

<b>NHS Lothian – University Hospitals Division</b>		<b>Department of Laboratory Medicine (Tissue Governance)</b>	
<b>Manual</b>	Tissue Governance	Version	1.4
<b>SOP number</b>	QP-TGU-A-HUTISRS	Issue date	30-Oct-2015
		Review date	30-Oct-2017
		Page	1 of 9

**PROCEDURE FOR USING HUMAN TISSUE SAMPLES IN RESEARCH**

**GUIDELINES FOR RESEARCHERS**

**Purpose and Scope**

This SOP outlines the procedure to be followed by researchers within NHS Lothian and the University of Edinburgh who intend to use human tissue in their research.

**Responsibilities**

All researchers using human tissue for research purposes.

**References**

Human Tissue (Scotland) Act 2006  
 Human Tissue Act 2004  
 HTA Codes of Practice

**Definitions**

SOP – Standard Operating Procedure, DI – Designated Individual for Tissue  
 PI – Principal Investigator, MTA – Material Transfer Agreement  
 SAHSC Scottish Academic Health Sciences Collaboration  
 HTA – Human Tissue Authority, R&D – Research and Development  
 IRAS – Integrated Research Application System.

**Documentation**

LP-TGU-A-TISDISPL – Disposal of human tissue used in research  
 NHS Lothian Waste Disposal Operational Policy  
 University of Edinburgh Policy on Clinical and Healthcare Waste  
 HTA Code of Practice 5 – Disposal of Human Tissue.  
 QP-TGU-A-TRNPTIS – Transport of Human Tissue Samples  
 QP-TGU-A-CONPOL – NHS Lothian Tissue Governance Policy on Consent for Research Involving Human Tissue  
 NHS Lothian R&D office Policy on Use of Patient Tissue and Samples.  
 QP-TGU-A-IMPEXPT – NHS Lothian Tissue Governance Policy on Import and Export of Human Tissue Samples.

<b>COPY</b>	1	Tissue Governance SOP folder
<b>Location of Copies</b>		

<b>Author</b>	Frances Rae	<b>Date</b>	30-Oct-2015
<b>Authority for Issue</b>	Craig Marshall	<b>Date</b>	30-Oct-2015
<b>Quality checked</b>	Craig Marshall	<b>Date</b>	30-Oct-2015

<b>NHS Lothian – University Hospitals Division</b>		<b>Department of Laboratory Medicine (Tissue Governance)</b>	
<b>Manual</b>	Tissue Governance	<b>Version</b>	1.4
<b>SOP number</b>	QP-TGU-A-HUTISRS	<b>Issue date</b>	30-Oct-2015
		<b>Review date</b>	30-Oct-2017
		<b>Page</b>	2 of 9

**Authorising signatures**

<b>Author:</b>		<b>Date:</b>	
<b>Authority for issue:</b>		<b>Date:</b>	
<b>Quality checked:</b>		<b>Date:</b>	

**Staff Review Form for Standard Operating Procedures**

**I have read and understood the above Standard Operating Procedure**

Name	Signature	Date

Author	Frances Rae	Date	30-Oct-2015
Authority for Issue	Craig Marshall	Date	30-Oct-2015
Quality checked	Craig Marshall	Date	30-Oct-2015

<b>NHS Lothian – University Hospitals Division</b>		<b>Department of Laboratory Medicine (Tissue Governance)</b>	
<b>Manual</b>	Tissue Governance	Version	1.4
<b>SOP number</b>	QP-TGU-A-HUTISRS	Issue date	30-Oct-2015
		Review date	30-Oct-2017
		Page	3 of 9


## TABLE OF CONTENTS

<b>STAFF REVIEW SHEET</b>	<b>2</b>
<b>INTRODUCTION</b>	4
<b>HAZARDS AND PRECAUTIONS</b>	4
<b>PROCEDURE</b>	5
<b>DOCUMENT REVIEW HISTORY</b>	8

For Information Only

Author	Frances Rae	Date	30-Oct-2015
Authority for Issue	Craig Marshall	Date	30-Oct-2015
Quality checked	Craig Marshall	Date	30-Oct-2015

<b>NHS Lothian – University Hospitals Division</b>		<b>Department of Laboratory Medicine (Tissue Governance)</b>	
<b>Manual</b>	Tissue Governance	Version	1.4
<b>SOP number</b>	QP-TGU-A-HUTISRS	Issue date	30-Oct-2015
		Review date	30-Oct-2017
		Page	4 of 9

## 1 INTRODUCTION

Human tissue includes any bodily part or fluid that contains cells. Plasma, serum and cells/cell lines grown outside of the body do not fall into this category.

This document outlines the current procedures to be followed when researchers within NHS Lothian and the University of Edinburgh use or intend to use human tissue samples in their research.

All researchers must have written procedures in place describing how they:

- Consent patients/participants
- Source
- Collect
- Receive
- Anonymise
- Store
- Keep records
- Use
- Dispose

of the tissue samples in their projects.

These procedures may be subject to audit by the Tissue Governance team.

Further guidance may be available from the Tissue Governance team at [rie.tissuegovernance@luht.scot.nhs.uk](mailto:rie.tissuegovernance@luht.scot.nhs.uk)

## 2 HAZARDS AND PRECAUTIONS

2.1 All fresh unfixed tissue samples should be handled as potentially infectious, and should be disposed of in accordance with LP-TGU-A-TISDISPL, (Tissue Governance SOP for Disposal of Human Tissue used in Research), NHS Lothian Waste Disposal Operational Policy, or University of Edinburgh Policy on Clinical and Healthcare Waste.

2.2 A laboratory coat and disposable nitrile gloves must be worn at all times when handling or disposing of unfixed human tissue samples.

Author	Frances Rae	Date	30-Oct-2015
Authority for Issue	Craig Marshall	Date	30-Oct-2015
Quality checked	Craig Marshall	Date	30-Oct-2015

<b>NHS Lothian – University Hospitals Division</b>		<b>Department of Laboratory Medicine (Tissue Governance)</b>	
<b>Manual</b>	Tissue Governance	Version	1.4
<b>SOP number</b>	QP-TGU-A-HUTISRS	Issue date	30-Oct-2015
		Review date	30-Oct-2017
		Page	5 of 9

### 3 PROCEDURE

#### 3.1 Approval

**Before starting research work with human tissue samples, the following must be obtained:**

- 3.1.1 Approval from an NHS Ethics committee. This may be in the form of an application to work under the generic ethical approval held by the Tissue Governance team.
- 3.1.2 Management approval. (If project involves tissue from NHS Lothian patients or staff). This may be from R&D or the DI for tissue. For further advice, contact the Tissue Governance team.

#### 3.2 Consent

- 3.2.1 Researchers must obtain valid informed consent for tissue that they obtain and use in research, with a few exceptions (see QP-TGU-A-CONPOL-NHS Lothian Tissue Governance Policy on Consent for Research Involving Human Tissue)

#### 3.3 Anonymity of Samples

- 3.3.1 On receipt of samples, each sample/patient must be given a unique identifying code which should be used to identify it throughout the research project.
- 3.3.2 The researcher should not keep any identifying information, or have any means by which they could identify the patient or donor of the sample.
- 3.3.3 The patient details pertaining to the samples should be kept on a secure database by the DI, Tissue Governance Manager, Tissue Governance Officer or other authorised individual.
- 3.3.4 No patient identifiable data should be held outwith the NHS without prior approval from the Caldicott Guardian.

#### 3.4 Sample Inventory

- 3.4.1 Sample details should be entered on a secure password protected database.

Author	Frances Rae	Date	30-Oct-2015
Authority for Issue	Craig Marshall	Date	30-Oct-2015
Quality checked	Craig Marshall	Date	30-Oct-2015

<b>NHS Lothian – University Hospitals Division</b>		<b>Department of Laboratory Medicine (Tissue Governance)</b>	
<b>Manual</b>	Tissue Governance	Version	1.4
<b>SOP number</b>	QP-TGU-A-HUTISRS	Issue date	30-Oct-2015
		Review date	30-Oct-2017
		Page	6 of 9

- 3.4.2 There must be sufficient information available on the database so that all events are recorded including date received, type of sample, location of sample, aliquots or derivatives created, sample use, storage and disposal.
- 3.4.3 If samples are being sent outwith NHS Lothian or the University of Edinburgh, a MTA (Material Transfer Agreement) must be in place.
- 3.4.4 Sample information must be made available to the Tissue Governance team for audit purposes if requested.

### 3.5 Sample Storage

- 3.5.1 All tissue samples must be stored appropriately, and this will depend on the type of sample eg fresh, frozen or fixed. (see QP-TGU-A-SAMSTOR - Storage of Human Tissue Samples Used in Research)

### 3.6 Sample Transport

#### Internally

- 3.6.1 Human tissue samples must be transported between sites as quickly and safely as possible.
- 3.6.2 Fresh tissue samples must be carried in a sealed container.
- 3.6.3 Paraffin embedded blocks should be transported in a box or similar suitable receptacle.
- 3.6.4 Tissue sections on glass slides should be carried in an appropriate slide transport box or tray.
- 3.6.4 Patient confidentiality must be adhered to at all times.
- 3.6.5 Samples must not be left unattended in a public area.

#### Externally

- 3.6.6 It is the responsibility of the sender to ensure specimens are packaged correctly. The sender must take all necessary steps to meet legal requirements and eliminate risks associated with transport of human tissue samples which may be potentially injurious to health.
- 3.6.7 Paraffin blocks can be sent by mail or courier at ambient temperature wrapped in bubble wrap and in a padded envelope or box.

Author	Frances Rae	Date	30-Oct-2015
Authority for Issue	Craig Marshall	Date	30-Oct-2015
Quality checked	Craig Marshall	Date	30-Oct-2015

<b>NHS Lothian – University Hospitals Division</b>		<b>Department of Laboratory Medicine (Tissue Governance)</b>	
<b>Manual</b>	Tissue Governance	Version	1.4
<b>SOP number</b>	QP-TGU-A-HUTISRS	Issue date	30-Oct-2015
		Review date	30-Oct-2017
		Page	7 of 9

- 3.6.8 Tissue sections on slides should be packed in appropriate slide transport boxes or trays and then wrapped in bubble wrap.
- 3.6.9 Fixed tissue which is rendered harmless should be marked “Exempt Patient Specimen” on the package.
- 3.6.10 Other human tissue specimens being sent by mail should be assigned UN3373, and packed according to packing instructions P650.
- 3.6.11 For further information, refer to SOP QP-TGU-A-TRNPTIS (Transport of Human Tissue Samples)

### **3.7 Upon Completion of Research Project**

- 3.7.1 The Research Ethics Committee and the R&D department or DI should be notified of the completion of a study.
- 3.7.2 All remaining tissue samples should be returned to source if relevant, or disposed of.

### **3.8 Sample disposal**

- 3.8.1 Sample disposal must be recorded, and carried out in accordance with LP-TGU-A-TISDISPL (Disposal of Human Tissue used in Research), NHS Lothian Waste Disposal Operational Policy, or University of Edinburgh Policy on Clinical and Healthcare Waste. Refer to the HTA Code of Practice 5 – Disposal of human tissue.

### **3.9 Security of premises**

- 3.9.1 Access to premises storing human tissue samples must be restricted to authorised personnel only.
- 3.9.2 Human tissue samples must be stored in an area that is lockable or secured by some other means eg swipe card or PIN number.

Author	Frances Rae	Date	30-Oct-2015
Authority for Issue	Craig Marshall	Date	30-Oct-2015
Quality checked	Craig Marshall	Date	30-Oct-2015

<b>NHS Lothian – University Hospitals Division</b>		<b>Department of Laboratory Medicine (Tissue Governance)</b>	
<b>Manual</b>	Tissue Governance	<b>Version</b>	1.4
<b>SOP number</b>	QP-TGU-A-HUTISRS	<b>Issue date</b>	30-Oct-2015
		<b>Review date</b>	30-Oct-2017
		<b>Page</b>	8 of 9

### Document Review History

<b>Review date</b>	<b>Version</b>	<b>New Version</b>	<b>Reviewed by</b>
04-Mar-2011	1.0	1.1	Frances Rae
<b>Summary of changes</b>			
Page 5 3.1.2 Changed to inform that management approval may also be from the DI for tissue.  3.1.3 Removed “management approval must be applied for using the IRAS system “  Page 7 3.7.1 DI added in to be notified of completion of a study.			
<b>Review date</b>	<b>Version</b>	<b>New Version</b>	<b>Reviewed by</b>
04-Mar-2012	1.1	1.1	Frances Rae
<b>Summary of changes</b>			
No changes apart from review date.			
<b>Review date</b>	<b>Version</b>	<b>New Version</b>	<b>Reviewed by</b>
08-Jan-2013	1.1	1.2	Frances Rae
<b>Summary of changes</b>			
Title change to add “Guidelines for Researchers” Page 3 3.1.1 Changed to reflect that ethical approval may be obtained via the Tissue Governance ethics.			
<b>Review date</b>	<b>Version</b>	<b>New Version</b>	<b>Reviewed by</b>
15-Jan-2015	1.2	1.3	Frances Rae
<b>Summary of changes</b>			
3.3.4 added in “No patient identifiable data should be held outwith the NHS without prior approval from the Caldicott Guardian”.			

<b>Author</b>	Frances Rae	<b>Date</b>	30-Oct-2015
<b>Authority for Issue</b>	Craig Marshall	<b>Date</b>	30-Oct-2015
<b>Quality checked</b>	Craig Marshall	<b>Date</b>	30-Oct-2015



<b>NHS Lothian – University Hospitals Division</b>		<b>Department of Laboratory Medicine (Tissue Governance)</b>	
<b>Manual</b>	Tissue Governance	<b>Version</b>	1.4
<b>SOP number</b>	QP-TGU-A-HUTISRS	<b>Issue date</b>	30-Oct-2015
		<b>Review date</b>	30-Oct-2017
		<b>Page</b>	9 of 9

<b>Review date</b>	<b>Version</b>	<b>New Version</b>	<b>Reviewed by</b>
30-Oct-2015	1.3	1.4	Frances Rae
<b>Summary of changes</b>			
3.9 added "Security of premises"			

For Information Only

<b>Author</b>	Frances Rae	<b>Date</b>	30-Oct-2015
<b>Authority for Issue</b>	Craig Marshall	<b>Date</b>	30-Oct-2015
<b>Quality checked</b>	Craig Marshall	<b>Date</b>	30-Oct-2015