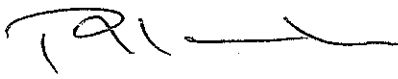
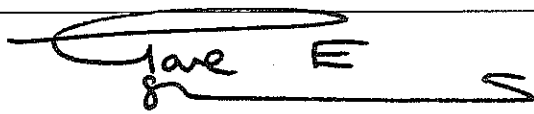
 <b>UNIVERSITY OF LEEDS</b> <b>Standard Operating Procedure</b>	Title	<b>LTHT / UoL Human Tissue Act Standard Operating Procedures</b>				
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Scope		<b>Details of the procedure for training individuals involved in the collection and/or storage of tissues under the LTHT and UoL Human Tissue Authority Research Licence</b>				

### Details:



<b>Author:</b>	Patricia Harnden, Designated Individual, LTHT/UoL HTA Research Licence
<b>SOP Pages:</b>	09
<b>Version No. of replaced SOP:</b>	2.0
<b>Effective date of replaced SOP:</b>	date of approval of this SOP
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	<b>Review date: By:</b>

### 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 Subgroup LTHT/UoL Human Tissue Act Research Licence	15.09. 2016	



### Distribution & Storage:

<b><u>Distribution to</u></b>
Persons Designated, LTHT/UoL HTA Research Licence
<b><u>Location of Document</u></b>
Paper: HTA Manager, Risk Management, The Trust Headquarters, St James's University Hospital
Electronic: Research and Innovation Website, UoL <a href="http://ris.leeds.ac.uk/info/72/relevant_legislation/107/hta/2">http://ris.leeds.ac.uk/info/72/relevant_legislation/107/hta/2</a>

<p>The Leeds Teaching Hospitals  NHS Trust</p> <p> UNIVERSITY OF LEEDS</p> <p><b>Standard Operating Procedure</b></p>	Title	<b>LTHT / UoL Human Tissue Act Standard Operating Procedures</b>			
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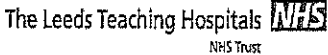

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## Section A LTHT / UoL Standard Operating Procedures

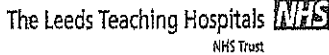

### 1. Training

- 1.1 The University of Leeds and Leeds Teaching Hospitals have agreed a joint policy, which is reinforced by the Standard Operating Procedures (SOPs) that document all activities relating to the use of human tissues in research.
- 1.2 The Designated Individual (DI) for research has statutory responsibility under the Act, but each research group has a Person Designated (PD) who oversees local activities. New PDs are provided with HTA relevant information in a one to one meeting with the HTA Manager. This includes directing to the HTA website which is a useful resource for relevant information. PDs are requested to familiarise themselves with this site and guide other staff to it where required: <https://www.hta.gov.uk/>
- 1.3 PDs require sufficient knowledge of the Leeds policies and procedures relevant to compliance to inform and direct individuals working within their local group. A generic Powerpoint presentation template for HTA relevant information is provided to PDs to use to train other staff.
- 1.4 Awareness of the Act for research staff will be raised at staff induction programmes run within Leeds University and Leeds Teaching Hospitals. They will be directed to the policies and procedures for compliance with the Research Licence granted by the HT Authority.
- 1.5 Attendance at the general induction programme will be recorded in accordance with University or Trust policy depending on staff affiliation.
- 1.6 Staff directly involved in collecting, storing or using human tissues for research will be required to maintain a training log to document their professional development activities.
- 1.7 It is the responsibility of the local line manager to ensure that all new staff have appropriate qualifications and experience for their post.
- 1.8 Individuals responsible for taking consent will need to be trained in Good Clinical Practice (<https://www.crn.nih.ac.uk/learning-development/good-clinical-practice/>).
- 1.9 The local line manager should consult with their PD to develop local mechanisms to ensure that all staff are aware of the SOPs relevant to their area of work in human tissue research.

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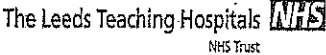

## 2. Research staff induction

- 2.1 All new research staff will undergo induction and training in accordance with local management arrangements. This will include Institute/Department based induction training and relevant Health and Safety training.
- 2.2 The line manager or PD will also ensure that the new staff member has access to and reads all SOPs relevant to the research licence granted by the Human Tissue Authority if their work involves collecting or storing tissues relevant to the Human Tissue Act, 2004.
- 2.3 Specific training will be given to individuals responsible for the consent process, for registering patients in the LTHT Patient Registration System (PRS), for recording specimens in the LTHT / UoL Laboratory management and Tissue Tracking System (Medical Achiever):
- 2.4 Evidence of this training will be included in the local induction record of the individual's personnel file (see 2.5 for example) and an SOP log (see 2.6) will be completed and signed.

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## 2.5 Local induction record

Personal Induction Record			
<b>Name</b>			
<b>Post</b>			
<b>Location</b>			
<b>Start Date</b>			
<i>Activity</i>	<i>Date completed</i>	<i>Initials</i>	<i>Supervisor signature</i>
Institutional Training including:			
Health & Safety training			
Institutional induction			
I D badge, security cards, bleeps received			
<i>LRTB training:</i>			Person Designated Signature
SOPs read (SOP log complete)			
Patient Registration Training			
Tissue Tracking System training			
Laboratory training			
<b>Specimen Signature</b>			
<b>Specimen Initials</b>			

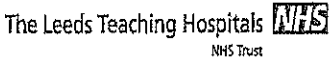

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## 2.6 SOP log

<b>SOP log</b>			
..... (name)			
<i>SOP number</i>	<i>SOP name</i>	<i>Date read</i>	<i>Initials</i>
LRTB M01	Data Protection and Confidentiality		
LRTB M02	Document Control of Standard Operating Procedures		
LRTB M03	Audit of Research Tissue Banks		
LRTB M04	Training		
LRTB M05	Equipment use, Maintenance and Failure Contingency		
LRTB M06	Disposal of Human Tissue		
LRTB M07	Transfer of Tissues between Organisations		
LRTB M08	Incident Reporting		
LRTB M09	Changes to PDs		
LRTB D01	Consenting procedure for LTHT patients		
LRTB D02	Withdrawal of Consent by Patients or other Donors		
LRTB D03	Patient or Donor Documentation		
LRTB D04	Patient/Donor Feedback or Complaints		
LRTB IT01	LTHT Patient Consent Registration		
LRTB IT02	Using Medical Achiever		
	Others to be added		

## 3. Training logs

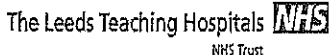

- 3.1 All staff have the opportunity to apply via their line manager to either to Leeds University or to Leeds Teaching Hospitals for funding for training, which is relevant to their post and/or necessary to gain and maintain their professional registration.
- 3.2 In accordance with Leeds University and Leeds Teaching Hospitals policies, training requirements should be regularly identified at probation and appraisal meetings.

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- 3.3 Each member of staff will keep a training log (see below for template or use Institution specific log) to document all courses, workshops, conferences and training events attended, as well as qualifications already gained relevant to the post.

### Training log template

Name	Title
How long in post	
Any courses attended since taking up post	
Any study days attended since taking up post	
Any mandatory training received in last year	
Date of last Appraisal Personal Development Plan	
By whom	
Any qualifications currently being studied for	
Any audits undertaken in last year	
Outputs of research undertaken in last year (presentations, publications etc)	
Professional Registration No Expiry date	

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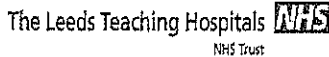

## **Section B                      Applicability**

- 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 training individuals involved in the collection and/or storage of tissues 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 adhere to the process of training of staff in the requirements for compliance with the Human Tissue Act, 2004.



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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