

NHS Lothian – University Hospitals Division Department of Laboratory Medicine (Tissue Governance)			
Manual	Tissue Governance	Version	1.4
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TISSUE GOVERNANCE POLICY

Purpose and Scope

To provide an overview of the function of the Tissue Governance Unit.

Responsibilities

All Tissue Governance staff

References

Human Tissue Act 2004, Human Tissue (Scotland) Act 2006
 IHC GCP Principles of Good Clinical Practice
 UK Policy Framework for Health and Social Care Research 2017.
 General Data Protection Regulation (GDPR) Data Protection Act 2018
 Caldicott Principles
 The Human Tissue Authority (HTA) Codes of Practice

Definitions

NRES – National Research Ethics Service, HTA – Human Tissue Authority,
 GCP – Good Clinical Practice
 NRS – NHS Research Scotland
 PIS – Participant Information Sheet ICF – Informed Consent Form
 RTB – Research Tissue Bank
 EoSRES – East of Scotland Research Ethics Service.
 DI – Designated Individual MTA – Material Transfer Agreement
 RTB- Research Tissue Bank UoE – University of Edinburgh

Documentation

QP-TGU-A-ACCESSR – Request for access to the Lothian NRS BioResource
 QP-TGU-A-TDACPOL – Tissue and Data Access Policy

COPY		ACCORD website
Location of Copies		Tissue Governance shared drive

Authorising signatures

Author	: Frances Rae	Date	: 18-Feb-2019
Authority for Issue	: Craig Marshall	Date	: 18-Feb-2019
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Quality checked:	<i>Craig Marshall</i>	Date:	<i>18-Feb-2019</i>

Staff Review Form

I have read and understood the above Policy

Name	Signature	Date
<i>Craig Marshall</i>	<i>Craig Marshall</i>	<i>18-Feb-2019</i>

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1 INTRODUCTION

- 1.1 NHS Lothian Tissue Governance Unit has been established to ensure appropriate governance of the use of human tissues for research. This applies to tissue specifically collected for research purposes and also tissue that is stored in the archives of Laboratory Medicine.
- 1.2 It is committed to ensure all such research complies with
- The Human Tissue (Scotland) Act 2006
 - Human Tissue Act 2004
 - The principles of Good Clinical Practice (GCP)
 - The Human Tissue Authority (HTA) Codes of Practice
 - The NPSA (National Patient Safety Agency)
 - The NRES (National Research Ethics Service)
 - General Data Protection Regulation (GDPR) Data Protection Act 2018
 - The Caldicott Principles.
 - Accreditation standards for Tissue Banks.
 - UK Policy Framework for Health and Social Care Research 2017.
- 1.3 It acts as a central resource and provides a governance framework through which NHS Lothian and University of Edinburgh projects using tissue samples obtained from NHS Lothian patients should be channelled. This does not include projects or collections covered by project-specific ethics but does include those whose approval has expired.
- 1.4 This policy outlines the research governance and management arrangements for the collection, use and access to human tissue within NHS Lothian and the University of Edinburgh. Patient samples held within the University of Edinburgh remain under the custodianship of NHS Lothian.

2 AIMS

- 2.1 To provide Lothian Health Board, as custodians, with oversight of patient samples collected for research under its stewardship.
- 2.2 To provide a central resource within NHS Lothian to co-ordinate all Tissue Banks and Tissue collections within the Health Board and University of Edinburgh.
- 2.3 To implement a defined governance infrastructure to ensure that all research studies using and storing human tissue samples and associated linked pseudonymised data are adequately and

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appropriately governed and are compliant with the applicable regulations (See 1.2)

- 2.4 To maintain a register of studies collecting, using and storing patient samples for research with a focus on Tissue Banks and tissue collections.
- 2.5 To support researchers by providing advice and paperwork including generic SOPs, prewritten ethics, patient information and consent forms, and database help.
- 2.6 To maximise the availability of good quality tissue to researchers.
- 2.7 To obtain generic consent from as many patients as possible for the use of their surplus tissue and linked clinical data in research.
- 2.8 To promote a culture of support for research within NHS Lothian.
- 2.9 To ensure accountability, audit trail, and transparency for tissue samples collected for research projects within NHS Lothian and the University of Edinburgh.
- 2.10 To maintain Human Tissue Bank accreditation status.

3 GOVERNANCE

- 3.1 All researchers using human tissue samples are expected to work within the Tissue Governance infrastructure.
- 3.2 Patient confidentiality must be observed at all times.
- 3.3 The Lothian NRS BioResource is managed by the Tissue Governance team and has been set up as a central hub to support as many NHS Lothian and University of Edinburgh Tissue Banks and tissue collections as possible.
- 3.4 Research Tissue Bank ethics has been obtained to encompass as many of the above without the need for project specific ethical approval.
- 3.5 Generic PIS and ICF including consent for future use and for the use of DNA are used as widely as possible.
- 3.6 All researchers are expected to register their tissue collections retrospectively with Tissue Governance.

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- 3.7 All researchers beginning a prospective tissue collection are required to obtain approval from Tissue Governance prior to commencement. (QP-TGU-A-ACCESSR)
- 3.8 All clinical data stored for research purposes must be stored in a linked anonymised fashion. No patient identifiable data should be held outwith the NHS IT system without the approval of the Caldicott Guardian.
- 3.9 Researchers and Research Tissue Banks are expected to agree and adhere to terms of Tissue Governance approval.
- 3.10 All researchers who store tissue samples are expected to make them available to other research groups if possible.
- 3.11 Research groups using and storing tissue samples will be subject to audit by the Tissue Governance team to ensure compliance.
- 3.12 The Tissue Governance team provide a central portal for the release of tissue from the archives of Laboratory Medicine and anyone wishing to access this resource must submit an application.

4 ACCESS TO THE NRS BIORESOURCE

- 4.1 The Lothian NRS BioResource has an access policy which requires researchers to formally apply for approval. (QP-TGU-A-TDACPOL)
- 4.2 All such requests are reviewed by the Tissue Governance Tissue Advisory committee chaired by the DI before being approved.
- 4.3 In certain circumstances, if the request is for archival tissue which is abundantly available, requires minimal data, or has been previously peer reviewed, Tissue Governance management may approve the release of the tissue without the need for full committee approval.
- 4.4 No tissue or associated clinical data is released without approval from Tissue Governance management.

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5 ETHICS

- 5.1 The Lothian NRS BioResource, managed by the Tissue Governance team, hold RTB (Research Tissue Bank) ethical approval reference number 15/ES/0094 from EoS REC (East of Scotland Research Ethics Committee).
- 5.2 This ethical approval grants permission to collect surplus tissue samples, and also to carry out most types of translational research provided approval has been granted by the Tissue Governance team.
- 5.3 This means that whenever a request to access stored tissue samples or to start up a prospective collection falls within the framework of this RTB approval, no further REC approval is required provided Tissue Governance approval has been obtained.
- 5.4 Requests for permission to carry out studies under this ethical approval are submitted to the Tissue Governance Committee which is chaired by the DI. The committee reviews the request for scientific merit and technical validity and approves or rejects as appropriate.
- 5.5 In certain circumstances, approval may be given by Tissue Governance management without the need for full committee approval (See section 4.3)
- 5.6 No tissue or associated clinical data is released without Tissue Governance approval.
- 5.7 Tissue Governance submits an annual report to the EoS REC detailing all projects which have been carried out under the RTB ethical approval.
- 5.8 Tissue Governance also reports annually to the Healthcare Governance Committee of NHS Lothian.

6 TISSUE BANKS AND RESEARCH TISSUE BANKS

- 6.1 Research groups wishing to establish or populate a tissue bank or RTB (Research Tissue Bank) within NHS Lothian or the University of Edinburgh using samples from NHS Lothian patients must have prior approval of Tissue Governance to do so (see 3.7)
- 6.2 In the case of tissue banks, these must be registered with Tissue Governance (see 3.6). Tissue Governance will provide guidance on the information required for this.

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7 SAMPLES BEING SENT OUTWITH LOTHIAN

- 7.1 The Tissue Governance Unit provides a portal for the transfer of tissue out with Lothian.
- 7.2 Prior to patient samples being sent outwith NHS Lothian or the University of Edinburgh, a MTA (Material Transfer Agreement) or contract must be in place. This documents the nature of the samples, who will receive them, and the purpose for which they are to be used. The Tissue Governance team will provide advice on this.

8 CONTACT DETAILS

The Tissue Governance team can be contacted on rie.tissuegovernance@nhslothian.scot.nhs.uk

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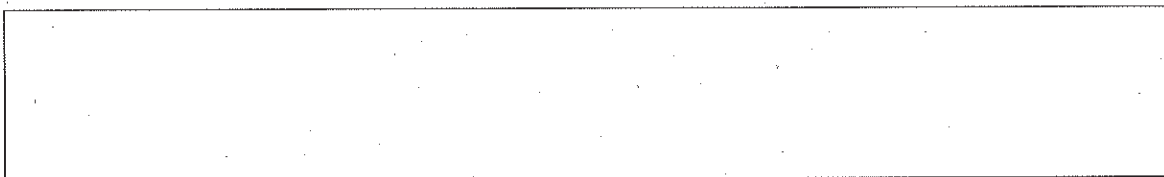
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DOCUMENT REVIEW HISTORY

Review date	Version	New Version	Reviewed by
22-Oct-2015	1.1	1.2	Frances Rae
Summary of changes			
2.10 changed to reflect accreditation status 3.8 information added about Caldicott approval being required for patient identifiable data if held outwith the NHS. 5.1 Ethics reference number updated 5.7 added			
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18-Apr-2016	1.2	1.3	Frances Rae
Summary of changes			
Section 4.3 added Section 5.5 amended to reflect the information in 4.3			
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Summary of changes			
GDPR added to references. UK Policy Framework for Health and Social Care Research 2017 added to references .			
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