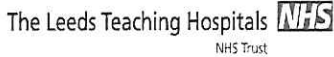




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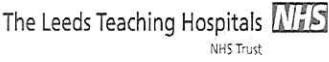

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| Author: | Patricia Harnden, Designated Individual, LTHT/UoL HTA Research Licence |
| SOP Pages: | 08 |
| Version No. of replaced SOP: | 2.0 |
| Effective date of replaced SOP: | date of approval of this SOP |
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| 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 |  |

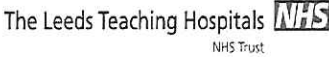

Distribution & Storage:

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

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Section A LTHT / UoL Standard Operating Procedures



Data Protection and Confidentiality

1. Protection of confidentiality

- 1.1 LTHT has devised a system (see LRTB IT01, Patient Consent Registration) to register LTHT patient consent for the removal, storage and use of their tissues for research.
- 1.2 This system creates a coded link between patients and their samples, which will be provided to the researcher each time the same patient donates tissues.
- 1.3 The link between the individual patient and their tissue donation(s) will be kept in this secure LTHT database.
- 1.4 After registration, all donor identifiable data will be removed from the specimens, which will be labelled only with the unique patient code.
- 1.5 The LTHT / UoL Tissue Tracking System (Medical Achiever) will not routinely contain any LTHT patient identifiable information.
- 1.6 The LTHT / UoL Tissue Tracking System (Medical Achiever) will only contain patient/donor identifiable data when the patients or donors are external to LTHT or such data are necessary for researchers to conduct their ethically approved research (eg to send questionnaires to individuals or invite them to participate in the study).
- 1.7 Any identifiable data held in The LTHT / UoL Tissue Tracking System (Medical Achiever) will be accessible only to high level, named users in individual research groups and such access will be password protected.

2. The Caldicott Report: Key principles in the use of confidential information

- 2.1 The purpose for which information is required must be justified.
- 2.2 Person-identifiable information should only be used if absolutely necessary.
- 2.3 The minimum necessary person-identifiable information to satisfy the purpose should be used.
- 2.4 Access to person-identifiable information should be on a strict 'need-to-know' basis.

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2.5. Every individual with access to person-identifiable information should be aware of his/her responsibilities.

2.6. Staff should understand and comply with the law.

3. The Data Protection Act (1998)

3.1. All personal information shall be obtained and processed fairly and lawfully i.e. donors must be informed of the purposes for which their details will be used.

3.2. Personal information should not be used for any purpose(s) incompatible with that for which it was obtained.

3.3. Personal information should be adequate but not excessive.

3.4. Personal information should be accurate and kept up-to-date.

3.5. Personal information should not be kept for longer than necessary.

3.6. The rights of the data subjects should be respected (including right of access to records).

3.7. Personal information should be stored securely and protected against unauthorised or unlawful processing, and loss, damage or destruction of the data.

3.8. Personal information should not be transferred overseas without reference to the policy.

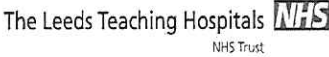

4. Strategy/Implementation

4.1 The data protection and confidentiality legislation applies to all UoL and LTHT activities and appropriate mechanisms for staff training are in place in both organizations. That the legislation has been communicated effectively to all staff involved in human tissue collection activities should be checked by:

4.1.1 Including data protection and confidentiality legislation during the induction and training sessions of Persons Designated and informing them that the LTHT Data Protection Policy and the Information Governance Policy are both available on Leeds Health pathways and the policy section of the Trust intranet.

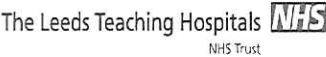

4.1.2 Keeping a list of names and signatures of all individuals who have contact with patient identifiable data to confirm that they have read and understood the LTHT policy in the site file held by the Person Designated of each research group.

4.1.3 Making sure that every employee with access to confidential data has either a substantive or honorary contract with the LTHT.

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5. Staff responsibilities

- 5.1 Records should be kept in secure locations e.g. doors locked.
- 5.2 Access to electronic records should be controlled by a password. Sharing of passwords is forbidden.
- 5.3 Identifiable material should not be left in places where unauthorised personnel may gain access.
- 5.4 Person-identifiable information can only be recorded in computers and systems approved by LTHT and/or UoL. This restriction does not apply to anonymised data.
- 5.5 All members of staff must report any suspected or actual breach of confidentiality according to LTHT or UoL policy and procedures depending on the affiliation of the staff concerned. Both organisations have policies and procedures in place to deal with investigating potential incidents and instituting disciplinary procedures, where appropriate. Incidents should also be reported to the Person Designated (PD).
- 5.6 The Person Designated (PD) will inform the Designated Individual (DI) to determine if a risk assessment and change of policy are required and whether the incident should be reported to the HTA as per SOP M08.
- 5.7 All staff must be aware of their responsibility to ensure confidentiality and that breaches of confidence may amount to gross misconduct and could result in disciplinary action/dismissal.
- 5.8 Staff members must co-operate in training programmes provided and maintain an awareness of confidentiality/data protection issues at all times.

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5.9 Confirmation of Staff Acknowledgment of this policy

Name of Research Group:.....

Location:.....

Person Designated:.....

Signature.....

Date

Other staff members with access to person identifiable data:

Name:.....Signature.....Date.....



Name:.....Signature.....Date.....

Name:.....Signature.....Date.....

Name:.....Signature.....Date.....

Name:.....Signature.....Date.....

One signed copy to be retained on site by the Person Designated and one to be sent to the Designated Individual for Research.

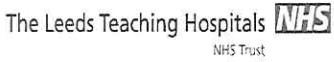

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Section B Applicability

- 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 The protection of donor/patient data and confidentiality is a core requirement and staff are advised to familiarize themselves with the legislation guidance which incorporates the recommendation of the Caldicott report and the principles of the Data Protection Act (1998) and identifies key legislation. This is provided on the LTHT website: (www.leedsth.nhs.uk/documents/19/dppolicy.doc). Staff involved in collecting tissues for research and working with identifiable patient data will hold either a substantive or honorary contract with LTHT and are under a legal obligation to comply with its Data Protection Policies and Procedures. University staff are advised to familiarise themselves with the UoL Policies and Procedures available at (<http://campus.leeds.ac.uk/dpa/code.htm>).
- 1.3 This SOP is not intended to replace the above documents but highlight their key points and the lines of accountability in the context of tissue collecting activities under the LTHT/UoL HTA Research Licence.
- 1.4 The main aim of this SOP is to ensure that relevant staff, by referencing this document, can easily apply the principles of data protection and confidentiality to the collection and storage of human tissues and data for research.

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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