The Leeds Teaching Hospitals NHS NHS Trust UNIVERSITY OF LEEDS Standard Operating Procedure	Title	LTHT / UoL Human Tissue Act Standard Operating Procedures **Document Control of Standard Operating Procedures**				
	Scope	**Details of the procedure for document control of standard operating procedures 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 M02

Details:

Author:	Patricia Harnden, Designated Individual, LTHT/UoL HTA Research Licence
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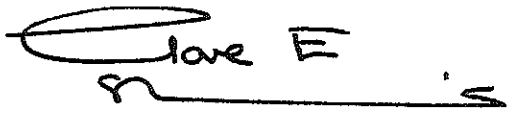
Approval:

Version No of the SOP being approved	Name of person approving this SOP	Date	Signature of the person approving this SOP
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, UoL http://ris.leeds.ac.uk/info/72/relevant_legislation/107/hta/2

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Section A LTHT / UoL Standard Operating Procedure

Document Control of Standard Operating Procedures

1. Document creation

1.1 All documentation regarding policy and project wide issues will be created centrally, led by the DI for Research in collaboration with the HTA research subgroup, the HT Act Management Group and individual research groups where appropriate.

1.2 Documents will follow a standard layout as per SOP LTU_SOP_01 (LTHT / UoL Sponsor Standard Operating Procedures), available from the LTHT Research and Development office, and will show the author, date of creation, version number, date of review and signature of the DI and authorising officer (where relevant) for the University of Leeds and Leeds Teaching Hospitals NHS Trust.

1.3 A log book detailing current version numbers and date of creation will record up to date documents to ensure the correct version numbers are referenced.

1.4 Persons Designated are responsible for ensuring the production of local working documents to detail the local application of the standards developed centrally (eg consent pathway specific to the relevant clinical discipline or research tissue bank). Working documents will be version controlled (see 1.2).

2. Document amendment

2.1 When amendment of centrally drafted documentation is necessary, an email notifying all Persons Designated of the new version number(s) and reminding them to access the amended document, will be circulated.

2.2 The Persons Designated will inform staff working under their supervision of these changes.

2.3 The log book will be updated with the new version number and date of creation.

3. Document retention

3.1 The HT Act Manager will hold a file of all centrally drafted current documentation and a log book detailing current version numbers and date of creation.

3.2 All centrally drafted current documents will be uploaded to the UoL Research and Innovation website (http://ris.leeds.ac.uk/hta). A link is available from the LTHT intranet site for HTA under A - Z index and H for Human Tissue.

3.3 It is the responsibility of individual laboratories to develop and maintain SOPs for all the techniques used in their research group to create data from human tissue samples.

3.4 Consent forms, will be scanned and kept securely in the LTHT Patient Registration System (PRS) as per SOP LRTB IT01 (LTHT Patient Consent Registration). A copy of the consent form will be filed in the patient notes and form part of the patient's health record therefore subject to LTHT policies regarding medical records.

4. Document destruction

4.1 The HTA Manager will keep an electronic archive file with all superseded centrally drafted SOP documentation for reference for 5 years.

4.2 The working file kept by the Person Designated at each location should only contain copies of the current version and only if required for regular reference in routine practice.

4.3 All outdated versions should be shredded at local sites.

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 creation, amendment, retention and destruction of standard operating procedures covering all aspects of donation, storage and release of biomaterials and data collected by any of the research groups covered under the research licence issued by the Human Tissue Authority to LTHT/UoL.

1.3 The main aim of this SOP is to ensure that relevant staff, by referencing this document, can easily follow the process of creating, amending, retaining or destroying standard operating procedures produced to comply with the requirements of the Human Tissue Act, 2004 (the "Act").

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