UNIVERSITY OF LEICESTER

University of Leicester Research Governance Office Standard Operating Procedures relating to the Human Tissue Act 2004

SOP HTA-A1004 UoL

Disposal of HTA-relevant material

Version 2.0

Effective Date: 01 December 2024

This SOP will be implemented in line with this document's effective date for all UoL HTA SOPs.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

1.0 Introduction

This document has been produced in accordance with *The Human Tissue Act 2004* (HT Act). It should be read in conjunction with the University's 'Policy on compliance with the Human Tissue Act in Research', and the Human Tissue Authority's *(HTA) Codes of Practice*.
The Human Tissue Act 2004 (HT Act) relates to HT Act-relevant material (HTA-relevant material) that is stored for a scheduled purpose since the HT Act came into force on 1 September 2006.

All HTA-relevant material used for research must be disposed of in accordance with the HT Act and Human Tissue Authority (HTA) codes of practice. These mandate that the disposal of relevant material is carried out in a dignified and respectful manner.

The HTA Research Codes of Practice on Disposal recognise that what is feasible at the local level needs to be taken into account. Relevant material must be disposed of in accordance with the terms of consent, and where no specific conditions have been specified, relevant material must be disposed of separately from other clinical waste. The HTA Code E (2023) for research (page 30) states the following:

- Processes should be in place to inform donors as to how their relevant material will be disposed of
- The HT Act permits disposal of surplus relevant material as waste
- It is not necessary for each tissue sample to be bagged and disposed of individually

Those who are responsible for the packaging and disposal of relevant 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. Please refer to UHSP-39 Hazardous Waste.

2.0 Scope

This SOP describes the practical process for disposing of HTA-relevant material 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
Cin Bin	Incineration Bin
DI	Designated Individual
HTA	Human Tissue Authority
HT Act	Human Tissue Act
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	Principal Investigator
REC	Research Ethics Committee
RGO	Research Governance Office
RTB	Research Tissue Bank
SOP	Standard Operating Procedure

UoL University of Leicester

3.0 Procedure

This process is to be followed for HTA-relevant material requiring disposal. Where samples require disposal from an NHS REC approved project up to within 12-months of the end-of-study (EOS) notification, these should go through the same clinical waste disposal process, but do not require the extra paperwork denoted in this HTA SOP to be completed.

For samples from external sources please check the terms of the agreements such as MTA's and/or other contracts before starting the disposal process as there could be further requirements that need to be considered e.g., certificates of disposal.

All samples' logs must be updated with the date, method and reason for disposal.

The waste should be disposed of within an appropriately sized incineration bin (cin bin) to fit the contents. Where there are only a few samples, it would be prudent to hold the samples in quarantine until a cin bin can be filled to capacity to avoid wastage of the bin.
Where the bin contains only microscope slides, please remain mindful that the bin will be heavy due to its contents, and use a smaller sized bin

Image 1. An image of a 30-litre incineration bin required for the disposal of clinical and HTA waste.

3.1 Disposal of small items of HTA-relevant material

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 bagged separately to other clinical waste and non-human material. It can be disposed of within the same incinerator as other clinical waste. It is not necessary for each tissue sample to be disposed of individually. Trimmed and surplus material (e.g., clinical waste produced by processing the sample) shall be disposed of in the most practical way.

All persons responsible for disposing of waste should be aware of the University of Leicester's Health and Safety guidelines.

Tracking of waste disposal will 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 (if tissue waste) or quantity of samples to be disposed of. They must contact their local PD to organise the collection of the waste as per the process detailed below.

Where possible material should be disposed of as soon as possible. There might be times where it is more applicable to hold the material in quarantine until there is a larger quantity to be disposed. This will be at the discretion of the PD and what works best for the department.

3.2 Disposal Process and Records

The 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:

- Project details and applicable REC approval numbers
- Collection name / PI of collection
- Material descriptions (Blood and Blood derivatives, FFPE Blocks, Glass slides, others)
- Material reference numbers (either waste container number or the unique tag number). Please refer to image 2 for an example of a tag tie.
- Date of disposal
- Amount of tissue disposed of or number of samples
- Person authorising the disposal (usually PI or study lead)
- Name of person witnessing disposal
- Unique samples numbers (samples logs or denoted within the appendix 2)

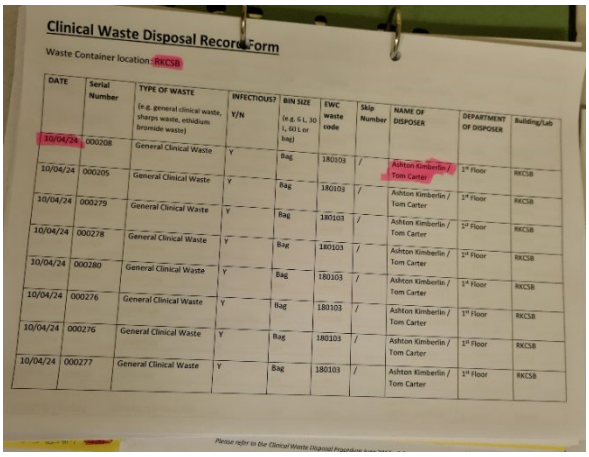
The researcher must complete the HTA-Relevant Material Disposal Request Form (Appendix 2) and a copy given to their local PD. The relevant material for disposal should be moved to a local holding area during this time to ensure those samples cannot be used any further.

Image 2. An example of three yellow tag ties containing unique reference numbers. The unique reference number should be documented with appendix 2 under the material reference number column.

Once there are enough samples to best utilise the incineration bin, the PD should arrange for the waste to be transferred to the appropriate incineration bin, if not already stored with a bin. Each container should be appropriately labelled using a unique tag tie, only one tag tie per incineration bin is required. Please refer to 3 below. Any sample logs held by the research team / CI/ PI must also be updated with the date, reason and method of disposal. The PD should log all material held in the holding area on the Awaiting Disposal Record Form (Appendix 3).

Image 3. An image of a unique numbered tag tie on a 30-litre incineration bin.

In addition to the completion of the appendices alongside this SOP, where applicable the following Clinical waste disposal form is required to be completed. This is applicable for the waste going through the clinical waste streams at the RKCSB at the Leicester Royal Infirmary, and waste going through the Hodgkin Building on main campus. Please see Image 4.


Clinical Waste Disposal Record Form

Waste Container location: RKCSB

DATE	Serial Number	TYPE OF WASTE (e.g. general clinical waste, sharps waste, ethidium bromide waste)	INFECTIOUS? Y/N	BIN SIZE (e.g. 6 L, 30 L, 60 L or bag)	EWC waste code	Skip Number	NAME OF DISPOSER	DEPARTMENT OF DISPOSER	Building/Lab
10/04/24	000208	General Clinical Waste	Y	Bag	180103	/	Ashton Kimberlin / Tom Carter	1st Floor	RKCSB
10/04/24	000205	General Clinical Waste	Y	Bag	180103	/	Ashton Kimberlin / Tom Carter	1st Floor	RKCSB
10/04/24	000279	General Clinical Waste	Y	Bag	180103	/	Ashton Kimberlin / Tom Carter	1st Floor	RKCSB
10/04/24	000278	General Clinical Waste	Y	Bag	180103	/	Ashton Kimberlin / Tom Carter	1st Floor	RKCSB
10/04/24	000280	General Clinical Waste	Y	Bag	180103	/	Ashton Kimberlin / Tom Carter	1st Floor	RKCSB
10/04/24	000276	General Clinical Waste	Y	Bag	180103	/	Ashton Kimberlin / Tom Carter	1st Floor	RKCSB
10/04/24	000276	General Clinical Waste	Y	Bag	180103	/	Ashton Kimberlin / Tom Carter	1st Floor	RKCSB
10/04/24	000277	General Clinical Waste	Y	Bag	180103	/	Ashton Kimberlin / Tom Carter	1st Floor	RKCSB

Image 4. Example of the clinical waste disposal record form.

Once all documentation is completed the waste incineration bins can be relocated to the clinical waste collection point. See image 5.

The relocation of the waste should ideally be undertaken by a PD and another member of staff to ensure that the logging of the samples for disposal is accurate and witnessed.

Image 5. The clinical waste collection point at the Robert Kilpatrick building at the Leicester Royal Infirmary.

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.

3.3 When a certificate of destruction is required

There are certain circumstances where a certificate of destruction might be required.

Examples of this are:

1. If it is stated as a requirement within the research ethics (REC committee)
2. Where specific instructions are received e.g., participant / pharmaceutical company
3. Where has been stipulated within a contract
4. Where the material is identifiable human tissue (see section below)

This list is not exhaustive. There might be other scenarios where a certificate of destruction is required; when this is the case, please follow the process outlined below.

Within the additional details / comments section on appendix 2, there is a check box that is required to be completed where a certificate of destruction is required. Please ensure this is selected. It is the CI/PIs responsibility to ensure this is completed so that the certificate of destructions can be obtained.

Contact with the waste supplier is required to organise a date of collection when a certificate of destruction is required. Please refer to safety services waste SOP for more information.

The type of the material should be specified for the waste contractor as this will form part of the certificate. As the waste disposal is undertaken through the normal healthcare route, the waste would not be treated as a priority so will form part of the normal queue. Certificates of destruction will only be produced once the waste has been incinerated.

3.4 Macroscopically Identifiable Relevant Material

This material includes material such as bodies, organs, and tissues, consisting largely or entirely of cells and clearly identifiable.

In cases where cremation is not possible, it is permissible to dispose of them via incineration, providing they are disposed of separately from other clinical waste.

3.5 Glenfield / General Hospital Sites

At these sites the waste goes through UHLs waste supplier. Please ensure the documentation is followed. In the absence of bag ties, a unique code should be used for the cin bin by writing clearly in laboratory marker on the bins and appropriate paper work.

Where a certificate of disposal is required for the Glenfield or General Hospital site, an *ad hoc* collection request should be made to the Universities waste supplier.

The waste should be disposed of within an appropriately sized cin bin ready for the collection.

Please refer to the process outlined in “when a certificate of destruction is required”.

4.0 Non-compliance

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

5.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator / Principal Investigator (CI/PI)	Chief Investigator / Principal Investigator (CI/PI)	The requirement whether a certificate of destruction is required (this needs assessing on a case-by-case basis). To ensure all the appropriate information relating to study and sample quantities are completed (appendix 2). Ensuring any samples logs are updated with date, method and reason for disposal.
Person Designated (PD)	Person Designated (PD)	Completion of appendix 3 and Clinical Waste disposal record form. Ensuring waste is relocated to the appropriate area ready for collection by the waste contractor. Ensuring the appropriate paperwork is retaining within the PD Masterfile’s or electronic Masterfile areas for inspection purposes.

Responsibility	Undertaken by	Activity
Research Governance Office (RGO)	HTA Monitor or equivalent role in RGO	Disposal traceability audits.
Designated Individual (DI)	Designated Individual (DI)	Ensuring suitable practices are in place within the licenced establishment.

6.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Amanda Sutcliffe	HTA Monitor	UoL Human Tissue Governance Committee (HTGC)	Professor Peter Bradding 	28/11/2024

7.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
November 2024	v2.0	A Sutcliffe	• Administrative changes. • Removal of appendix 4 • Change to clinical waste procedure • Addition of photos. • Clarity around HTA materials required to follow this SOP. • Addition of section 4.3 • Clarity around waste from Glenfield / General Hospital.