations), should be directed to the HTGO in the first instance. All complaints will be escalated to the DI and, where appropriate, to the Health Board R&D Manager. Complaints will be managed as per SU's complaints policy.

A register of complaints will be maintained as part of the QMS and will be reviewed at the SU HTA Sub-Committee to facilitate quality improvement.

8. Definitions

Audit	The evaluation of a system, process or procedure in order to ascertain its effectiveness and the validity and reliability of the information.
Capacity	The ability to use information to make a decision.
Chain of Custody	Documentation to evidence the chain of possession from sample collection until it reaches the laboratory or other final destination. It includes information such as sample number and location where sample was taken, dates and times of collection, type of sample and the name of person dispatching and receiving the sample. Every time the sample changes possession, the person relinquishing the sample and the person receiving it must sign and date/time the Tissue Transfer Log form.
Consent	Process by which an individual confirms his/her willingness to participate in a particular procedure. The individual must have been informed of all aspects of the procedure/request that are relevant to the decision to participate. The individual must be competent to take the particular decision, be acting voluntarily and not be acting under duress.
Designated Individual (DI)	The person who is authorised and who supervises activities under a licence issued by the Human Tissue Authority.
Freezer	A refrigerated cabinet that is kept below freezing, typically held at -20 degrees Celsius.
Fridge	A refrigerated cabinet that maintains a temperature range between 0-4 degrees Celsius.
HTA Codes of Practice	Provide guidance and lay down expected standards for each of the sectors regulated by the HTA (e.g. research) and under the HT Act.
HTA Standards	Core standards in four key areas that must be met for an organisation to obtain an HTA licence, relating to the provisions in the HT Act and the regulatory requirements: Consent;

	Governance and Quality Systems; Premises, Facilities and Equipment; Disposal.
Human Tissue	Any and all constituent parts of the human body that consists of, or includes, human cells.
Human Tissue Act 2004	Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland.
Human Tissue Authority	The independent regulator established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that collect, store and use human tissue for the Scheduled Purposes, for which appropriate consent is required (unless exemptions apply).
Quality Management System	Centralised governance framework policies, procedures, training, provision of advice and guidance, documentation and data records relating to all aspects of acquisition, storage, use and disposal of human samples.
Relevant Material	Any material, other than gametes, removed from the body which consists of or includes human cells.
Research	A study that 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.
Risk Assessment	*A document which carefully evaluates what could cause harm to people or resources and what precautions should be implemented.*
Scheduled Purposes	The activities relating to the removal, storage and use of human organs and other tissue that require consent, listed in Schedule 1 of the HT Act, e.g. research in connection with disorders or the functioning of the human body.

Standard Operating Procedure (SOP)	Detailed, written instructions to achieve uniformity of the performance of a specific function which an integral part of a quality management system.
Storage	Maintaining the tissue under appropriate controlled conditions.
Ultra Low Temperature (ULT) Freezer	A refrigerated cabinet that maintains a temperature range of –45 to -86 degrees Celsius.
Validation	Prospective evaluation of equipment to ensure compliance with user requirements, relevant standards and usability.

9. Document History

Document History				
Version	**Review Date**	**Comment**	**Replaces**	**Reviewed by**
2.0	01/09/2016	Review following granting of licence; amended references to proposed licences and acting DI.	1.0	Lisa Wakeman
3.0	23/04/2018	Review to reflect updated HTA codes of practice and research standards. Minor amendments to content and readability.	2.0	Lisa Wakeman
4.0	14/03/2024		3.0	Dr Bethan R Thomas & DI

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