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Human Samples in Research

Disposal of Human Tissue

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure that staff and students involved in research covered by the Human Tissue Act 2004 (HT Act) 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. Background

The HT Act came fully in to force on 1 September 2006 to provide a legal framework regulating the storage and use of human tissue from the living and the removal storage and use of tissue from the deceased. The Human Tissue Authority (HTA) requires that an establishment have in place appropriate documented procedures for the disposal of human tissue that recognize the nature of the material being handled, sensitivities of the bereaved and the need for clarity of information provision.

3. Roles and Responsibilities

This SOP applies to all Swansea University and Abertawe Bro Morgannwg University Health Board (ABM UHB) employees and students who are responsible for collecting, using or storing human tissue for research and employees of other organisations holding relevant material under the HTA Licence. The SOP must be used in conjunction with the HTA Codes of Practice and all other relevant University and, where appropriate, ABM UHB policies and SOPs.

The Designated Individual is responsible for 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 Act Governance Officer is responsible for ensuring that this SOP remains fit for purpose.

4. Procedure

4.1 General Principles

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 is not sufficient for the disposal of human tissue.

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

4.1.1 Documentation

Staff and students who acquire, use, store and dispose of human tissue in the course of 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 in accordance with *HTA-07-SOP-Management of records*.

4.1.2 Communication

When discussing the options for disposal of tissue with donors, researchers should consider the needs of individuals whose first language is not English and document any difficulties encountered and measures taken to overcome them.

4.1.3 Sensitivities

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

4.2 Disposal of Relevant Material from the Living

All relevant material must be disposed of with respect for the donor of the tissue. The HTA recognizes the need for a balanced approach between what is sensitive and what is feasible at the local level. Where practical, human tissue should be bagged separately from other clinical waste but may be disposed of in the same incinerator.

4.2.1 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 scheduled purpose can also be dealt with as human tissue waste.

Individuals giving consent for the storage of tissue should be offered the option of allowing the establishment to dispose of the material after its use.

Basic disposal options are incineration, burial and cremation. The HTA empowers establishments to decide the most appropriate method of disposal based on its Code of Practice E: Research.

Relevant material taken from the living should normally be disposed of by incineration in accordance with current guidelines from the Health and Safety Executive (HSE) on the Safe Disposal of Clinical Waste. It is normal practice to dispose of surplus tissue by incineration in accordance with the Department of Health's guidelines on Safe Management of Healthcare Waste v2.0.

4.2.1.1 Disposal on the Swansea University Site

Researchers must follow Swansea University guidance on the disposal of hazardous waste from the Occupational Safety, Health and Environment Unit.

Human tissue should be disposed of in separate red-lidded anatomical waste containers. These containers are suitable for unrecognisable body parts, body organs and blood bags. Orange bags are not incinerated and therefore must not be used for the disposal of human tissue.

4.2.1.2 Disposal on Abertawe Bro Morgannwg University Health Board Sites

The Health Board is required to adopt the colour codes as specified in the "*Health Care Technical Memorandum HTM 07-01: The Safe Management of Healthcare Waste*"

Health Board guidance should be adhered to in accordance to the local policies entitled *Safe Handling of Waste* and *Waste Types and Colour Coding*, available on the Health Board intranet.

Anatomical waste should be disposed of in rigid yellow medibins (European Waste Catalogue code 18-01-03).

Placenta may be disposed of in small grey placental containers with yellow lids.

4.2 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.

4.2.1 Disposal Method

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:
    - The death was registered
    - A valid application for cremation has been made
    - 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.

Relevant material should be bagged separately from clinical waste and placed in a separate labeled, sealable container. It is not necessary to bag individual tissues separately. Although relevant human tissue should be disposed of in a separate container to clinical waste, it can be disposed of within the same incinerator.

4.3 Disposal of Foetal Tissue (Pregnancy loss before 24 weeks gestation)

Foetuses and foetal material should be stored separately in opaque containers fit for transporting the tissue. Foetal tissue should be disposed of by burial or cremation. Foetal tissue must not be disposed of by incineration, maceration or sluicing.

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.

4.4 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 foetus 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.

4.5 Existing Holdings

Identifiable and unidentifiable tissue from the living may be disposed of by incineration subject to the considerations outlined in section 4.2.

Existing holdings which include stored foetuses and foetal tissue should be disposed of with consideration to the issues outlined in sections 4.1 and 4.4.

4.6 Disposal Records and Documentation

Human tissue samples must be tracked and all activities pertaining to the tissue must be documented. A template disposal log for local use or modification is available in *HTA-03-TEMPLATE-Human Tissue Disposal Log*. Records of the use human tissue should include:

- Where and when the material was acquired
- What activities have been consented to
- The uses to which the material has been put and any processes applied to it
- If the material is transferred elsewhere, to whom and when the transfer took place

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 person authorizing disposal
- Name of person undertaking disposal
- Contact details of third parties involved in disposal

4.7 Risk Assessment

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 risk assessment must comply with the Swansea University Health and Safety Policy Arrangements and/or the ABM UHB Risk Management Strategy and Policy and guidance How to Complete a Risk Assessment.

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-09-SOP-Risk Management*. A risk assessment template is available *HTA-05-TEMPLATE-Risk Assessment*.

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

5. References

ABM University Health Board Safe Handling of Waste:

http://howis.wales.nhs.uk/sites3/page.cfm?orgid=743&pid=53903

ABM University Health Board Waste Types and Colour Coding:

http://howis.wales.nhs.uk/sites3/Documents/743/Waste%20Types%20and%20Colour%20Coding1.pdf

Department of Health Environment and Sustainability: Health Technical Memorandum 07-01: Safe Management of Healthcare waste:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/167976/HTM_07-01_Final.pdf

Health and Safety Executive Safe Disposal of Clinical Waste:

http://www.hse.gov.uk/biosafety/information.htm

HTA Code of Practice E: Research; Code of Practice and Standards

https://www.hta.gov.uk/sites/default/files/Code%20E.pdf

6. Risk Assessment

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

7. Definitions

Consent - Process by which an individual confirms his/her willingness to participate in a particular procedure. The individual must be informed of all aspects of the procedure/request that are relevant to the decision to participate. The individual must be competent to take the particular decision, be acting voluntarily and not be acting under duress.

Designated Individual - The person who is authorised and, supervises the activities under a licence issued by the Human Tissue Authority (HTA).

Disposal – Incineration, burial, cremation or use in processing of human tissue.

Existing Holdings – Identifiable or unidentifiable material that was stored for a scheduled purpose when the HT Act came into force on September 1st 2006.

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

Human Tissue Act 2004 - Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The Human Tissue Act lists the purposes for which consent are required (Scheduled Purposes).

Human Tissue Authority – The governing body set up to regulate activities that come under the HT Act. The HTA is a watchdog that supports public confidence by licensing organisations that store and use human tissue for purposes such as

research, patient treatment, post-mortem examination, teaching, and public exhibitions.

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.

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; Traceability; Premises, Facilities and Equipment.

Principal Investigator – A Principal Investigator is the primary individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research.

Research - A study that addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. 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.

Risk Assessment - An evaluation of the risks posed to the handler and to the tissue being disposed. The risk assessment should include a plan to minimise risk to both.

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

Storage – Maintaining the tissue under appropriate controlled conditions.