


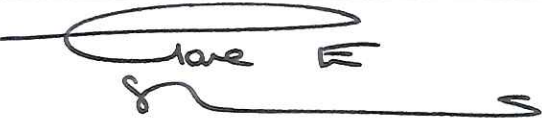


<p>The Leeds Teaching Hospitals  NHS Trust</p> <p> UNIVERSITY OF LEEDS</p> <p>Standard Operating Procedure</p>	Title		<b>LTHT / UoL Human Tissue Act Standard Operating Procedures</b>  <b>Changes to Persons Designated</b>			
	Scope		<b>Details of the process required for PD changes to be made under the LTHT and UoL Human Tissue Authority Research Licence</b>			
	Version	1.0	Date	September 2016	SOP ID	LRTB SOP M09

## Details:

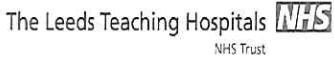

<b>Author:</b>	Patricia Harnden, Designated Individual, LTHT/UoL HTA Research Licence
<b>SOP Pages:</b>	04
<b>Version No. of replaced SOP:</b>	N/A
<b>Effective date of replaced SOP:</b>	N/A
<b>Review date for updated SOP:</b>	Biennially from date of approval or review
	Review Date: By:
	Review Date: By:

## Approval:

Version No of the SOP being approved	Name of person approving this SOP	Date	Signature of the person approving this SOP
1.0	Dr Patricia Harnden Designated Individual LTHT/UoL Human Tissue Act	15/09/16	
1.0	Chair of the Research Subgroup LTHT/UoL Human Tissue Act Research Licence	13.09.2016	



## 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.

  <b>UNIVERSITY OF LEEDS</b> <b>Standard Operating Procedure</b>	Title		<b>LTHT / UoL Human Tissue Act Standard Operating Procedures</b>				
	Scope		<b>Changes to Persons Designated</b>				
	Version		<b>1.0</b>	Date	<b>September 2016</b>	SOP ID	<b>LRTB SOP M09</b>
		Scope		<b>Details of the process required for PD changes to be made under the LTHT and UoL Human Tissue Authority Research Licence</b>			

## CONTENTS

Front page	page 01
Contents	page 02
Section A Standard Operating Procedure	page 03
Section B Applicability	page 03
Section C Background	page 04
Section D Definitions	page 04
Section E References	page 04



  <b>UNIVERSITY OF LEEDS</b> <b>Standard Operating Procedure</b>	Title	<b>LTHT / UoL Human Tissue Act Standard Operating Procedures</b>				
	Scope	<b>Changes to Persons Designated</b>				
	Version	1.0	Date	September 2016	SOP ID	LRTB SOP M09

## Section A LTHT / UoL Standard Operating Procedure

- 1.1 Staffing changes to existing groups, the addition of new groups to the research licence or changes in the storage locations of relevant tissues will lead to the requirement to identify new members of staff to take on the role of Person Designated (PD). The responsibility for approving and appointing a PD rests with the Designated Individual (DI).
- 1.2 A new PD can be identified through nomination by:
- 1.2.1 Local academic or NHS staff
  - 1.2.2 Current bank staff
  - 1.2.3 The DI
  - 1.2.4 The HTA Manager
  - 1.2.5 The Chair of the Research Subgroup
- 1.3 The PD must have a level of authority and experience to assist the Designated Individual in ensuring compliance with the HT Act. This level of experience will be confirmed by either CV or reference from a Line Manager or experienced PD.
- 1.4 The nomination(s) will be considered by the Research Subgroup. After taking advice from the subgroup and others as appropriate, the DI will formally approach the potential PD.
- 1.5 The potential PD will be given a copy of the "Role of the research PD", where the duties and responsibilities associated with the role are clearly identified. If the PD is willing to take on these duties, he or she will sign a formal letter of agreement.
- 1.6 The HTA Manager will provide the new PD will copies of Standard Operating Procedures, and will oversee the induction process to ensure that training is formally recorded.

## 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

  <b>UNIVERSITY OF LEEDS</b> <b>Standard Operating Procedure</b>	Title		<b>LTHT / UoL Human Tissue Act Standard Operating Procedures</b>				
	Scope		<b>Changes to Persons Designated</b>				
	Version		1.0	Date	September 2016	SOP ID	LRTB SOP M09
		Scope		<b>Details of the process required for PD changes to be made under the LTHT and UoL Human Tissue Authority Research Licence</b>			

## 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 change in PD at a location on the Research Licence
- 1.3 The main aim of this SOP is to ensure that any individual who takes on the role of PD is approved by the DI, is of an appropriate level of seniority and supported by their line management.

## 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