Human Tissue in Research

HTA-CORE-SOP- Disposal

1. Purpose

This standard operating procedure (SOP) is to ensure that staff and students involved in research working with human tissue understand the procedure and mechanisms for the disposal of relevant material in the context of research. This SOP must be followed for the disposal of relevant material.

2. Scope

This SOP applies to all Swansea University (SU) staff and students involved in research projects intending to use human tissue considered relevant material under the HT Act. However, it can be applied to any type of human tissue sample, including material that is not considered relevant under the HT Act, human DNA and RNA, acellular human biological fluid and human-derived cell lines.

The Human Tissue Authority (HTA) requires that an establishment, such as SU with a HTA licence, have appropriate documented procedures in place for the disposal of human tissue. Procedures should recognize the nature of the material being handled and where applicable consider the sensitivities of the bereaved when tissue is donated from the deceased.

All individuals, whether staff, student or visitor, conducting research with human samples under the auspices of SU on or off-site must follow the requirements set out in this SOP.

3. Roles and Responsibilities

This SOP applies to all SU employees and students who are responsible for collecting, using or storing human tissue for research and employees of other organisations holding relevant material under SU's HTA Licence. The SOP must be used in conjunction with the HTA Codes of Practice and all other relevant University policies and SOPs.

The Designated Individual is responsible for the implementation and supervision of this SOP and the practices herein.

It is the responsibility of the Principal Investigator (PI), as custodian of the samples, to understand and follow the organisational procedures and practices for the disposal of relevant material.

The Human Tissue Governance Officer (HTGO) is responsible for ensuring that this SOP remains fit for purpose.

4. Standards for Safe and Compliant Disposal

Where practical, human tissue should be bagged separately from other clinical waste but may be disposed of in the same incinerator. Relevant material for disposal must be incinerated therefore tissue must be placed into containers specifically destined for incineration. Disinfection by heat activation or other methods is not sufficient for the disposal of human tissue.

In keeping with medical confidentiality, the identity of the donor should remain anonymous during disposal.

4.1 Sample Traceability and Documentation

Staff and students who acquire, use, store and dispose of human tissue for their research should maintain records of all tissue acquired or passed on. Records should include, amongst others, the time, place, method of and reason for disposal. Documentation should be retained per HTA-CORE-SOP-Management of records.

4.2 Consent Assurance

Individuals giving consent for the storage of tissue should be informed that the establishment will dispose of the material after its use. Your PIS should state that tissue will be disposed of following the completion of the analysis/study.

4.3 Reverence for Donor's wishes

Researchers should consider and respect the varying attitudes towards disposal between different cultures and religions.

4.4 Appropriate Disposal of Surplus Material

The HT Act makes it lawful to treat as 'waste' any relevant material that has come from a person in the course of:

- Receiving medical treatment
- Undergoing diagnostic testing
- Participation in research

Relevant material from a human body which ceases to be used or stored for use for any recognised scheduled purpose can also be dealt with as waste.

The HTA empowers establishments to decide the most appropriate method of disposal based on its Code of Practice E: Research, e.g. incineration, burial or cremation.

For practicality, all tissue used in research at Singelton Park and Bay campuses of SU must be disposed of by incineration.

4.5 Appropriate Disposal of Tissue from the Deceased

Tissue should be handled in accordance with any reasonable wishes expressed by the donor as long as the proposed methods are legal. All such requests should be risk assessed and options for disposal should be available to the donor or relatives.

The HTA stipulates that relevant material held for scheduled purposes must be disposed of by:

- Incineration – care should be taken that this method is appropriate.
- Burial – where relatives require reassurance about the suitability of burial or other arrangements they should be provided with the available options and related costs.
- Cremation – human tissue may be cremated under the Cremation (England and Wales) Regulations 2008 provided that all of the conditions below are satisfied:
    a) The death was registered
    b) A valid application for cremation has been made
    c) A certificate or other evidence that the body parts were removed in the course of a post-mortem has been provided by the holder

Some crematoria may not accept glass slides due to health and safety risks.

4.6 Appropriate Disposal of Fetal Tissue (Pregnancy loss before 24 weeks gestation)

The Human Tissue Act 2004 (HT Act) makes no distinction between the disposal of pregnancy remains and the disposal of other tissue from a living person; pregnancy remains are regarded as the tissue of the woman. Although under the HT Act, consent is not required for the disposal of pregnancy remains, the particularly sensitive nature of this tissue means that the wishes of the woman, and her understanding of the disposal options open to her, are of paramount importance and should be respected and acted upon.

Under normal treatment, the health board involved will ensure the fetal tissue is disposed of by burial or cremation.

When women choose to donate their fetal tissue for research, they should be informed verbally and provided with written information about the options as part of the consent process. Information should include what the mode of disposal will be, where this is known, whether any options will be available in that regard and whether the woman will be able to change her mind at a later date. Where options are available, the woman's wishes should be recorded so that they can be acted upon when the time comes. Each woman should be supported in an individual and sensitive manner to ensure that she can make a decision that is right for her.

Although incineration and cremation both involve the pregnancy remains being burnt, they are not the same. The woman must understand what is meant by incineration and the distinction between this and cremation so that she can make an informed choice. The

staff involved with communicating the information to the woman should have detailed knowledge of the processes to ensure that they can properly explain this information.

In studies where unidentifiable fetal remains have been donated, sensitive incineration is the only disposal option.A crematoria will not accept unidentifiable fetal remains as there is no record of the consent of the woman. .

Where incineration is the disposal method used, it must be done as sensitively as possible. The date of the collection and the location of the incineration should be recorded. Pregnancy remains should be packaged and stored separately in suitable containers before their disposal.

Embyros created *in vitro* are regulated under the Human Fertilisation and Embryology Act 2008. Unidentifiable stillbirths stored for teaching or research fall outside the guidance in this section.

4.7 Appropriate Disposal of Stillbirths and Neonatal Deaths

Babies born dead after 24 weeks gestation are defined under the law as stillbirths and must be buried or cremated. A baby or fetus of any age that shows signs of life at birth and dies before 28 days is considered a neonatal death and **must be buried or cremated.**

4.8 Appropriate Disposal of Existing Holdings

Identifiable and unidentifiable tissue from the living may be disposed of by incineration. Existing holdings which include stored fetuses and fetal tissue should be disposed of with consideration to the issues outlined in **sections 4.8 and 4.9.**

4.9 Disposal Records and Documentation

Human tissue samples must be tracked and all activities pertaining to the tissue must be documented. Specifically for the disposal of human tissue, records should include:

- Sample identifier (or name of custodian if unidentifiable existing holdings)
- Reason for disposal
- Date of disposal
- Amount of tissue disposed
- Method of disposal (including where the sample has been used up in processing)
- Name of the person authorising the disposal
- Name of the person undertaking disposal
- Contact details of third parties involved in the disposal

A Disposal Log Form for local use is available online HTA-FORM-Human Tissue Disposal Log.

4.10 Risk Management

Disposal of any human tissue used for research purposes should be risk assessed. All individuals carrying out disposal should familiarise themselves with the assessment and ensure they are aware of the associated risks and hazards. The risks addressed should include those to the handler and the tissue (e.g. accidental disposal). The carrying out of the risk assessment must comply with the SU Health and Safety Policy Arrangement. A specific human tissue risk assessment for compliance with HTA requirements must be undertaken when relevant material held under a licence is disposed of and should comply with HTA-CORE-SOP-Risk Management. A risk assessment template is available HTA-TEMPLATE-Risk Assessment.

All individuals involved in the disposal of human tissue must be involved in the risk assessment and must read and acknowledge the content of the final version.

5. Procedure for Disposal

For practicality, all human tissue used in research at the Singleton Park and Bay campuses of SU must be disposed of by incineration. Researchers must follow SU's guidance on the disposal of hazardous waste.

5.1 Red-lidded clinical waste

Human tissue should be disposed of in separate, red-lidded clinical waste containers. These containers are suitable for unrecognisable body parts, body organs and blood bags/tubes.

- Relevant material should not be mixed with other forms of clinical waste.
- Relevant material should be placed in a separate sealable container.
- It is not necessary to dispose of different tissue types separately, they can be disposed of within the same sealable container.
- All clinical waste can be disposed of in the same incinerator.

Yellow/Orange bags <u>are not</u> incinerated and therefore **must not be used** for the disposal of human tissue.

5.2 Log the Disposal

Disposal of tissue should be minimised as far as is practical. However, tissue may need to be disposed of due to:

a) The ethical approval or consent for a given sample stating that it must be disposed of at the end of the research project.
b) Sample is damaged, contaminated or fails quality assurance tests
c) The donor withdraws consent for the use of the sample in research
d) Being a health and safety risk to research staff
e) Material is surplus to requirement

The reason for disposal should be recorded in your Tissue Disposal Log.

5.3 Disposal of donor identification

Any information which can be used to identify the donor of the tissue sample should also be removed/disposed of.

5.4 Adverse Event Disposal

If disposal was due to damage caused to the tissue due to an adverse event such as

- Freezer malfunction
- Sample is damaged, contaminated or fails quality assurance tests
- Being a health and safety risk to research staff

The research team must complete and submit an adverse event reporting form to the HTGO such that corrective and preventative actions can be put in place to prevent this from occurring again in the future.

5.5 Transferred/Imported Material Disposal

If relevant material is transferred or imported from non-commercial sources outside of SU, then the method of disposal or return should be chosen as specified in the Material Transfer Agreement (MTA).

For example, this might include securely packaging samples in a biohazard container and returning them to the health board where the tissue collection activities took place. This should be documented in the HTA-FORM-Human Tissue Disposal Log.

6. Related Documents

HTA-FORM-Human Tissue Disposal Log

HTA-CORE-SOP-Risk Management

HTA-TEMPLATE-Risk Assessmenthttps://www.swansea.ac.uk/research/research-integrity-ethics-governance/research-governance/human-tissue-act/hta-qms/

7. Reference

- HTA: Guidance professionals "Disposal of pregnancy remains FAQs"
- HTA: Guidance on the disposal of pregnancy remains following pregnancy loss or termination (March 2015)
- HTA Code of Practice E: Research; Code of Practice and Standards
- Health Technical Memorandum: Safe Management of Healthcare Waste

8. Risk Assessment

A risk assessment for this HTA governance SOP is not required.

9. Definitions

A list of useful definitions of technical terms used within SU's HTA Core SOPs can be found in the HTA-Research Quality Manual.

10. Document History

Document History				
Version	**Review Date**	**Comment**	**Replaces**	**Reviewed by**
2.0	23/09/2015	Update front page, hyperlinks and removal of appendix to standalone template	1.0	Lisa Wakeman
3.0	01/09/2016	Post-licence grant review, amendment from acting designated individual reference; minor text amendments	2.0	Lisa Wakeman
4.0	18/04/2018	Amendments to reflect revised HTA Codes of Practice and Standards	3.0	Lisa Wakeman
5.0	07/02/2024	Revised SOP to reflect the separation of the previous joint HTA licence between SU and SUHB and to establish new SU procedures moving forward.	4.0	Bethan R Thomas & DI

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Effective Date:	01/04/24	**Next Review Date:**	07/02/2025