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Paper copies of this document might not be the most up to date version.

The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

SOP: HTA-A1004-UoL

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Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
Author	Amanda Sutcliffe	HTA Monitoring Officer		17/02/2021
Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
Authoriser	Professor Peter Bradding	Designated Individual		17/02/2021

Background

All human tissue used for research must be disposed of in accordance with the *Human Tissue Act 2004 (HT Act)*. The Human Tissue Act requires that the disposal of stored tissue is carried out in a dignified and respectful manner. The HTA Code of Practice on *"Disposal of human tissue"* sets out the main disposal options; the chosen disposal method should reflect the type of tissue ensuring respectful disposal.

Those who are responsible for the packaging and disposal of the material should familiarise themselves with the HTA Code of Practice, which should be read in conjunction with the University of Leicester's Health and Safety guidelines.

Any human tissue must be disposed of in accordance with the terms of consent and where no specific conditions have been placed upon disposal, human tissue must be disposed of separately from other clinical waste in accordance with the Human Tissue Act. The Human Tissue Act relates to relevant material identifiable or unidentifiable stored for use for a scheduled purpose when the HT Act came into force on 1 September 2006.

Purpose and Scope

This SOP describes the practical process for disposing of human tissue used in research. This SOP applies to all University of Leicester staff and students and any external individuals who conduct research.

Definitions:

CI	Chief Investigator
DI	Designated Individual
HRA	Health Research Authority
HTA	Human Tissue Authority
MTA	Material Transfer Agreement – A contract that governs the transfer of tangible research materials between two organisations, when the recipient intends to use it for his or own research purposes.
PI	Principle Investigator
REC	Research Ethics Committee
REGI	Research Governance Ethics and Integrity

RTB	Research Tissue Bank
SOP	Standard Operating Procedure
UoL	University of Leicester

Roles and Responsibilities

It is the responsibility of the Designated Individual (DI) to ensure that suitable practices take place within the licensed establishment that comply with the HTA Codes of Practice.

It is the responsibility of the HTA Monitoring Officer for ensuring this SOP remains fit for purpose taking into consideration any changes in legislation and/or Codes of Practice.

It's the responsibility of the Persons Designate (PD) to assist the DI in implementing and adhering to the governance processes and ensuring the disposal of relevant material complies with this SOP. In addition, it's the PDs responsibility to ensure that a copies of the relevant disposal paperwork is filed appropriately in the PD HTA Materfiles.

All researchers involved in using relevant material should be aware of this SOP and ensure that all relevant material outside the scope of the original ethical approval, or has been sourced from a RTB, is disposed of using the appropriate clinical waste pathway and to ensure that the samples have a fully auditable trail right through to the disposal of the material. It's the researcher's responsibility to ensure the weight volume of the waste is accurately logged.

Procedure to follow

This process is to be followed for relevant material samples requiring disposal that are being disposed of once they have been officially transferred to the HTA licence, and for samples that are held as part of a HTA licenced Research Tissue Bank (RTB).

Disposal of Small Items of Tissue

It is normal practice to dispose of small items of material by incineration. HTA relevant material such as blood samples, bodily fluids, excreta and small tissues (i.e. tissue blocks, sections on slides) should be disposed of with respect and not with other clinical waste. Where practical, it is good practice for human tissue to be bagged separately from clinical waste, but disposed of within the same incinerator. It

is not necessary for each tissue sample to be disposed of individually. Trimmed and surplus material shall be disposed of in the most practical way.

All persons responsible for disposing of waste should be aware of the HTA Codes of Practice for Disposal: including *University of Leicester's Health and Safety guidelines*.

Tracking of waste disposal shall be managed locally. An overview of the process is given in the *flow diagram of disposal process (Appendix 1).* The individual researcher/ responsible person will determine the weight and volume of material to be disposed of and will log the waste details in the *Disposal Request Form (Appendix 2).* They should contact their local Persons Designated to arrange collection of the waste as per the process detailed below.

It is advisable to hold material in a suitable departmental holding area until a full waste disposal bin can be filled specifically for the HTA waste.

Disposal Process and Records

The Persons Designated (PD), researcher and /or laboratory manager with appropriate training will prepare and supervise the disposal of tissue waste. They will ensure clear and accurate records are kept of the material being disposed of.

Disposal information/documentation must include:

- Unique study number
- Identification of the relevant tissue to be disposed (batch ID)
- Reason for disposal
- Date of disposal
- Amount of tissue disposed of
- Method of disposal
- Person undertaking disposal
- Name of person witnessing disposal

The researcher should complete the HTA Relevant Material *Disposal Request Form (Appendix 2)* and a copy given to their local PD. Each container should be appropriately labelled using a permanent marker pen. Any sample logs held by the research team / principle investigator should also be updated with the date, reason and method of disposal.

The reference number on the container label should reflect the area/number/year. Examples of reference numbers can be found below

- RKCSB/001/2018
- GGH/002/2018

The Human Tissue for disposal should be moved to a local holding area. The PD should log all material held in the holding area on the *Awaiting Disposal Record Form (Appendix 3).*

Once there are enough samples to fill a waste container, the PD should arrange for the waste to be transferred to the clinical waste collection area. The *Waste Collection Record Form (Appendix 4)* should be completed by the PD using a separate line for each container. Ideally this should be undertaken by a PD and another member of staff to ensure that the logging of the samples for disposal is accurate and witnessed. Each container should be appropriately labelled in permanent marker pen and match the information recorded on the *Waste Collection Record Form (Appendix 4).*

The information recorded on the *Waste Collection Record Form (Appendix 4)* should be checked prior to the day of disposal to avoid any errors during the disposal.

The original paperwork will be retained by the department in their HTA files. Local processes for managing the receipt of waste collection will be noted in the departmental HTA file. Confirmation of destruction is required by the HTA Code of Practice. The proof of disposal shall be kept for a minimum of 5 years.

Non compliance

In the event of a non-compliance refer to *HTA-A1024-UoL*.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

Review Record

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SOP identifiers	SOP details
ID number	HTA-A1004-UoL
Title	Disposal of Human Tissue Samples
Version	1.1
Page Number	Page **6** of **6**

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
12/08/2022	1.1	Peter Bradding	Change to adopt local clinical waste streams / corrected review dates

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