The Leeds Teaching Hospitals NHS NHS Trust UNIVERSITY OF LEEDS Standard Operating Procedure	Title	LTHT / UoL Human Tissue Act Standard Operating Procedures Patient or donor documentation				
	Scope	Details of the procedure for providing documentation to patients/donors for the collection and/or storage of tissues under the LTHT and UoL Human Tissue Authority Research Licence				
	Version	3.0	Date	September 2016	SOP ID	LRTB SOP D03

Details:

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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:

Distribution to

Persons Designated, LTHT/UoL HTA Research Licence

Location of Document

Paper: HTA Manager, Risk Management, The Trust Headquarters, St James's University Hospital

Electronic: Research and Innovation Service Website, UoLhttp://ris.leeds.ac.uk/info/72/relevant_legislation/107/hta/2

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Section A LTHT / UoL Standard Operating Procedure

Patient or donor documentation

1.0 Patient Information Sheet

1.1 The patient information sheet should be given to the patient or donor to allow sufficient time for them to read and digest the information.

1.2 Patients and donors are advised that they should keep the information sheet.

2.0 Patient or donor consent form

2.1 The patient or donor consent form has two copies, one each for:

2.1.1 The patient or donor
2.1.2 The patient's medical records. This will first be scanned into the Patient Registration System (PRS) as part of the registration of patient consent as per SOP IT01;

2.2 It is important to ensure that the signature is visible on all copies before distribution, and if not to take photocopies of the original. If the signature is not visible, it will not be possible to proceed with tissue collection and storage.

2.3 Details of the consenting patient should be entered onto the LTHT Patient Registration System (PRS) to record the consent, as per SOP LRTB IT01 (LTHT Patient Consent Registration). The consent form is scanned and appended to the patient's electronic record by the person registering consent.

2.4 An anonymised copy of the original consent form accompanies the samples to the research laboratory..

2.5 If required (eg to accompany a sample to histopathology) a copy of the scanned original consent form, now with the unique patient ID / consent reference and the barcode in the top right hand corner can be printed from PRS

3.0 Specimens

3.1 Details of the samples, including their storage location, should be entered into the LTHT / UoL Tissue Tracking System (Medical Achiever) using the unique patient code (LRTB IT01, LTHT Patient Consent Registration), as per SOP LRTB IT02 (Managing Human Tissues within Achiever).

3.2 Samples are to be stored as detailed in the relevant Standard Operating Procedure.

3.3 Where transfer of samples is necessary the transfer of tissues SOP LRTB M07 (Transfer of Tissues between Organisations) should be adhered to.

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 refers to all documentation associated with the donation of samples and data in the context of 1.1.

1.3 This SOP has been written to formally establish a consistent procedure for providing patient or donor documentation.

1.4 The main aim of this SOP is to ensure that relevant staff, by referencing this document, can easily follow the process of providing patient or donor documentation.

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