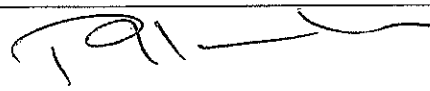
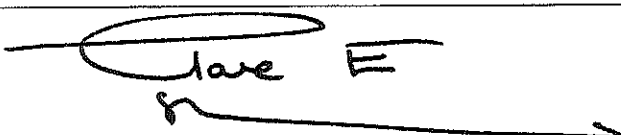
 UNIVERSITY OF LEEDS Standard Operating Procedure	Title		LTHT / UoL Human Tissue Act Standard Operating Procedures Patient/Donor Feedback and Complaints			
	Scope		Details of the procedure for feedback or complaints from patients or donors for the collection and/or storage of tissues under the LTHT and UoL Human Tissue Authority Research Licence			
	Version	3.0	Date	September 2016	SOP ID	LRTB SOP D04

Details:



Author:	Patricia Harnden, Designated Individual, LTHT/UoL HTA Research Licence
SOP Pages:	05
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Effective date of replaced SOP:	date of approval of this SOP
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	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
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:

<u>Distribution to</u>	
Persons Designated, LTHT/UoL HTA Research Licence	
<u>Location of Document</u>	
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Electronic:	Research and Innovation Service Website, UoL http://iris.leeds.ac.uk/info/72/relevant_legislation/107/hta/2

<p>The Leeds Teaching Hospitals  NHS Trust</p> <p> UNIVERSITY OF LEEDS</p> <p>Standard Operating Procedure</p>	Title		LTHT / UoL Human Tissue Act Standard Operating Procedures Patient/Donor Feedback and Complaints			
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Section A LTHT / UoL Standard Operating Procedure

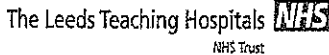

Patient/Donor Feedback and Complaints

1.0 Issues arising around the time of donation

- 1.1 If patients / donors have comments, concerns, complaints or compliments, they are encouraged to contact their clinical team or the member of staff who has taken their consent.
- 1.2 If the clinical team or consent taker is unable to respond fully to the satisfaction of the patient, he or she will pass the matter onto the PD for the relevant research team, who will inform the DI for Research in Leeds.

2.0 Issues arising at a later date

- 2.1 If LTHT patients have a complaint regarding the individual taking consent or the use/storage of tissue, they should, in the first instance, speak to a member of their clinical team.
- 2.2 If the clinical team or consent taker is unable to respond fully to the satisfaction of the patient, he or she will pass the matter onto the PD for the relevant research team, who will inform the DI for Research in Leeds.
- 2.3 If the complaint is not rectified at the local level, LTHT patients can formally complain, by contacting the LTHT Patient Relations Department and an investigation will be undertaken in accordance with the National Statutory Regulations, direct information link via:
<http://www.leedsth.nhs.uk/patients/patient-relations/index.php>
- 2.4 If donors outside the LTHT framework have a complaint regarding the individual taking consent, or the use/storage of tissue, they should in the first instance, contact the DI for Research.
- 2.5 The DI will contact the appropriate Person Designated (PD), who will escalate to the appropriate Line Manager.
- 2.6 The Line Manager will escalate to the Faculty Head of Research Support for Medicine and Health, who as lead for NHS Governance will activate the UoL misconduct process as appropriate.
- 2.7 The PD will provide a written report of the actions taken and outcome of the complaint to the DI.

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3.0 Withdrawal of consent

The overarching principle will be that at any time, the patient / donor can exercise their right to withdraw consent, as per SOP LRTB D02 (Withdrawal of Consent by Patients or other Donors), and all unused samples will be destroyed.

4.0 Feedback

Patients / Donors are encouraged to send any positive comments, suggestions or feedback to the individual taking consent, their clinical team or to the DI for Research in Leeds, e mail: P.Harden@leeds.ac.uk

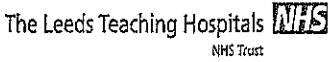

We may ask permission to use the comments either in the literature we may produce to inform and involve patients and donors or on our website.

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 tissue 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 supported by Person Designated (PDs) within individual research teams.
- 1.2 The DI for research would welcome feedback, positive and negative from patients and other donors. The information sheets received by patients and other donors contain the contact details of the PDs or their delegate, who will feed back to the DI as appropriate.

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1.3 This SOP has been written to formally establish a consistent procedure for patients or other donors to provide feedback or make a complaint and for staff to take action on receiving such contact.

1.4 The main aim of this SOP is to ensure that relevant staff, by referencing this document, can easily understand the mechanism by which patients or other donors can provide feedback or make a complaint and easily follow the process of responding to such feedback or complaints.

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