The Leeds Teaching Hospitals NHS Trust UNIVERSITY OF LEEDS Standard Operating Procedure	Title	LTHT / UoL Human Tissue Act Standard Operating Procedures Equipment use, Maintenance and Failure Contingency				
	Scope	Details of the procedure for maintaining records of equipment 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 M05

Details:

Author:	Patricia Harnden, Designated Individual, LTHT/UoL HTA Research Licence
SOP Pages:	07
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 Support Unit website, UoL.

CONTENTS

Section A LTHT / UoL Standard Operating Procedures

Equipment (use, maintenance and security) and Contingency Plans for Failure

1. Equipment inventory

1.1 Each research group covered by the LTHT/UoL Research Licence must maintain an inventory of each piece of equipment, together with evidence that it is fit for purpose. It is expected that the establishment and maintenance of such an inventory is a general requirement for any laboratory but details of where the inventory is held and by whom must be clear.

1.2 Each piece of equipment must be identified by a unique code and a record made of its location, model and product numbers, date of purchase, supplier, dates of maintenance and name of member of staff responsible.

1.3 The inventory list must be held and updated locally.

1.4 The inventory must be accurate as each storage unit (cupboard or freezer) must be included in the LTHT / UoL Tissue Tracking System (Medical Achiever), to allow precise localization of each tissue sample at all times.

1.5 Service logs, agreements and user guides for each piece of equipment will be held where needed on site but these must be clearly sign posted and easily identified for inspection purposes.

2. Use of equipment

2.1 Laboratory Health and Safety training will be provided to all staff who work within a laboratory setting, as part of Leeds University and Leeds Teaching Hospitals policy.

2.2 All personnel involved in using laboratory based equipment will be trained by a suitably qualified person. This will be institution or department based and entered in the individual's training record.

2.3 Access to relevant instruction manuals will be available on site.

2.4 Staff will observe the level of personal protection equipment necessary for working within laboratories and with particular pieces of equipment, as per local policy.

3. Maintenance

3.1 As per local policy, staff responsible for using equipment will ensure that regular maintenance, e.g. cleaning, is carried out and documented.

3.2 All equipment should be calibrated, where applicable, on a regular basis with calibration results stored locally with the equipment service log.

3.3 Regular electrical checks should be carried out as part of the regular laboratory/office schedule.

3.4 Equipment will normally be covered by a maintenance contract, which will be monitored by a nominated member of staff.

3.5 A record of maintenance visits will be held as per local policy, but the location of the maintenance log should be specified in the site specific inventory.

3.6 Whether or not equipment is the subject of a maintenance contract, any disintegration in performance or failure should be immediately reported to the member of staff responsible for equipment.

3.7 If there is any possibility that the preservation of research tissues may be compromised, he/she will follow the procedure for reporting an adverse event (SOP M08)..

4. Security

4.1 Freezers and other storage facilities should be in locked premises, with access restricted to designated members of staff.

4.2 Any changes to the location or status of the tissues should be recorded in the LTHT / UoL Laboratory Management and Tissue Tracking System (Medical Achiever).

5. Failure contingency

5.1 A contingency plan in case of freezer failure should be developed by each research group and this should include, if needed, agreed arrangements with other groups or NHS laboratories for the safe transfer of tissues to alternative freezers.

5.2 Subject to local regulations, freezers should be attached to a back-up system and/or a manned alarm system.

5.3 Responsible members of staff will be notified when the alarm is triggered and will take appropriate action.

5.4 If the freezer is not opened and has a CO_2 back up system, this will keep the temperature low enough for several hours to allow repair or contingency.

5.5 Where there is no CO_2 back-up system staff should immediately attend the site and take appropriate action.

5.6 An emergency contact number to contact an engineer should be displayed close to the relevant equipment and all staff who are likely to be called as a result of equipment failure must be able to access such numbers from their current location.

5.7 Failure of any other equipment should be dealt with in accordance with local policy.

5.8 Implementation of the contingency plan for freezer breakdown should be reported to the PD and DI.

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 The Human Tissue (HT) Act specifies that equipment and facilities used to handle and store tissues for research must be suitable, secure and regularly monitored with contingency plans for equipment failure.

1.3 This SOP has been written to formally establish a consistent procedure for maintaining the records of inventory, use, maintenance, security and failure contingency plans for the equipment used to collect and store tissues under the LTHT/UoL Human Tissue Authority Research Licence.

1.4 The main aim of this SOP is to ensure that relevant staff, by referencing this document, can easily follow the process of maintaining records of the equipment used to collect and store tissues relevant to the Human Tissue Act, 2004.

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