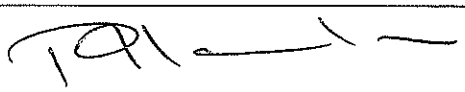
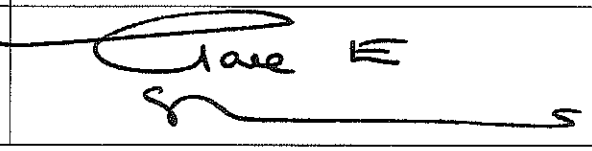
The Leeds Teaching Hospitals NHS NHS Trust UNIVERSITY OF LEEDS Standard Operating Procedure	Title	LTHT / UoL Human Tissue Act Standard Operating Procedures Withdrawal of Consent by Patients or other Donors				
	Scope	Details of the procedure for withdrawal of consent by patients or other donors for the storage of tissues under the LTHT and UoL Human Tissue Authority Research Licence				
	Version	3.0	Date	September 2016	SOP ID	LRTB SOP D02

Details:

Author:	Patricia Harnden, Designated Individual, LTHT/UoL HTA Research Licence
SOP Pages:	09
Version No. of replaced SOP:	2.0
Effective date of replaced SOP:	Date of approval of this SOP
Review date for updated SOP:	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
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

CONTENTS

Section A LTHT / UoL Standard Operating Procedure

Withdrawal of Consent by Patients or other Donors

1.0 Consent procedure

It is made clear to patients and other donors, by the individual seeking consent, in the information sheet and consent form that:

1.1 They can withdraw their consent for further storage and use of their tissues at any time without the need to explain their decision.

1.2 Withdrawal of consent will not affect their clinical care.

1.3 If withdrawal of consent occurs after some or all of the samples have been used, recall of the used samples will not be possible and data or materials generated from their used samples may need to be retained in order for the study as a whole and its findings to remain valid.

1.4 A standard letter is used to withdraw consent (see Appendix A), and this is provided with the patient information sheet

2. 0 Mechanism of withdrawal of consent

2.1 The individual taking consent will provide the patient/donor with their contact details and those of the team responsible for storing the tissues.

2.2 If the decision to withdraw consent is made while the patient is still in hospital, the patient should contact that individual or request that a member of the clinical team does so.

2.3 Once the individual taking consent has been advised that the patient wishes to withdraw consent they should establish whether the sample has already been collected.

2.4 If the sample has been collected then they will need to arrange for the patient, his/her nominated representative or person in a qualifying relationship to make their intention to withdraw in writing using the form of words suggested in Appendix A or in their own words and follow steps 2.7 onwards.

2.5 If the sample has not been collected then the Individual taking consent needs to:

2.5.1 Make a handwritten note on the consent document that consent has been withdrawn, sign and date the written comment, prior to sample collection.

2.5.2 If the consent has already been registered in the Patient Registration System (PRS), as per LRTB IT01 (LTHT Patient Consent Registration), then withdrawal will need to be recorded here also (see 2.12 below). No further action would then be required.

2.6 If the decision is taken at a later date, the patient or donor, nominated representative or person in a qualifying relationship should return the letter of decision to withdraw consent provided at the time of initial consent to the research team nominated in section 2.1.

2.7 If patients/donors use their own form of words rather than Appendix A, they must ensure that they provide the details required to correctly identify their tissue as in appendix A.

2.8 The minimum required to correctly identify the patient is:
- Full name
- Date of birth
- Address including postcode

2.9 The individual taking consent or the research team will acknowledge the conversation or the registration of the decision to withdraw consent in writing within 10 working days using the letter in Appendix B.

2.10 The individual taking consent or research team will then forward copies of the "original letter from the donor (Appendix A)" and the "dated letter of acknowledgement to the donor (Appendix B)" to the DI for action. This will be backed up by an email to the DI, HTA Manager (who is also the PRS administrator) and PD informing them of the request.

2.11 The research team will keep the original correspondence until further advised by the HTA Manager.

2.12 The DI or HTA manager, within 10 working days of receiving the withdrawal request will record withdrawal of consent in the same LTHT Patient Registration System (PRS) used to register initial consent and generate the unique patient ID (see LRTB IT01, LTHT Patient Consent Registration).

2.13 The research team/Person Designated will be informed that samples should be destroyed in accordance with the donor's wishes or as per SOP LRTB M06 (Disposal of Human Tissue). The research group/Person Designated will have 25 calendar days to action this.

2.14 Once the tissue has been destroyed, the research team/Person Designated will send an acknowledgment email to the DI and HTA manager confirming that this has been done.

2.16 The DI or HTA manager will then send out the letter in Appendix C to the donor informing them that their tissue has been destroyed, within 10 working days of receipt of email.

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 withdrawal of consent by patients or other donors in the context of 1.1.

1.3 The main aim of this SOP is to ensure that relevant staff, by referencing this document, can easily apply the process that allows a patient or other donor to withdraw consent for the use of their tissues in research.

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

APPENDIX A

LETTER TO REGISTER WITHDRAWAL OF CONSENT

To whom it may concern

I had previously agreed to donate tissue samples for research under the research study reference number ---------- but I have now changed my mind.

I understand that this will not affect my clinical care now or at any time in the future. I understand that some or all of my samples may have been used, and that the research already conducted cannot be undone. I would like you to dispose of any remaining samples. I understand that you will send me a letter of confirmation when this has been done.

I understand that you require my details in order to trace the samples that I have donated, but that all information will be dealt with in strict confidence.

Full name (please print):

Date of birth:

Address (including post code):

Comments or special requests:

Signature: .....

Date:.....

APPENDIX B

LETTER TO ACKNOWLEDGE WITHDRAWAL OF CONSENT BY RESEARCH TEAM OR INDIVIDUAL TAKING CONSENT

Details of person responding

Name:.....

Direct contact number: .....

Dear

We acknowledge receipt of your letter stating that you wish to withdraw your consent for the collection and storage of your tissue specimens under the research study reference number ---------- . This has now been forwarded to the appropriate person for action and we will confirm in writing when your tissue samples have been appropriately removed from storage and destroyed

This will not affect your care in any way now or in the future.

Please to not hesitate to contact me if you have any further questions.

Yours sincerely,

Person taking consent or Person Designated or deputy

APPENDIX C

LETTER TO CONFIRM TISSUE HAS BEEN DESTROYED

Dear

I would like to confirm that as per your request on the *...(insert date).....* your tissue samples collected for the research study reference number ---------- have now been appropriately destroyed.

This will not affect your care in any way now or in the future.

Please to not hesitate to contact me if you have any further questions.

Yours sincerely,

Designated Individual for Research