Human Samples in Research

Quality Manual

The collection, storage and use of tissue for research in accordance with the Swansea University and Abertawe Bro Morgannwg University Health Board research sector Human Tissue Authority licence

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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 a number of Scheduled Purposes (requiring consent) such as research, transplantation, human application and public display.

Human tissue is widely used in research studies across Swansea University and Abertawe Bro Morgannwg University Health Board (ABM UHB). Human tissue that falls under the Human Tissue Authority (HTA) definition of relevant material must only be stored under the governance of Health Research Authority (HRA) Research Ethics Committee (REC) approval or a HTA licence. The requirements that an establishment is required to meet to hold a HTA licence must be understood and respected by all employees who work with human tissues.

This Quality Manual has been produced as part of a quality management system to provide a comprehensive guide for the legal storage of human samples for research in Swansea University and ABM UHB.

2. 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.

Swansea University and ABM UHB 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 referenced organisational standard operating procedures (SOPs). For a summary of minimum and best practice for the use of human tissue in research, refer to Appendix A.

The objectives of the Quality Manual are:

a) To maintain an effective Quality Management System in compliance with the Human Tissue Act 2004 and the standards and guidance issued by the HTA.

b) To provide a practical framework for employees and students to ensure compliance with licensing requirements of the HTA.

c) To enhance Swansea University and ABM UHB reputations for the delivery of standalone and collaborative research to the highest quality and ethical standards.

d) To ensure continued public confidence in the ethics of scientific research to secure ongoing sample donations.

This Quality Manual and associated organisational HTA SOPs provide researchers with a summary of the HT Act regulations and a description of the range of processes that must be applied in order to organise, conduct, and document all research using relevant material that is held under the HTA licence.. Employees and students may only store relevant material under a HTA licence with the approval of the Designated Individual (DI) and following registration with the HTA Governance Officer. All individuals working under the licence are accountable for the material involved in their research and must abide by this manual and associated SOPs. All activities taking place under the HTA licence must comply with the HTA standards

https://www.hta.gov.uk/sites/default/files/Code%20E%20Research%20Standards%20and%20Guidance.pdf and will be subject to internal audit and external inspection by the HTA.

This Quality Manual, and appropriate training, will be made available to all employees and students working with relevant material under the HTA licence.

3. THE HUMAN TISSUE ACT

3.1 Human Tissue Act Overview

The HT Act (2004) is a legal framework that regulates the removal, storage, use and disposal of human bodies, organs and tissues. The Act has consent as its fundamental underlying principle and aims to ensure that all relevant material is managed ethically and sensitively.

The Act applies to England, Wales and Northern Ireland and was enforced as a direct response to the findings of the Redfern report in which the unauthorised removal, retention, and disposal of human tissue was found at the Alder Hey Children's Hospital and Bristol Royal Infirmary.

3.2 Human Tissue Authority

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 to on best practice.

The HTA has created a number of codes of practice to provide guidance for researchers and set out expected standards for each of the sectors regulated by the HTA. These are listed in table 1 and can be accessed from the HTA website:

https://www.hta.gov.uk/codes-practice

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 -	Donation of solid organs and tissue for transplantation
Code G -	Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation

3.3 Materials covered by the Act

Human tissue as defined in The 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. 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 comprehensive list of materials included in the HT Act, researchers may refer to the HTA website:

http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm

A definition of a relevant material is provided below:

> ***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.***

3.4 DNA

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:

> ***Bodily material:***
>
> ***Defined as all material that comes from a human body and contains at least one cell, including gametes and nail and hair from a living person.***
>
> ***Extracted DNA and RNA (where no whole cells remain) is not classed as bodily material.***

An offence will be committed where somebody stores bodily material intending to analyse its DNA and use the results for non-excepted purposes without consent. One of the excepted purposes relates to research and is highlighted below:

A researcher is using the results of analysis of DNA extracted from tissue biopsies from living people as part of a research project that has been approved by a recognised REC. The researcher will not come into possession of any patient identifiable information. No offence will be committed if consent is not obtained.

The Secretary of State may also specify the circumstances in which the High Court, or in the case of Scotland, the Court of Session may order that use of the results of DNA analysis for research purposes is an excepted purpose.

Other excepted purposes are set out below:

1. Medical diagnosis or treatment of the person whose body made the DNA

2. Purposes of the coroner (England, Wales and Northern Ireland) / Procurator Fiscal (Scotland)

3. Prevention/detection of crime

4. Conduct of a prosecution

5. National security

6. Court / tribunal order or direction

7. Where the bodily material is from the body of a living person - use for clinical audit, education or training relating to human health, performance assessment, public health monitoring and quality assurance.

8. Where the bodily material is an existing holding the use for clinical audit, determining the cause of death, education or training relating to human health, establishing after death the efficacy of any drug or treatment administered, obtaining scientific or medical information about a living or deceased person which may be relevant to another person (including a future person), performance assessment, public health monitoring, quality assurance, research in connection with disorders or functioning of the human body and transplantation.

9. Obtaining scientific or medical information about the person from whose body the DNA has come where the bodily material is the subject of either a direction by the HTA or a court order under paragraph 9 Schedule 4 of the HT Act and the information may be relevant to the person for whose benefit the direction or order is made.

10. Where the DNA has come from an adult lacking capacity under the law of England, Wales and Northern Ireland or is an adult with incapacity under the law of Scotland and neither a decision of that person to consent or not to consent to DNA analysis is in force, use for purposes specified in Regulations made by the Secretary of State.

4. HTA LICENSING

4.1 Sectors regulated by the Human Tissue Act

The HTA licenses and inspects a number of different sectors. These are summarised in table 2 below. For full information, refer to the Human Tissue Authority website: https://www.hta.gov.uk/regulated-sectors

Table 2- Sectors licensed and inspected by the Human Tissue Authority

Sector	Activity
Anatomy	For establishments carrying out anatomical examinations or storing anatomical specimens. For example, where human bodies are used to teach students and to train surgeons and other healthcare professionals.
Human application	For organisations that use human tissue and cells to treat patients. For example, stem cells, skin and heart valves, eye banks, maternity units and organisations that store skin and bone.
Post mortem	For establishments carrying out post mortems, storing human bodies or organs, tissues or cells from a deceased person and/or removing relevant material from a deceased person other than in the course of a post mortem.
Public Display	For establishments wishing to put human bodies, body parts and specimens on public display, e.g. as part of an exhibition in a gallery or museum. This is only applicable if material is taken from the body of a deceased person who died less than 100 years ago.
Organ Donation and Transplantation	For establishments working in the field of organ donation and transplantation covering both procurement (characterisation of donor, characterisation, retrieval, preservation and transport of an organ) and transplantation (organ characterisation, preservation, transport and implantation).
Research	For establishments **storing** human organs, tissues and cells for research purposes other than for a specific HRA Research Ethics Committee (REC) approved research project.

For all sectors (with the exception of the Human Application sector), the Human Tissue Authority offers licences under the Human Tissue Act (2004). For the Human Application sector, licences are offered under the Human Tissue (Quality and Safety for Human Application) regulations 2007.

This Quality Manual relates specifically to the collection, storage and use of human tissues for research, this manual relates to the joint University and Health Board research sector licence only. This licence and the activities that can be conducted under their remit, are described in section 5.

4.2 Licensable Activities

Each HTA licence clearly sets out the activities that may be conducted under that licence type. These activities, called **Licensable activities**, fall into the following categories:

1. Carrying out an anatomical examination
2. Making of a post mortem exam
3. Removal of relevant material from a deceased person
4. Storage of relevant material for a number of scheduled purposes (including research)
5. Storage of anatomical specimens
6. Public display of relevant material from deceased persons.

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. A list of **scheduled purposes** is provided in Table 3.

Table 3 - Scheduled Purposes – Activities requiring consent

For living and deceased persons	For deceased persons
Purposes requiring consent: • Anatomical examination • Determining the cause of death • Establishing after a person's death the efficacy of any drug or other treatment administered to him • Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person) • Public display • Research in connection with disorders, or the functioning, of the human body • Transplantation	**Purposes requiring consent:** • Clinical audit • Education or training relating to human health • Performance assessment • Public health monitoring • Quality assurance

4.3 Holding Samples under a HTA Licence

A HTA licence is only required for the storage of relevant Mmaterial for scheduled purposes. The categories of relevant material are:

1. **Specifically identified:**This includes material like bodily organs and tissues, consisting largely or entirely of cells, and clearly identifiable and regarded as such. This category of relevant material includes human bodies, internal organs and tissues, skin and bone.
2. **Processed material:** Where a process has been conducted which results in a material retaining its cells (where the cells have been purposefully removed the material is rendered acellular and is not considered to be relevant).

Key points:

- A HTA licence is only required to store cells. If the cellular component is removed, or disrupted (rendered acellular) within 7 days, a HTA licence is not required for storage. If material is stored

for longer before being rendered acellular, the material must be stored under a HTA licence unless an exemption applies (see section 4.4).

- Where it is believed that the processing has rendered the material acellular, the processes applied must be documented as the HTA may seek assurance that appropriate processing has been carried out.
- Plastinated tissue and body parts (where the cellular structure is retained by the plastination process) are to be regarded as relevant material.
- Serum is generally regarded as non-relevant material.
- Plasma is considered to be relevant material unless the processing is intended to be sufficient to render the samples acellular.
- A HTA licence is not required to store relevant material for up to 7 days pending transfer to HTA licensed premises.
- The temporary storage for any period of relevant material prior to analysis is **not** an exemption from the licensing requirements. Relevant material stored for research can only be stored legally under a HTA licence or approval by a recognised REC.

Other relevant materials include:

Bodily waste: The HTA classifies bodily waste as relevant material as it may contain human cells. In cases where a researcher believes that such material, intended for a scheduled purpose, is acellular the researcher should consult the HTA or the HTA Governance Officer for advice.

Cell deposits and tissues on microscope slides: In general, cell deposits or tissue sections on microscope slides are considered to be relevant material since such deposits or sections are likely to contain whole cells or are intended to be representative of whole cells.

The fundamental principle remains 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.

The HTA has produced a supplementary list of materials to provide researchers with guidance on whether specific materials fall within the definition of a relevant material under The Act. A copy of this list is provided in Appendix B and on the HTA website. If a researcher determines that the material they wish to store is classified as relevant material then the material must be held under a HTA licence. However, a number of exemptions in which a licence is not required to store relevant material are described in section 4.4.

4.4 Licensing Exemptions

Importantly, a number of exemptions exist in which a HTA licence is not required to store relevant material. Cases where a HTA licence is not required include:

- If the material is to be rendered acellular within 7 days
- If the material is to be transported to a HTA licensed establishment within 7 days
- If the material is to be stored for diagnostic purposes or as part of a diagnostic archive
- If a study has HRA REC approval in place to store the material
- If the material has come from a person who died at least 100 years previously
- If the material has come from a HTA licensed, HRAREC approved research tissue bank where there is permission in place to use the material

A summary of requirements for licensing for sample storage is provided in Appendix C. Any researcher with concerns that a HTA licence is required for storage of their human material should contact the HTA Governance Officer at abm.HTA@wales.nhs.uk.

4.5 Licensing of Premises

The HTA licenses premises in three ways:

1. Standalone premises
2. Hub premises
3. Satellite premises

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

Where licensable activities are conducted at different locations, such as a university with an affiliation to a NHS site, one location can become the hub premises and the second location can become a satellite of the hub.

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. Management of the hub and satellite premises

requires the DI to put robust systems in place to ensure that the same governance systems are implemented across all licensed premises.

The HTA expects the DI to make regular visits to any and all satellite premises to verify that the governance systems are working in practice. Additionally, the HTA requires the DI to nominate, and inform the HTA, of appropriate individuals termed Person(s) Designate based at each of the satellite premises to oversee the activities taking place under the licence.

4.6 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, 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 to be undertakenIn a position to ensure that activities are conducted properly by people who are suitableto carry out those activities, and that all the necessary requirements are complied withHas primary (legal) responsibility under Section 18 of the HT Act to secure:

        i. that suitable practices are used in undertaking the licensed activity
        ii. that other persons working under the licence are suitable
        iii. that the conditions of the licence are complied with

2. 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 Designated Individual has documented evidence of the PD's acceptance of the PD role. The individuals assigned these roles on the Swansea University HTA licence are set out in section 5.3.

4.7 Licence Non-Compliance

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

1. **Removal, storage or use of relevant material for scheduled purposes without appropriate consent.**
2. **Storage or use of relevant material donated for a Scheduled Purpose but used for another purpose.**
3. **Trafficking of human tissue for transplantation purposes.**
4. **Carrying out licensable activities without holding a licence from the HTA.**
5. **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 from, or of those close to them if they have died. The exemptions to this are detailed in section 3.4.**

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

<u>Non-compliance with the Act has the following implications for researchers, the University and the Health Board:</u>

- May invalidate any research conducted using the tissue.
- Risk to the research and ethical reputation of Swansea University and ABM UHB.
- 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 on the future of research in both organisations.

It is important that all researchers work with the DI, PDs and HTA Governance Officer to ensure that relevant material is only used in high quality, ethical research across the University and Health Board.

5. JOINT SWANSEA UNIVERSITY AND ABM UHB RESEARCH LICENCE

Swansea University and ABM UHB hold a joint Research Sector HTA licence (12651) to license the **storage** of human organs, tissues and cells for research purposes other than for a specific HRA RECapproved research project i.e. relevant material held in storage for future, unspecified, research studies. The Swansea University Medical School (Corporate Licence Holder) is licensed as the hub site and Morriston and Singleton Hospitals as satellite sites.

5.1 Scope of Licences

The licensable activity covered is *Storage of relevant material for a number of scheduled purposes.*

The licence lists a number of **scheduled purposes** (activities that require consent) for which a material can be stored. These are:

- Determining the cause of death
- Establishing after a person's death the efficacy of any drug or other treatment administered
- Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
- Public display
- Research in connection with disorders, or the functioning of the human body

Additionally for deceased persons:

- Clinical audit
- Education or training related to human health
- Performance Assessment
- Public Health monitoring
- Quality Assurance

It should therefore be noted that:

- The licence is for the **Storage** of relevant material for research, and <u>does not license or approve any research on the stored material</u>.

- For researchers to use the relevant material stored under the HTA licence HRA REC approval of the research study is required, unless the material is obtained from a tissue bank with HRA REC tissue bank approval. Studies using material from a tissue bank must fall within the scope of activities that the bank has acquired REC approval for..
- Material may be stored for a range of purposes, such as, public display or determining the cause of death (scheduled purposes). However, this licence only covers the storage for these purposes. Should an individual want to actually perform these activities, the appropriate licence would be required (e.g. public display, or post mortem).

5.2 Premises

At Swansea University, the Medical School (including ILS1, Centre for Nanohealth (CNH) and the Grove building) is considered to be the hub with Morriston and Singleton hospitals as satellite sites. Each of these premises must display a copy of its associated HTA licence. The addresses of each of these sites are provided below:

Hub site:

Swansea University Named individual for correspondence: Professor Cathy Thornton c.a.thornton@swansea.ac.uk Swansea University Medical School Institute of Life Science 1 Singleton Park,SA2 8PP

Satellite Premises:

Singleton Hospital Sketty Lane Swansea SA2 8QA	Morriston Hospital Heol Maes Eglwys Swansea SA6 6NL

5.3 Roles and responsibilities under the University research sector HTA licence

As required by the HTAct, Swansea University has assigned a named Licence Holder (LH) and Designated Individual (DI) to oversee the licence. An organogram is provided in figure 2.

The DI has the support of a number ofPDs to oversee compliance with the HT Act in their local area.

To support compliance, Swansea University and ABM UHB has implemented the additional joint role of:

- **Human Tissue Act Governance Officer** – 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.

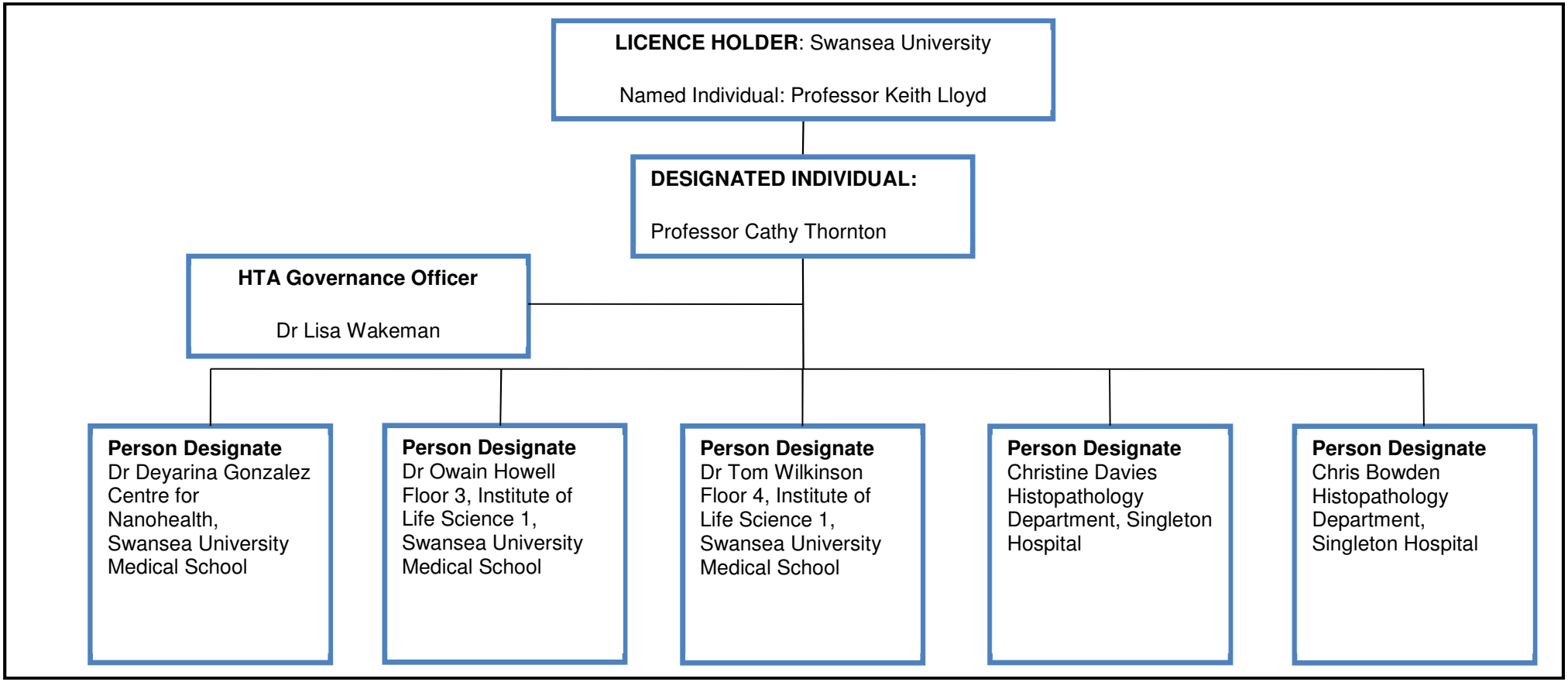


Figure 2 - **Organisational chart – Swansea University research sector HTA licence**

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 HTA Governance Officer or Designated Individual. A new PD should then be appointed, where required.

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

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

Role	Name	Contact Details
Named contact for Licence Holder (LH)	Professor Keith Lloyd for correspondence	Institute of Life Science1 Swansea University Singleton Park Swansea SA2 8PP Email: K.R.Lloyd@swansea.ac.uk
Designated Individual (DI)	Professor Catherine Thornton	Room 214, Institute of Life Science1 Swansea University Singleton Park Swansea SA2 8PP Email: C.A.Thornton@swansea.ac.uk
HTA Governance Officer	Dr Lisa Wakeman	Room 104, Institute of Life Science 2 Swansea University Singleton Park Swansea SA2 8PP Email: Lisa.Wakeman@wales.nhs.uk HTA email: abm.HTA@wales.nhs.uk
Person Designate	Dr Deyarina Gonzalez	Centre for Nanohealth Institute of Life Science 2 Swansea University Singleton Park Swansea SA2 8PP Email: D.Gonzalez@swansea.ac.uk
Person Designate	Dr Owain Howell	Wales Epilepsy Research Network Floor 3 Institute of Life Science 1 School of Medicine

Role	Name	Contact Details
		Swansea University Singleton Park Swansea SA2 8PP Email: o.w.howell@swansea.ac.uk
Person Designate	Dr Tom Wilkinson	Floor 5 Institute of Life Science 1 School of Medicine Swansea University Singleton Park Swansea SA2 8PP Email: t.s.wilkinson@swansea.ac.uk
Person Designate	Christine Davies	Histopathology Department Singleton Hospital Swansea SA2 8QA Email: Christine.Davies10@wales.nhs.uk
Person Designate	Chris Bowden	Histopathology Department Morriston Hospital Swansea SA6 6NL Email: Chris.Bowden@wales.nhs.uk

5.4 Responsibilities of researchers

All researchers storing human tissue under the research HTA licence have a responsibility to know and abide by the HT Act and HTA regulations. All researchers should comply with the Swansea University and ABM UHB joint HTA SOPs. A list of current SOPs is available in section 11.3.

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

In accordance with the terms of the research HTA licence, the DI must have oversight of all relevant material stored at the hub and satellite sites. This includes all relevant material stored under HRA REC approved research where a HTA licence is not required for the storage of the material. Therefore, regardless of the method of obtaining tissue, all researchers storing relevant material at the University have a responsibility to disclose this material to the DI. Such declarations should be made via the HTA Governance Officer at abm.HTA@wales.nhs.uk

Guidance on how researchers can obtain, store, track and dispose of material is contained in sections 6 to 10.

6. OBTAINING RELEVANT MATERIAL

There are three main options available for researchers for obtaining tissues:

1. Obtaining pre-existing tissue from a Research Tissue Bank (RTB) (biobank)
2. Collect new material
3. Purchase material from a commercial supplier

These options are described in full in sections 6.1 to 6.3. 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 *HTA-02-SOP-Consent*.

6.1 Research Tissue Banks (biobank)

A research tissue bank (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, research tissue banks 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 research tissue bank is that this negates the need for researchers to obtain separate REC approval for research study 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 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.

Any RTB containing relevant material established in the University under the HTA licence must be managed in strict compliance with the licence, the HT Act, HTA Codes of Practice and the joint Swansea University / ABM UHB core HTA SOPs. The DI must be aware of and oversee all such tissue collections.

To use material stored as part of a RTB, researchers must:

- Submit an access request to the tissue bank custodian for review

  and

- Obtain REC approval to use the material unless the RTB has ethical approval.

If the required tissue is stored as part of a RTB and the proposed research falls within the scope of the HRA REC approval that has been granted and the consent obtained, the tissue may be used without the need to seek any further approval.

- The custodian of the tissue collection reserves the right to audit the recipient's use of samples if this is considered necessary, and to request regular progress reports on the research project. This may include study progress, sample quality, findings and publications.
- Researchers may also be requested to acknowledge the RTB as the source of samples used in their research.
- If the tissue is not stored as part of RTB and HRA REC approval is not in place to use the material, researchers must obtain study-specific HRA REC approval to use the material.
- Studies using relevant material from a RTB may also be subject to audit by the HTA and the HTA Governance Officer or DI.

The DI must be consultedby any group wishing to establish a new research tissue bank under the Swansea University research sector HTA licence and the DI must sign off the REC application on IRAS. To enhance governance, efforts should be made wherever possible to avoid the unnecessary creation of additional research tissue banks, where the tissue collection may be feasible under a pre-existing research tissue bank.

For any queries regarding setting up a RTB or the details of established RTBs, please contact the HTA Governance Officer in the first instance:

Telephone enquiries: 01792 530891
General email enquiries: abm.hta@wales.nhs.uk

General guidance on applying to a RTB:

Step 1: Submit an access request to the RTB

- Once it has been identified that a tissue of interest is stored in a RTB, a researcher must contact the tissue custodian to discuss access.
- A formal application to access samples must then be submitted by the researcher specifying the proposed use of the sample. Biobanks should have a formal access policy with clear steps to be followed.
- Access requests will be reviewed based on scientific merit, sample availability and consent in place, other research proposals and the ethics of the proposed research. Often laypersons are asked to sit on access committees to review the use of human tissue in research from a public perspective and enhance public engagement.
- The researcher will be informed of the outcome of the application and inform the applicant if they need to obtain ethical approval to use the samples (step 2). The provision of tissue may incur some handling costs.

Step 2: Obtain HRAREC approval to use the material – if required.

- If the scope of RTB REC approval does not cover the planned research study it may still be possible to obtain material as long as the applicant obtains study-specific REC approval.
- Researchers can apply to use human material using the Integrated Research Application System (IRAS) accessed by https://www.myresearchproject.org.uk/.

- For full information refer to the HRA website: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/.

NOTE: Possession of current or pending HRA REC approval for a specific research project negates the need for a HTA licence to store the material for the duration of the ethical approval. However, on expiry of the ethical approval, a HTA licence is required to govern the storage of any residual material. The researcher then has the following options:

- Apply to extend the REC approval and continue the project
- Transfer of the material to HTA licensed premises
- Dispose of the tissue

6.2 Collect new material

Where a new tissue collection is required and NHS patients are involved, researchers must gain HRA REC approval to collect and store the tissue. HRA REC approval is also required to store relevant material from healthy volunteers. This can be arranged by either:

1. applying for study-specific REC approval through IRAS
2. applying via IRAS to set up a new RTB to build a tissue collection over time. RTBs of relevant material must be onHTA licensed premises and set up with the approval of the DI.
3. applying to the curators of an established RTB to collect and store new tissue under the tissue banks pre-existing REC approval and HTA licence.

6.3 Purchase material from a commercial supplier

It is legal for commercial suppliers to sell relevant material for research purposes. Researchers wishing to purchase relevant material must be confident that they have purchased from a reputable source, and that appropriate consent is in place for the use and storage of the samples. Where researchers wish to import human bodies, body parts or tissue into England, Wales and Northern Ireland, they should be able to demonstrate that the purposes for which they wish to import such material cannot be adequately met by comparable material available from sources within those countries, or is for a particular purpose which justifies import. This process will help importers to assure themselves of the integrity of the material and that, as a minimum, it has been sourced with appropriate consent. They should be able to satisfy themselves and document the need for importing in terms of accessibility, quality, timeliness of

supply, risk of infection, quality of service, cost effectiveness, or scientific or research need. Such documentation should be available for inspection by the HTA. Furthermore, it is good practice for approval to be obtained from a REC or the local equivalent in the source country beforehand. For more information on importing material, please refer to

HTA Code of Practice E: Research; Code of Practice and Standards and *HTA-06-SOP-Import and Export*.

Relevant material should only be imported with the approval of the Designated Individual in line with the procedures set out in *HTA-06-SOP-Import and Export* and following DI approval of an application to import tissue using *HTA-05-FORM-Authorisation to Import Human Tissue*.

7. CONSENT

7.1 Activities requiring consent

Consent is the principle that a person must give their permission for their tissues to be retained or used. The principle of consent is an important part of medical ethics and the international human rights law, and is a fundamental underlying principal of the HT Act.

The key principles of consent under the HTA, including cases where consent is not required, are summarised in sections 7.2 to 7.5, below. The HTA's full requirements for consent are set out in the HTA Code of Practice A: Guiding Principles and the Fundamental Principle of Consentand in the consent standards, as set out in Appendix A, part 1. Please also refer to *HTA-02-SOP-Consent.*

Under the terms of the Human Tissue Act (2004), consent must be obtained for the removal, storage and use of human tissue or organs for certain scheduled purposes.

Scheduled purposes (i.e. activities requiring consent) are set out in Table 3 on page 10. However, in broad terms, the Act and the HTA's codes of practice require that consent is required to:

1. store and use dead bodies

2. remove, store and use relevant material from a dead body

3. store and use relevant material from the living

However, a number of exemptions exist in which consent is not required.

Consent may be:

- Project specific – where the donor only consents to the use of their tissues for a specific research project
- Tiered – where opt-outs are available to allow the donor to select the activities for which they do and do not want their samples to be used e.g.
    - Commercial research
    - Genetic analysis
    - Animal research
    - Export
- Generic – where the donor provides broad consent in terms of duration and scope for the tissue to be used in current and future research studies.

It is recommended to request generic consent, wherever possible, to avoid the need to return to the donor to ask for further consent to use the sample in additional research, and prevent the unnecessary disposal of samples when a research project ends.

It is essential that researchers understand what type of consent has been granted, and do not use relevant material outwith the terms of the patients consent. Information on the type of consent granted by donors, including any specific wishes, and the location of signed consent forms, should be kept alongside sample information in sample tracking systems, and made clearly visible to those accessing samples. All patient identifiable data should be kept confidentially in secure systems, and only accessed by individuals with the authority to do so.

The availability of signed consent forms and security of patient data can be audited at any time by internal or external auditors (the HTA) to ensure that samples are being stored and used in accordance with donor wishes and confidentiality maintained.

7.2 Exemptions to consent

Tissue from the living may be legally stored and used without consent provided that the:

Research is approved by a HRA REC (university/school ethical approval is not recognised as sufficient for this exemption).

AND

- The tissue is anonymised such that the researcher is not in possession, and is unlikely to come into possession, of information identifying the person from whose body the material has come.

Whilst the above exemptions to consent exist, it is best practice to obtain consent at all times.

Further exemptions to consent are detailed in *HTA-02-SOP-Consent*.

7.3 Appropriate and valid consent

The term appropriate consent is used in the HT Act to define who may give consent. The consent requirements for the living and deceased and the hierarchy for qualifying relationships is detailed in *HTA-02-SOP-Consent*.

The term valid consent is used to describe the process of seeking consent with the assurance that the donor is fully informed and gives consent voluntarily. This requires ensuring that the donor is provided with the required information regarding, for example, what samples types will be collected, what they will be used for, whether they will be used for sensitive research (e.g. animal research), whether they will be exported, whether they will be sold or used for commercial research and whether genetic analysis will be conducted on the samples. The HTA encourages the seeking of generic consent to ensure that donors are fully aware of the scope of possible activities and will not need to be re-contacted for further consent.

7.4 Seeking consent

The person obtaining consent does not have to be a clinician but consent should be sought by someone suitably trained and who understands the risks and benefits to the donor of tissue donation. Where

donation is for a specific research study the person seeking consent should be fully knowledgeable about the study and be in a position to discuss the research with the potential donor.

Those seeking consent for sample collection for storage under a HTA licence must have completed Good Clinical Practice (GCP) training, HTA training and informed consent training. More information on how to access HTA training courses is available in *HTA-08-SOP-Training*. Training records for those obtaining consent should be up-to-date and available for inspection.

Consent does not have to be in writing however it is easier to demonstrate that consent is in place if it is written. Non-written consent (taken verbally, or non-verbally e.g. hand gesture) may be taken provided that an explanation is put into the notes, and is witnessed to explain the reason why consent is not written.

In longitudinal research it may be necessary to explain the need for (and limitations of) enduring consent; it may also be necessary to re-negotiate consent during the lifetime of the research and is best practice to confirm ongoing consent where possible.

7.5 Withdrawal of consent

Consent for relevant material for use for a scheduled purpose remains valid unless the donor withdraws it. The person seeking consent should explain to the donor that they may withdraw consent at any time but that there may be limitations to withdrawal if the samples have already been used for research or have been irreversibly anonymised.

All groups must have documented procedures in place to ensure that samples are removed from use where research is withdrawn.

8. STORAGE

A HTA licence is required for establishments storing human organs, tissues and cells for research purposes other than for a specific ethically approved research project i.e. Biobanking for future, yet un-specified use**.**

A HTA licence is not needed for storage of tissue for certain ethically approved research or a specific research project for which ethical approval is pending from a **recognised** REC, which is either:

• a REC established under and operating to the standards set out in the governance arrangements issued by the UK Health Departments, or

• an ethics committee recognised by the United Kingdom Ethics Committee Authority (UKECA), to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004.

Importantly – University ethical approval is not recognised by the HTA and is not sufficient to store relevant material where a HTA licence is not in place.

8.1 Sample storage requirements

The HTA does not stipulate exact requirements for the storage of relevant material; however, the premises must be maintained and fit for purpose as detailed in the HTA Standards for the Research Sector. This means that areas used for storage of human tissue for use in research must provide an environment that is safe for those working under the licence and preserves the integrity of the tissue. Furthermore these conditions must be maintained regardless of whether a tissue is to be held only for a short period of time, or if there are only a few items held under the authority of the licence.

The HTA's general requirements and the Swansea University / ABM UHB requirements for sample storage are detailed in *HTA-03-SOP-Storage*. For details of the HTA standards relating to premises, facilities and equipment (PFE) refer to Appendix A; part 3.

8.2 Data storage requirements

In the UK, the use of patient data is tightly controlled within a complex regulatory and governance framework. All personal information must be stored, handled and disposed of in accordance with the Data Protection laws. Patient data should be appropriately stored, and confidentiality maintained in line with data protection legislation and as detailed in *HTA-07-SOP-Management of Records*.

Researchers must always ensure that where patient identifiable data is stored, confidentiality is maintained in compliance with the terms of The Act, including the use of secure, password protected computer systems with restricted access.

Researchers wishing to store or use patient identifiable information from NHS patients must apply for permission to do so and consent must be obtained. Please contact the R&D office for further advice ABM.rd@wales.nhs.uk

8.3 Storage of relevant material

Relevant material which requires storage under a HTA licence must be stored in a designated, approved storage location which is agreed and documented by the HTA Governance Officer or Designated Individual.

These storage locations must be maintained to high quality standards and will be subject to regular internal audit and periodic inspection by the HTA. All areas containing material stored under a HTA licence must be clearly identified.

To request to store material under the HTA licence, researchers should contact the Designated Individual or HTA Governance Officer at abm.HTA@wales.nhs.uk

Relevant material which has HRA REC approval in place for its use does not need to be stored under a HTA licence for the duration of the ethical approval. Therefore, there are no HTA stipulations as to where this material is stored. However, it is Swansea University and ABM UHB policy that all relevant and non-relevant human samples be held in compliance with the HTA standards.

In some cases it may be preferable to subcontract the storage of relevant material to another organisation. In this case the suitability of the 3rd party should be assessed before undertaking a contract (e.g. audit of facility, review of compliance). A formal agreement should be signed to confirm these storage arrangements and responsibilities.

9. SAMPLE TRACEABILITY

Traceability is a fundamental principle of the HT Act. It is essential that records are maintained which provide an audit trail throughout the lifespan of the sample (i.e. from collection, transfer, storage, and use, through to disposal).

Sample tracking can be by many means, but records of how many samples are in storage at any one time is key for HTA reporting. Each research group working under a HTA licence must therefore have a secure, clear and documented sample tracking system in place that includes a clear process for

tracking samples including traceability for the import and export of samples to and from countries outside England, Wales and Northern Ireland.

9.1 Key principles of sample tracking

Researchers should be able to retrospectively inform a donor exactly for which purpose each sample or sub-sample of their material has been used. This means that each sample and derivative must be uniquely labelled and individually traceable from collection to disposal or depletion in analysis.

9.2 Unique sample identification

Each sample of human material collected or stored must be assigned a unique donation identifier, where the sample is further divided; each individual part of the sample must also receive a separate unique identifier. Further guidance is available in *HTA-13-SOP-Chain of Custody*.

The fundamental principles of sample tracking are set out in *Code of Practice E: Research*, HTA standards on Governance and Quality (see Appendix A, part 2) and *HTA-07-SOP-Management of Records*.

9.3 Material transfer

When human tissue is transferred between organisations, consideration must be given to the possible risks to the tissue including theft, damage, accidental disposal or loss during transport. In addition, data associated with the material should be carefully controlled during transfer to protect donor confidentiality.

The transfer of any relevant material into or out of the University or Health Board must be governed by a Material Transfer Agreement (MTA) or appropriate contract agreements between all organisations and signed by authorised signatories. MTAs must not be signed by researchers.

The transfer of relevant material must comply with *HTA-05-SOP-Transportation*.

In some instances, the terms of the transfer may be covered by another formal agreement e.g. a collaboration agreement, or protocol. For any queries or request for review and signature of agreements related to the transfer of relevant material, please contact the HTA Governance Officer abm.HTA@wales.nhs.uk.

10. SAMPLE DISPOSAL

Sample destruction should be avoided unless it is absolutely necessary such as where:

- the integrity of the samples has been irretrievably compromised
- the patient has withdrawn consent for use
- the ethical approval or consent for a study dictates that samples must be destroyed at the end of a particular study.

However, where sample destruction is required, researchers must be aware of the ethical consideration, and associated requirements under the HT Act. Researchers should therefore consult

HTA Code of Practice E: Research; Code of Practice and Standards and *HTA-04-SOP-Disposal*.

The key requirements of disposal are summarised below.

10.1 Key considerations in sample disposal

There are particular sensitivities relating to the disposal of human material, therefore it is essential for researchers to recognise the nature of the material being handled and the sensitivity of the feelings of the donors and the bereaved where material from the deceased is being used and stored for research. Disposal issues may be particularly sensitive in cases following pregnancy loss.

Where researchers are responsible for collecting relevant material, processes should be in place to inform individuals, or their relatives, how tissue will be disposed of after use. Staff should be prepared to discuss the issue of disposal, explaining the options available and who will be responsible for any associated costs.

Staff should be sensitive to cultural/religious and language differences, whilst being aware that choices are for the individual or relative to make.

Prior to disposal; donor consent and any decisions made by REC regarding disposal should be examined to determine the donor wishes.

10.2 Disposal options

Depending on whether the tissue is from the deceased or the living, a number of different disposal options are available, which must be carefully selected. These options are detailed in *HTA-04-SOP-Disposal*.

In general, the disposal of any relevant material should be handled in accordance with any reasonable wishes expressed by the donor or their relatives, as long as the method of disposal is legal. Appropriate documentation of the disposal route must be maintained. Template logs for recording tissue disposal are available or the information can be recorded a tissue tracking database in accordance with local policies/procedures. These records must be made available to internal auditors and HTA inspectors on request to demonstrate sample traceability throughout its full lifecycle. The retention period for this documentation should be in line with *HTA-07-SOP-Management of Records*.

10.3 Disposal documentation

Establishments must have systems in place to maintain complete records of all tissue that is acquired, passed on to others or destroyed. Documentation for the disposal of human material should include as a minimum:

- Date and time of disposal
- Disposal method
- Location of disposal
- Reason for disposal

These details should be recorded in a tissue tracking database within each department and must be available for audit on request.

Further guidance is available in *HTA-04-SOP-Disposal*.

10.4 Preventing unnecessary disposal

To avoid any unnecessary destruction of human tissue, which may have otherwise been kept for use in valuable research, generic consent for research should be sought wherever possible. The provision

of generic consent ensures that tissues can be retained for further use, hence promoting the most effective use of the tissue.

Risk assessments for the entire process of sample procurement through to disposal should be prepared by each department/group to ensure that human samples are not at risk of loss, damage, accidental disposal or failure to obtain proper consent for use. A template risk assessment is available to researchers *HTA-05-TEMPLATE-Risk Assessment*.

11. THE QUALITY MANAGEMENT SYSTEM (QMS)

To promote high quality standards at Swansea University and ABM UHB, and ensure compliance with The Act, a Quality Management System (QMS) for the management of human tissue for research has been implemented. This system is described in sections 11.1-11.10.

11.1 The Quality Manual

This Quality Manual sets out the key features of the Human Tissue Act 2004 and the Organisation's responsibilities under its remit. All researchers working under a HTA licence must therefore abide by the standards set out in this manual. Researchers should always check that they are using the most up to date version of the Quality Manual.

11.2 Document Management

All research groups and biobanks working under a HTA licence should establish and maintain a procedure to control all documents that form part of their QMS, and comply with HTA standards on Governance and quality systems (see Appendix A, part B). Compliance with these standards will be assessed by the HTA Governance Officer during internal audits.

Research group-specific quality documents (SOPs, policies, training documents etc.) may be stored in hard copy or electronic and may be digital, photographic or written, provided that document management complies with the HTA quality standard.

A document control system should be in place covering all quality documents, which is regularly audited. Change control should be in place for the implementation of new or revised operational procedures. Documentation should be managed in line with *HTA-07-SOP-Management of Records*. Standard operating procedures should be created and managed in accordance with *HTA-01-SOP-SOPs*.

In addition, biobank managers of each tissue collection should ensure that a master list is maintained of all groups documents that are currently authorised for use and their location.

11.3 Standard operating procedures

Organisational SOPs covering the requirements of researchers who use human tissue are detailed in table 5. These SOPs provide a working framework for compliance across Swansea University and ABM UHB under a single QMS. These SOPs are subject to regular revision therefore researchers must be confident that they are using the most recent version. Please contact abm.HTA@wales.nhs.uk for confirmation if required.

Table 5 - Core Organisational SOPs supporting the QMS

Document	Title
HTA-01-SOP-SOPs	Human Samples in Research - Preparation, Issue, Approval and Review of HTA Standard Operating Procedures
HTA-02-SOP-Consent	Human Samples in Research - Obtaining Informed Consent
HTA-03-SOP-Storage	Human Samples in Research - Storage of Human Tissue
HTA-04-SOP-Disposal	Human Samples in Research - Disposal of Human Tissue
HTA-05-SOP-Transportation	Human Samples in Research - Transportation of Human Tissue
HTA-06-SOP-Import and Export	Human Samples in Research - Import and Export of Human Tissue

HTA-07-SOP-Management of Records	Human Samples in Research - Management and Retention of Records
HTA-08-SOP-Training	Human Samples in Research - Training
HTA-09-SOP-Risk Management	Human Samples in Research - Risk Management and Contingency Planning
HTA-10-SOP-Equipment Management	Human Samples in Research - Equipment Management and Maintenance
HTA-11-SOP-Adverse Event Reporting	Human Samples in Research - Adverse Event Reporting
HTA-12-SOP-Internal Audit	Human Samples in Research - Internal Audit
HTA-13-SOP-Chain of Custody	Human Samples in Research - Human Tissue Chain of Custody and Sample Labelling

Additional documents may be added to the QMS at any time, including other SOPs/policies related to the work under the Human Tissue Act.

The HTA standards require that appropriate risk management systems are in place to protect staff and samples. Risk assessment of the establishment's practices and processes must be completed regularly to ensure they are fit for purpose, and recorded and monitored appropriately. The focus of risk assessments should be on risks to the donated tissue.

For any further advice, please contact the HTA Governance Officer abm.HTA@wales.nhs.uk

11.4 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-11-SOP-Adverse Events*. All corrective and preventative actions must be managed in a timely manner to maintain the integrity of samples, protect patient data and ensure staff safety.

For any further advice should an adverse event occur, please contact the HTA Governance Officer abm.HTA@wales.nhs.uk

11.5 Validation and change control

For computer systems that support HTA relevant material or clinical trial material, (e.g. electronic document control systems (e.g. Q-Pulse) and sample traceability software (e.g. FreezerPro)) validation may be required dependent on the complexity of the system being utilised). Bespoke software solutions will require more intensive validation than off the shelf packages.

Critical procedures, processes, equipment (such as freezers), facilities and utilities should be validated to ensure they are secure and appropriate for use.

In all cases a risk assessment should be completed to ensure that the level of validation is proportionate to the risk and establish which elements require validation. Validation may be conducted as part of the manufacturer installation process, in which case regular checks may be made to maintain the validation e.g. through a maintenance contract to provide calibration of the system.

Changes to systems that have previously been validated, or hold a validation exemption certificate need to be controlled to maintain the validated state. These changes must be assessed to determine what level of re-validation or testing is required to test the new functionality, or to document the reason why no further testing is required.

11.6 Audit

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

Internal audits	• Conducted by the HTA Governance Officer, Person Designate and/or Designated Individual. • Self-inspection audits within groups
External audits	• Licence standard compliance inspections conducted by the Human Tissue Authority

The format of internal audits, and what researchers can expect, is set out in *HTA-12-SOP-Internal Audit*. Audit frequency will be conducted based on a risk analysis. All internal HTA audit reports will be stored electronically by the HTA Governance Officer and can be provided to regulators on request.

11.7 Local SOPs

In addition to the core HTA documents, all groups working under the HTA licence should maintain records to evidence that activities are being performed in compliance with the requirements of the QMS. Suggestions for the scope of information that should be included to provide such evidence, are summarised in Table 6.

Table 6 - Recommended topics to be included in local SOPs

Topic	To include
Sample receipt, storage and tracking	Details of the procedure for receiving, logging and tracing samples to ensure traceability. Description of local procedures for transferring samples
Access policy	A formal access policy should be in place to document the procedure for requesting and reviewing access to samples held in tissue collections and RTBs.
Consent	The procedure for obtaining valid and appropriate consent. Information should be provided on how evidence of consent is obtained, and where consent forms are stored where consent is obtained through a third party.
Training	Department specific methods for identifying training requirements and recording training
Storage unit monitoring	Description of methods used to ensure sample integrity e.g: • Temperature monitoring system

Topic	To include
	• Contingency arrangements
Equipment validation	Description of steps to be taken on procurement and receipt of new equipment to include: • Specification of user requirement • Commissioning records (installation qualification) • Internal validation of fitness for use (performance qualification) • Ongoing checks of fitness for use (performance qualification)
Equipment maintenance and calibration	Methods and frequency of equipment maintenance and calibration
Cleaning and decontamination	Methods and frequency
Contingency arrangements	Procedures to be followed in the event of equipment/system failure
Risk assessment	Methods for conducting and documenting risk assessments in the local environment
Disposal	Disposal methods and recording disposal

11.8 Training

All staff working with human tissue under a HTA Licence must be trained and regularly updated in the techniques relevant to their work. All staff should therefore receive appropriate training, which is appropriately documented. Documentation of such training and qualifications of staff (e.g. CV, job description) should also be readily accessible and available for inspection. Further information on the training requirements for staff working with human tissue are detailed in *HTA-08-SOP-Training*.

11.9 Governance

To ensure compliance with The 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 HTA Governance Officer 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 following committees are held:

- Swansea University Medical School HTA Sub-Committee
- ABM UHB HTA Committee

11.10 Complaints

Complaints relating to the University's research sector HTA licence, received either internally (from University or Health Board staff) or externally (from patients, visitors or other organisations), should be directed to the HTA Governance Officer in the first instance abm.HTA@wales.nhs.uk. All complaints will be escalated to the DI and, where appropriate, to the Health Board R&D Manager. Complaints will be managed in accordance with the Complaints policies of the respective organisation.

A register of complaints will be maintained as part of the QMS and will be reviewed at the committees listed in 11.9 to facilitate quality improvement.

12. APPENDICES

12.1 APPENDIX A - Minimum and best practice standards for the use of human samples for research

The following table provides researchers with the minimum and best practice standards for the use of human samples for research. However researchers should always strive to achieve best practice, wherever possible.

Furthermore, it is recommended that these standards should be applied to all human samples, including DNA, regardless if they are included in the scope of the Human Tissue Act (i.e. relevant & non-relevant material, and samples held with or without REC approval) to promote best practice at all times.

This section is divided into 5 parts

Part 1:	Consent
Part 2:	Governance and quality systems
Part 3:	Traceability
Part 4:	Premises, facilities and equipment

PART 1 – CONSENT STANDARDS

Consent Standards		
C1	Consent is obtained in accordance with the requirements of the Human Tissue Act (2004) and as set out in the HTA's Code of Practice	
	Standard:	**Best practice examples:**
	Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA Codes of Practice.	• Generic consent should be obtained from the outset wherever possible to avoid the need to obtain further consent in the future, and to make the best use of available samples. • Where DNA is to be stored and used for genetic research, this should be explicit in the patient information leaflet and consent form. • Other options in tiered consent should also be included where appropriate e.g. commercial use, export, use in animal research.
	Consent forms are available to those using or releasing relevant material for a scheduled purpose.	• Where original consent forms are not available or not to be transferred with relevant material then copies of blank consent forms should be obtained alongside a material transfer agreement to document that consent obtained in compliance with the HT Act 2004 and the HTA's Codes of Practice. • As tissue samples and consent forms may be received separately, consent forms should be routinely audited to provide further assurance that valid consent is in place for all samples.
	Where applicable, there are agreements with third parties to ensure consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA Codes of Practice	• Agreements with third parties, including the location of consent forms and methods for confirming that consent is in place should be documented.
	Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.	• Donor information sheets should be written by individuals trained in the requirements of the HTA and the HT Act.
	Language translations are available when appropriate.	• Provision of options for Welsh translation must be included for use in the Welsh population.

Consent Standards		
		• Translation into other languages should be available if requested.
	Information is available in formats appropriate to the situation	• Consider the use of visual, audible or novel means of providing information during the process of seeking consent where this may enhance the participant understanding. • Where appropriate, information should be made available in a number of different formats, such as large font, audio tapes, videos, computer programmes, Braille.
C2	Staff involved in seeking consent receive training and support in the essential requirements of the HT Act and the HTA's Codes of Practice	
	Standard:	**Best practice examples:**
	There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.	• All individuals obtaining consent for the use and storage of relevant material for research should access Good Clinical Practice, HTA and informed consent training.
	Records demonstrate up-to-date staff training.	• Training record files be in place for all staff documenting all training completed, reading records and competencies. • Informed consent training and HTA training documented in the HTA file and staff personal development records.
	Competency is assessed and maintained.	• Where appropriate, formal competency assessments based on consent SOPs should be devised and completed to evidence that those seeking consent are doing so correctly and competently.

PART 2 – GOVERNANCE AND QUALITY SYSTEMS STANDARDS

Governance and Quality Systems Standards		
GQ1	**All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process**	
	Standard:	**Best practice examples:**
	Ratified, documented and up-to-date policies and procedures are in place covering all licensable activities.	• Overarching HTA SOPs • Local SOPs as required
	There is a document control system.	• Local SOPs and policies should be ratified and subject to document management as detailed in HTA-01-SOP-SOPs. • All documents should be identified in a document control database that records review dates. • Systems in place to ensure the regular review of quality documents (e.g. regular self-inspection). • An audit trail should show any changes to electronic records, who made the changes and the date. • New versions of documents should be disseminated and old versions archived.
	There are change control mechanisms for the implementation of new operational procedures.	• Where changes are to be made to activities or processes these follow a formal process to introduce change in a co-ordinated and controlled manner. Examples include processes for raising change requests and for implementation and communication of changes. • The change control system should incorporate the requirements to undertake an assessment of the risks associated with the change, to validate fully any new technique and procedures before they are introduced and to monitor the potential cumulative effects of multiple minor changes.
	Matters relating to HTA-licensed activies are discussed at regular governance meetings, involving establishment staff.	• Regular meetings should be held at defined intervals. • All minutes, actions and timescales to be recorded.

		• Agendas and minutes should be made available electronically for audit and inspection.
	There is a system for managing complaints	• Complaints system clearly visible on website or other suitable visible location. • Complaints system to include internal complaints (e.g. staff, students) and external complaints (public).
GQ2	**There is a documented system of audit**	
	Standard:	**Best practice examples:**
	There is a documented schedule of audits covering licensable activities.	• Regular internal audits of collections of relevant material. • Regular self-inspection traceability audits should be conducted by custodians of tissue collections.
	Audit findings include who is responsible for follow-up actions and the timeframes for completing these.	• Audit findings presented and managed at organisational or local meetings as appropriate.
GQ3	**Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills**	
	Standard:	**Best practice examples:**
	Qualifications of staff and all training are recorded, including records showing attendance at training.	• CVs and job descriptions available on request for all staff. • Individuals have their own training record files with up to date information and attendance certificates where applicable. • Reading and comprehension of quality documents is recorded. • All staff working under a HTA licence must complete HTA training. • All staff should undertake documented Continuing Personal Development (CPD). • Equipment manuals or equipment specific SOPs should be available to all staff. Reading should be documented.

	There are documented induction training programmes for new staff.	• Attendance to be documented and records available for inspection.
	Training provisions include those for visiting staff.	
	Staff have appraisals and personal development plans.	• Arrangements and records of attendance at staff appraisal/personal development review are available for inspection as part of the internal audit process.
GQ4	**There is a systematic and planned approach to the management of records**	
	Standard:	**Best practice examples:**
	There are suitable systems for the creation, review, amendment, retention and destruction of records.	• All tissue bank documents should be identified with the document title, author, owner, approver, date issued, version number and for paper-based systems, a copy number. • Superseded versions of documents archived and copies removed from circulation. • A description of changes made should be included in revised documents. • Regular self-inspection of completed consent forms, equipment maintenance logs, service records, training records etc.
	There are provisions for back up/recovery in the event of loss of records.	• To cover electronic and paper records • Documented back up/recovery systems should be in place at the local level
	Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).	• Evidence of training of all staff to University and Health Board policies should be available.

GQ5	**There are systems to ensure that all adverse events are investigated promptly**	
	Standard:	**Best practice examples:**
	Staff are instructed in how to use incident reporting systems.	• Evidence of training documented
	Effective corrective and preventative actions are taken where necessary and improvements in practice are made.	• Documented CAPA
GQ6	**Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored**	
	Standard:	**Best practice examples:**
	There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	• All aspects of risk assessed from procurement to disposal
	Risk assessments are reviewed regularly.	• Process in place to ensure participant's wishes are checked before forwarding their material, and notification given to receiving organisation of their wishes if required. • The audit trail contains full details of consent (i.e. specific, tiered, generic consent and location of signed consent form), full details of where samples were received from and sent to. • A suitable transfer agreement (e.g. MTA /SLA) is used where appropriate when material is being transferred to other organisations. • Risk assessment of transportation method includes verification of maintenance of cold conditions where necessary by use of data loggers, with data retained on file.
	Staff can access risk assessments and are made aware of risks during training.	

PART 3 – TRACEABILITY

Traceability Standards		
T1	**A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail**	
	Standard:	**Best practice examples:**
	There is an identification system that assigns a unique code to each donation and to each of the products associated with it.	• A local SOP should be in place describing how each sample and derivative will be uniquely labelled.
	A register of donated material, and the associated products where relevant, is maintained.	
	An audit trail is maintained, which includes details of: when and where the bodies or tissues were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.	
	A system is in place to ensure that traceability of relevant material is maintained during transport.	• Relevant material transported in line with *HTA-05-SOP Transportation*. • Specialist couriers used wherever possible. • SLAs in place with courier companies. • Local SOPs developed where relevant material is transported using private vehicles. • Local risk assessments must be performed where private vehicle are used. Transfer of relevant material must be subject to a chain of custody process. • SOPs should detail the local arrangements for traceability of samples throughout the transfer process. • Chain of custody logs should be completed in accordance with *HTA-13-SOP-Chain of Custody* or electronically.
	Records of transportation and delivery are kept.	• Records should detail individual samples of relevant material.

Traceability Standards		
	Records of any agreements with courier or transport companies are kept.	• Agreements should be reviewed regularly. • Copies should be held in HTA files
	Records of any agreements with recipient of relevant material are kept.	• Responsibilities of provider and recipient parties should be clearly set out in a material transfer agreement or as part of a service level agreement. • Agreements must be signed by a Health Board R&D representative or appropriate University representative. • Agreements must not be signed by researchers. • Agreements are stored centrally and accessible on demand for internal audit/HTA inspection. • Copies of signed material transfer agreements to sit with HTA Governance Officer and in laboratory HTA site files
T2	**Bodies and human tissue are disposed of in an appropriate manner**	
	Disposal is carried out in accordance with the HTA's Codes of Practice	
	The date, reason for disposal and method are used and documented.	

PART 4 – PREMISES, FACILITIES AND EQUIPMENT STANDARDS

Premises, Facilities and Equipment Standards		
PFE1	**The premises are secure and fit for purpose**	
	Standard:	**Best practice examples:**
	An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.	• Risk assessments should be performed to cover all aspects of storage and use of relevant material • Risk assessments should be reviewed at defined intervals or when changes to the premises may affect the risks.

	Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.	• Fridges/freezers/cabinets are locked when in areas accessible to general laboratory personnel.
	There are documented cleaning and decontamination procedures.	• Cleaning and decontamination of premises and storage and processing facilities should be scheduled and recorded. Logs should be subject to document control. • Responsibility for performing cleaning and decontamination should be assigned to suitable individuals.
		• Relevant material
PFE2	**There are approved facilities for the storage of bodies and human tissue**	
	There is sufficient storage capacity	• . • Facilities should allow for appropriate separation of relevant material to avoid contamination. • Equipment and storage areas should be restricted to use with human tissue where appropriate. • Tissue held under a HTA licence is stored separately. • All storage units containing relevant material held under the licence are identified as such.
	Where relevant, storage arrangements ensure the dignity of the deceased.	• Facilities should allow for appropriate separation of relevant material to avoid contamination. • Equipment should be restricted to use with human tissue where appropriate.
	Storage conditions are monitored, recorded and acted on when required.	• Storage conditions should be monitored with software that facilitates alerts in the event of temperature excursions. • Environmental monitoring systems in place to monitor facility conditions (e.g. temperature, humidity).

		• Alarm system is checked for correct working on a minimum once a month basis. • Web based systems • Freezer temperature is recorded by an independent device on a 24 hour basis. • Records indicate exact location of the sample including for example building, floor and storage unit (e.g. freezer).
	There are documented contingency plans in place in case of failure in storage area.	• Provision of formal contingency plan with clear roles and responsibilities and back-up arrangements. • Contingency plans in line with *HTA-09-SOP-Risk Management* should be in place with defined contact details. • Contingency storage areas should be identified and labelled as such. • UPS (Uninterruptible Power Supply) available to storage area • Fire safes used for backup tapes and system software for critical equipment and for critical documentation e.g. validation documentation, backup manual procedures for emergency use.
PFE3	**Equipment is appropriate for use, maintained, validated, and where appropriate monitored**	
	Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.	• • All critical equipment (refrigerators, freezers, centrifuges, pipettes etc) should be subject to a maintenance contract. • Prospective validation of new equipment should be conducted before placing into use. • Equipment should be re-assessed following any maintenance or repair procedures before returning to service.
	Users have access to instructions for equipment and are aware of how to report an equipment problem.	• SOPs or user manuals should be available to detail the safe and correct operation of equipment.

		• Individuals responsible for actioning reports of equipment failure should be identified and documented.
	Staff are provided with suitable personal protective equipment.	• Visitors should be provided with protective garments to the same level as staff, even if they are not in direct contact with the samples. •
		• A validation file should be maintained for each piece of critical equipment. To include commissioning, validation and performance data, details of maintenance contracts and preventative maintenance records.
		• References to paper instruction manuals should be maintained on a document management system. • Training should be documented and available for inspection.
		• Documented procedure in place
		• Documented plan in place

12.2 APPENDIX B– Supplementary list of materials

Material	Relevant materials for the purposes of the Human Tissue Act 2004?
Antibodies	No
Artificially created stem cells*	No
Bile	Yes
Blood	Yes
Bone Marrow	Yes
Bones/Skeletons	Yes
Brain	Yes
Breast Milk***	Yes
Breath Condensates and exhaled gases	No
Buffy coat layer (interface layer between plasma and blood cells when blood is separated)	Yes
Cell lines**	No
Cells that have divided in culture	No
CSF (Cerebrospinal fluid)	Yes
Cystic fluid	Yes
DNA	No
Eggs*	No
Embryonic stem cells (cells derived from an embryo)**	No
Embryos (outside the body)*	No
Extracted material from cells, e.g. nucleic acids, cytoplasmic fraction, cell lysates, organelles, proteins, carbohydrates and lipids.	No
Faeces	Yes
Fetal tissue	Yes
Fluid from Cystic lesions	Yes
Gametes*	No
Hair (from deceased person)	Yes
Hair (from living person)	No
Joint Aspirates	Yes

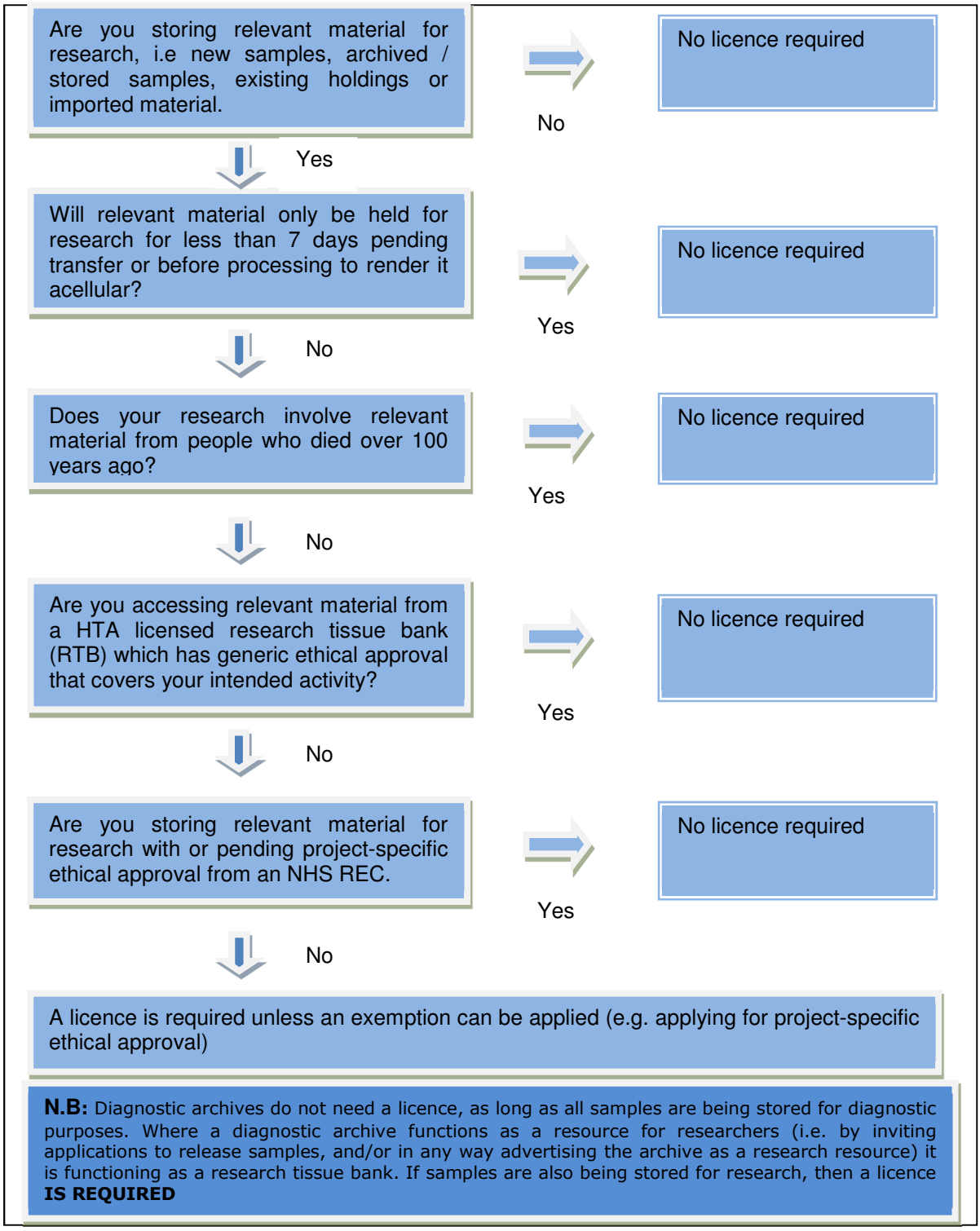
Lysed Cells	No
Mucus	Yes
Nail (from deceased person)	Yes
Nail (from living person)	No
Nasal and Bronchial Lavage	Yes
Non blood derived stem cells (i.e. derived from the body)	Yes
Non fetal products of conception (i.e. the amniotic fluid, umbilical cord, placenta and membranes)	Yes
Organs	Yes
Pericardial fluid	Yes
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).	No
Platelets	Yes
Pleural fluid	Yes
Primary cell cultures (whole explant/biopsy present)	Yes
Pus	Yes
RNA	No
Saliva	Yes
Serum	No
Skin	Yes
Sperm*	No
Sputum (or Phlegm)	Yes
Stomach contents	Yes
Teeth	Yes
Tumour tissue samples	Yes
Umbilical cord blood stem cells	Yes
Urine	Yes

* While outside the definition of relevant material for the purposes of the HT Act, these materials fall under the remit of the Human Fertilisation and Embryology Act 1990, and are regulated by the Human Fertilisation and Embryology Authority (HFEA).

** Cell lines and embryonic stem cell lines fall within the regulatory remit of the HTA by virtue of the Human Tissue (Quality and Safety for Human Application) Regulations 2007, which regulates the processing, storage and distribution of stem cell lines for human application. Both the HFEA and the Medicines and Healthcare products Regulatory Agency (MHRA) also have a regulatory remit in respect of cell lines and embryonic stem cells lines. A joint position statement issued by the HTA, HFEA and MHRA provides guidance on the relevant regulatory remits.

*** Breast milk does not constitute tissue or cells for human application under the (Quality and Safety for Human Application) Regulations 2007, but is classified as relevant material for the purposes of the Human Tissue Act 2004 where stored or used for a scheduled purposes.

12.3 Appendix C - Licensing Summary



12.4 APPENDIX D - Glossary

Acquisition: The collection and receipt of human samples. Consent from the donor must be in place unless exemptions to the consent provisions under the HT Act apply.

Adverse event/incident: An event or incident that may, or has the potential to, result in the theft, damage or loss of human samples or may compromise the University's compliance with the licensing obligations under the HTA, or with the codes of practice as issued by the HTA, or the good governance and output of research using human samples.

Appropriate Consent: This must be in place to use and store relevant material, taken from the living or the deceased for research and to hold bodily material with the intention of analysing its DNA. The HT Act defines appropriate consent in terms of the person who may give consent. This is either the consent of the person concerned (the donor of the human samples), their nominated representative or (in the absence of either of these) the consent of a person in a qualifying relationship with the donor (e.g. spouse or partner; parent; child; etc.).

Audit: The evaluation of a system, process or procedure in order to ascertain its effectiveness and the validity and reliability of the information.

Biobank: a collection of human tissues, cells and blood that can be used for medical research, or for other purposes. 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).

Designated Individual (DI): The named individual designated for the licence as the person under whose supervision the licensed activity is authorised to be carried out. This person is responsible for ensuring that other persons to whom the licence applies are suitably trained and qualified; that suitable practices are carried out in the course of carrying-on the licensed activity; and for compliance with the conditions of the licence. The HTA must be satisfied as to the suitability of the person nominate as DI.

Disposal: The permanent removal or destruction of human samples previously used and/or stored for research.

Existing Holdings: Human samples (relevant material) held immediately prior to 1st September 2006.

Hub site: HTA term for the main site under a licence.

Human Tissue: Any and all constituent parts of the human body formed by cells.

Human Tissue Act 2004 (HT Act): 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, although the use of DNA extends to Scotland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body part, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The HT Act lists the purposes for which consent are required (Scheduled Purposes).

Human Tissue Authority (HTA): 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 consent from the donor is required (unless exemptions apply).

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. They are designed to support professionals by giving advice and guidance based on real-life experience. The most recent code for Research, along with revisions of previously published codes, were approved by Parliament in July 2009 and came into force on 15 September 2009.

HTA Governance Officer: The individual responsible for managing the governance support for research using human tissues, including samples registered under the HTA Research Licence and across Swansea University and ABM UHB.

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.

Licence Holder: The person or corporate body responsible for applying for the Licence and who would also apply to vary the Licence e.g. to change or substitute the DI. In the case of a corporate body, a named individual will act as its representative. The HTA must be satisfied as to the suitability of this person and prefers individual licence holders to be more senior than the DI.

Material transfer agreement (MTA): Agreement established between organisations that govern the transfer of one or more materials from the owner (or authorised licensee) ('the provider') to a third party ('the recipient') who may wish to use the material for research purposes.

Person Designated (PD): A person to whom the Licence applies, and who is named on the licence. The PD assists the DI in supervising the licensable activities within their groups or area.

Principal Investigator (PI): Is the appropriately qualified individual at each project site who has responsibility for the conduct of the project at that site.

Procurement: The process by which tissues and cells are made available, including the physical act of removing tissue and the donor selection and evaluation.

Quality Management System (QMS): 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 within their organisation.

Relevant Material: Material other than gametes, which consists of or includes human cells. In the Human Tissue Act, references to relevant material from a human body do not include:

a) embryo's outside the human body

b) hair and nail from the body of a living person

c) cell lines

d) any other human material created outside the human body

e) serum, plasma, DNA and RNA.

The HTA has produced a supplementary list of materials on which guidance as to their status as relevant material has been given. This list (provided in Appendix D) is not intended to be exhaustive or exclusive.

Research: 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 of new knowledge.

Research Ethics Committee: An National Research Ethics Service committee established to advise on matters which include the ethics of research investigations on relevant material which has come from a human body.

Research Tissue Bank: A tissue collection which has gained generic ethical approval for a broad range of future, yet unspecified research within a given scope.

Sample label: Indelible and unique identification code securely attached to the container holding each individual human sample which must be appropriate to the storage conditions.

Sample Tracking: Process by which all human samples can be identified and traced from their acquisition through to their disposal.

Satellite site: Premises within the same organisation on a different site to the main (hub) site, that is under the same governance processes and quality management system, and supervised by the same Designated Individual.

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.

Service level agreement: Agreement that exists between a client and their service provider(s) detailing the level of service that will be provided.

Standard Operating Procedure (SOP): Detailed, written instructions to achieve uniformity of the performance of a specific function which is an integral part of the quality management system. In the context of research using human samples, the centralised SOPs document all the processes that affect the quality and safety of those samples e.g. acquisition, storage, transfer and disposal.

Storage: The holding of human samples securely in appropriate facilities and under appropriate controlled conditions to ensure the integrity and traceability of the samples and protect the health and safety of the individuals handling them. Samples which are relevant material and are not subject to licensing exemptions (e.g. held for the purposes of a REC-approved research project) must be held under an HTA licence.

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