Bournemouth University

Medical Sciences Department

Human Tissue Facility

SOP title:	Disposal of human tissue
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Amendment log

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Abbreviations:

SOP: Standard operating Procedure

HTA: Human Tissue Authority

CoP: Code of Practice

CI: Chief Investigator

MTA: Material Transfer Agreement

PIS: Participant Information Sheet

ID: Individual Designated

Purpose: This SOP describes the process for disposal of human tissue as required by the HTA standards.

Scope: This SOP applies to BU researchers or students whose activities involve collecting, storing using and disposing of human tissue or primary human cells.

1. Introduction:

The Human Tissue Act (2004) [(1)] is the legal framework regulating the storage, use and disposal of human tissue. Organisations involved in such activities are licensed and regulated by the HTA and must comply with the HTA Code of Practice. The CoP E – Research, stipulates that bodies and human tissue must be disposed of in an appropriate manner, and that the date and reason for disposal and the method used are documented (T2) [(2)]

In order to comply with the above requirements, establishments should develop a clear and sensitive policy for disposal. It should describe when disposal is appropriate and how it should be done, including how any specific donor's wishes will be taken into consideration. Disposal should be carried out in line with the HTA CoP and a series of documents are available summarising good practice and legal requirements related to the disposal of human tissue which has been stored for research purposes [(3)] [(4)] [(5)] [(6)]

2. **Procedure**:

Although it is accepted that human tissue is a very valuable resource and organisations may wish to store tissue indefinitely for future research, there are instances where it will be necessary to dispose of stored samples such as:

- When the donor has withdrawn consent
- When the conditions for ethical approval dictate that samples must be destroyed at the end of the study
- When, due to an adverse event, it is deemed that the integrity and/or scientific value of the sample has been compromised
- When material is surplus to requirements
- When material presents a health and safety risk to staff

Disposal methods

When deciding on the disposal route, the wishes of the donor should be a central consideration. Individuals responsible for taking consent, or designing studies should ensure processes are in place to inform donors or their relatives, how tissue will be disposed and to record their wishes.

Material from the living: It is generally accepted to dispose of tissue from the living by incineration unless there are donor-specific wishes for disposal. This applies to surplus tissue which is "relevant material" taken whilst receiving medical treatment, undergoing diagnostic testing or participating in research. Surplus tissue includes:

- Tissue fragments from histology samples
- Tissue in the sections trimmed from a wax-embedded block before usable sections are cut
- Unrecoverable "bodily material" washed out of the tissue during processing into a wax block

Material from the deceased: Under the HTA, consent is required to remove tissue from the deceased to store it or use it for research. Those giving consent may specify a preferred method of disposal. All reasonable wishes should be adhered to, provided they are legal and don't pose a potential hazard to health (e.g. releasing tissue to relatives where formalin was used as a fixative).

Imported material: Unless stipulated otherwise, the disposal of imported material should follow the same process as material sourced from England, Wales and Northern Ireland. Any specific requests specified during consent must be adhered to, including the return of the material to the country of origin.

Material sourced from other organisations: If the relevant material has been imported from sources outside BU, the method of disposal should be in agreement with the formal transfer agreement such as MTA or SLA, or as described in consent paperwork.

Disposal options

These are cremation, burial or incineration. All human tissue should be disposed of sensitively and respectfully. Unless otherwise specified, human tissue should be disposed of as clinical waste in accordance with current BU policy.

Clinical material should be disposed of separately from non-clinical waste. There is however no need to bag individual samples separately. In keeping with data protection guidelines, any identifiable information must be removed from samples prior to disposal, and the identity of the donor should under no circumstances be disclosed.

If disposal was due to damage caused to the tissue due to adverse event (e.g. freezer malfunction, tissue damaged in transit) then the research team must complete and submit an adverse event reporting form to the relevant person so that a preventative plan can be put in place.

Disposal records

All staff involved in the users of human tissue are responsible for ensuring that appropriate records are made to document sample disposal. Researchers should always record the following information in the tissue tracking system or spreadsheets:

- Date, reason and method for disposal
- Confirmation that the chosen disposal method complies with the donor's wishes (or their relatives)
- Confirmation that the disposal method used is in agreement with the relevant SOPs

The above information should be made available to internal or external auditors upon request to demonstrate traceability throughout the sample's life cycle.

3. References

(1) Human Tissue Act 2004: http://www.legislation.gov.uk/ukpga/2004/30/contents

(2) Human Tissue Authority code of practice and standards. Code E - Research: https://www.hta.gov.uk/hta-codes-practice-and-standards-0

(3) National Cancer Research Institute (NCRI)/Confederation of Cancer Biobanks: Biobank Quality Standard, collecting, storing and providing human biological material and data for research, version 1, 2014.

(4) Medical research Council (MRC) ethics series. Human tissue and biological samples for use in research: Operational and ethical guidelines. 2014.

(5) Mendy, M; E. Caboux; R.T. Lawlor; J. Wright; and C.P. Wild. 2017. Common minimum technical standards and protocols for biobanks dedicated to cancer research. International Agency for Research on Cancer (IARC) technical publication number 44.

(6) Medical Research Council, 2019. Research and the human tissue act 2004 – Disposal. Version 2. MRC regulatory support centre.