

 UNIVERSITY OF LEEDS Standard Operating Procedure	Title	LTHT / UoL Human Tissue Act Standard Operating Procedures				
	Scope	Disposal of Human Tissue				
	Version	3.0	Date	September 2016	SOP ID	LRTB SOP M06
Scope		Details of the procedure for disposing of human tissues collected and/or stored under the LTHT and UoL Human Tissue Authority Research Licence				

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3.0	Dr Patricia Harnden Designated Individual LTHT/UoL Human Tissue Act	15/09/16	
3.0	Clare Skinner, Chair of the research Sub Group LTHT/UoL Human Tissue Act Research Licence	15. 09. 2016	

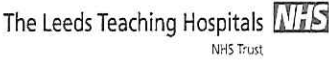

Distribution & Storage:

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Section A LTHT / UoL Standard Operating Procedure



Disposal of Human Tissues

1. Reasons for disposal of human tissues

- 1.1 Withdrawal of consent: All donations to the Leeds Tissue Banks for research purposes are altruistic and patients are free to withdraw consent at any time. LRTB SOP D02 (Withdrawal of Consent for Patients or other Donors) documents the process employed when a patient wishes to withdraw consent.
- 1.2 Given the spirit of generosity behind the donor consent, disposal of tissues other than because of withdrawal of consent should always be a last resort. Tissues that are no longer suitable for one research technique may still be suitable for another, and this possibility, within the boundaries of the original consent, should be explored prior to disposal.
- 1.3 Reasons for the disposal of tissue from all relevant donor samples should be recorded in the UoL Tissue Tracking system Medical Achiever as per LRTB SOP IT02.

2. Tissue from the living

- 2.1 Patients and other donors are advised at the time of consent that some of their samples may already have been used at the time of withdrawal and that only tissue remaining can be destroyed.
- 2.2 If, at the time of withdrawal, patients or other donors express reasonable wishes regarding the method of disposal, or request the return of specimens to them, researchers undertake to accommodate these wishes wherever practicable.
- 2.3 In the absence of a specific request from a patient or donor, samples will be treated as clinical waste and dealt with as per the relevant organisation's policy for disposal of clinical waste.
- 2.4 Tissues may be stored in Leeds following transfer from another organization. This must be covered by a Tissue Transfer Agreement (TTA), which will include reference to the process to follow in the event of withdrawal of consent
- 2.5 Samples of human tissue for disposal must be segregated from other types of waste and packaged and disposed of according to either LTHT or UoL policies, depending on the lines of accountability and location of the staff handling the tissues.
- 2.6 The relevant waste disposal policy and consequent standard operating procedure must be accessible to all staff who deal with human tissues and included in the documented training of new and existing staff.

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- 2.7 The relevant organisation's Waste Policy can be found at:
LTHT Policy for the Safe Disposal of Waste:

<http://thehub.leedsth.nhs.uk/Documents/PoliciesandProcedure/Waste%20Policy.doc>
from a Trust networked PC or via the HTA manager.

University of Leeds guidance on the disposal of healthcare waste:
<http://wsh.leeds.ac.uk/info/212/waste/229/guidance>

3. Tissue from the deceased

- 3.1 The storage and disposal of tissues for research taken from deceased persons in Leeds are covered by the LTHT Post Mortem Licence.
- 3.2 Only tissues retrieved from deceased persons outside of Leeds and subsequently transferred to Leeds are covered by the Research Licence.
- 3.3 Researchers sourcing HTA relevant tissues from external providers should obtain details of the consent procedure and ensure that generic rather than project specific consent was obtained to avoid the need for disposal of any residual material following completion of the planned research.
- 3.4 A Tissue Transfer Agreement (TTA) should be established when the tissue is sourced. The standard TTA agreed by LTHT and UoL is available from the UoL Research and Innovation Service website http://ris.leeds.ac.uk/info/72/relevant_legislation/107/hta/4
- 3.5 The protocol attached to the TTA should give details of whether residual tissues on completion of the planned research should be returned to the supplier, or stored in Leeds under licence for future unspecified research.
- 3.6 In the event of withdrawal of consent, the method of disposal should always follow the reasonable wishes of the relative or qualifying individual withdrawing consent. Researchers should ensure that the TTA covers the eventuality of withdrawal of consent and places the responsibility of liaising with relatives on the supplier.
- 3.7 Basic disposal options are incineration, cremation or burial.
- 3.8 If instructed by the relatives, the supplier may delegate to Leeds researchers the duty of disposing of the tissues by incineration following the guidance in section 2 of this SOP.

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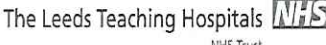

- 3.9 If the relatives choose cremation or burial as the method of disposal, the supplier is responsible for informing Leeds researchers, who will return the tissues to the supplier.

Section B Applicability

- 1.1 This SOP is relevant to all staff collecting and storing human tissues relevant to the Act. The list of relevant tissues can be found on the Human Tissue Authority website by following the link:
<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm>
- 1.2 This SOP can also be used as a training tool for new members of staff who have never worked with human tissues before, or who need to follow a new process.

Section C Background

- 1.1 Different sample types (blood or other bodily fluids, surgical resections etc) and data are collected from patients and other donors in Leeds for future unspecified research into a wide range of conditions including the investigation of normal cellular functions and their disruption in disease states, whether cancer or non-cancer. The tissue collections resulting from these different research activities are grouped under one research licence granted by the Human Tissue Authority to cover both Leeds Teaching Hospitals NHS Trust and the University of Leeds and referred to as the Leeds Research Tissue Banks. The single individual responsible for ensuring that robust processes and procedures have been developed for compliance with the Act is the Designated Individual (DI) for Research.
- 1.2 This SOP has been written to formally establish a consistent procedure for the disposal of human tissues collected and/or stored under the LTHT and UoL Human Tissue Authority Research Licence.
- 1.3 The main aim of this SOP is to ensure that relevant staff, by referencing this document, can easily follow the process of disposing of human tissues in compliance with the Human Tissue Authority Code of Practice 5 - Disposal
- 1.4 This SOP complements the policies on waste disposal developed by LTHT and UoL. Staff working in University premises are advised to familiarize themselves with the University waste policy.

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Section D Definitions

The Act	The Human Tissue Act, 2004
DI	Designated Individual as defined by the Human Tissue Authority
HTA	The Human Tissue Authority
LTHT	Leeds Teaching Hospitals NHS Trust
PD	Person Designated as defined by the Human Tissue Authority
R&I	Research & Innovation Department, Leeds Teaching Hospitals NHS Trust
SOP	Standard Operating Procedure
UoL	University of Leeds

Section E References

Human Tissue Act, 2004

Human tissue Authority, Codes of Practice

Code of Practice 1	Consent
Code of Practice 5	Disposal of human tissue
Code of Practice 8	Import and export of human bodies, body parts and tissues
Code of Practice 9	Research