

NHS Lothian – University Hospitals Division		Department of Laboratory Medicine (Tissue Governance)	
Manual	Tissue Governance	Version	1.3
SOP number	QP-TGU-A-RTBREG	Issue date	09-Feb-2021
		Review date	09-Feb-2025
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PROCEDURE TO BE FOLLOWED BY RESEARCHERS IN ORDER TO REGISTER THEIR RESEARCH TISSUE BANK OR HUMAN TISSUE COLLECTION WITHIN NHS Lothian AND THE UNIVERSITY OF EDINBURGH

Purpose and Scope

This SOP outlines the procedure to be followed by researchers within NHS Lothian and the University of Edinburgh to register their Research Tissue Bank or human tissue collection with NHS Lothian via the Tissue Governance team

Responsibilities

All researchers using human tissue for research purposes and have a Research Tissue Bank or human tissue collection.

References

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

Definitions

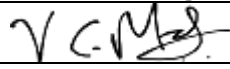
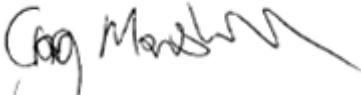
SOP – Standard Operating Procedure DI – Designated Individual for Tissue
R&D – Research and Development

Documentation

QF-TGU-A-TCBREG – Registration Form for Research Tissue Banks or Human Tissue Collections

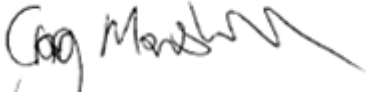
COPY	1	Tissue Governance SOP folder
Location of Copies		

Authorising signatures

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Authority for issue:		Date:	09-Feb-2021

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1 INTRODUCTION

This document outlines the procedure researchers should follow in order to register their Research Tissue Bank or other human tissue collection with NHS Lothian.

2 HAZARDS AND PRECAUTIONS

N/A

3 PROCEDURE

3.1 All researchers who have Research Tissue Banks or other human tissue collections should register this with NHS Lothian.

3.2 The following information should be sent to the Tissue Governance team:

- 3.2.1 A copy of the ethics application and letter of approval.
- 3.2.2 A copy of R&D approval letter where appropriate. (Research Tissue Banks do not require local R&D approval, but they do require management approval which may be delegated to the Lead for Tissue Governance).
- 3.2.3 Blank copy of the approved consent form and patient information leaflet used for sample collection.
- 3.2.4 A completed registration form (QP-TGU-A-TCBREG).
- 3.2.5 Nominated PI, responsible for ensuring that the collection is appropriately managed and provides regular reports to Tissue Governance.
- 3.2.6 Information on location of storage of samples.
- 3.2.7 Evidence that there is a password-protected database with appropriate security in place for sample tracking. This should include a full audit trail of all samples from receipt to usage, storage or disposal.
- 3.2.8 Evidence that data is backed up.
- 3.2.9 Evidence that they have written procedures in place describing how they:
 - Consent
 - Source
 - Collect

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- Receive
- Anonymise
- Store
- Keep records
- Use
- Dispose of human tissue samples

3.3 Following registration, the Tissue Governance team should be provided with:

- 3.3.1 Regular updates (approximately 6 monthly) regarding the number of samples received, used in research, distributed, and disposed of.
- 3.3.2 Notification of any significant change to the details provided at registration, such as contact details or location of storage.

Further guidance may be available from the Tissue Governance team at rie.tissuegovernance@nhslothian.scot.nhs.uk
Vishad.patel@nhslothian.scot.nhs.uk
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Document Review History

Review date	Version	New Version	Reviewed by
09-FEB-2011	1.0	1.1	Frances Rae
Summary of changes			
Page 1 1 Title changed to include the University of Edinburgh. 2 Documentation added – QF-TGU-A-TCBREG – Registration Form for Research Tissue Banks or Human Tissue Collections. Page 4 3.2.3 Appendix I changed to QF-TGU-A-TCBREG Page 5 3.3.1 Regular updates changed from approximately 3 to 6 monthly to 6 monthly			
Review date	Version	New Version	Reviewed by
09-Feb-2012	1.1	1.1	Frances Rae
Summary of changes			
No changes other than review date			
Review date	Version	New Version	Reviewed by
18-Jul-2014	1.1	1.1	Frances Rae
Summary of changes			
No changes other than review date			
Review date	Version	New Version	Reviewed by
09-Feb-2016	1.1	1.1	Frances Rae
Summary of changes			
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Review date	Version	New Version	Reviewed by
09-Feb-2019	1.1	1.2	Frances Rae
Summary of changes			

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3.2.3 Added			
Review date	Version	New Version	Reviewed by
09-Feb-2021	1.2	1.3	Vishad Patel
Summary of changes			
<p>Staff Review sheet removed</p> <p>Email address changes from luht to nhslothian: rie.tissuegovernance@nhslothian.scot.nhs.uk Craig.Marshall@nhslothian.scot.nhs.uk</p> <p>Added Vishad.patel@nhslothian.scot.nhs.uk Removed frances.rae@luht.scot.nhs.uk</p> <p>3.2.2 – ‘DI for Tissue’ changed to ‘Lead for Tissue Governance’.</p>			
Review date	Version	New Version	Reviewed by
09-Feb-2023	1.3	N/A	Craig Marshall
Summary of changes			
No changes other than review date			

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