

NHS Lothian – University Hospitals Division		Department of Laboratory Medicine (Tissue Governance)	
Manual	Tissue Governance	Version	1.7
SOP number	QP-TGU-A-GOVCOMS	Issue date	23-May-2024
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TERMS OF REFERENCE AND MEMBERSHIP OF TISSUE GOVERNANCE/ACCESS COMMITTEE OF THE LOTHIAN NRS BIORESOURCE

Purpose and Scope

To define terms of reference and membership of Tissue Governance Committee of the NHS Lothian NRS BioResource.

Responsibilities

Tissue Governance staff including Tissue Governance Committee members.

References

Definitions

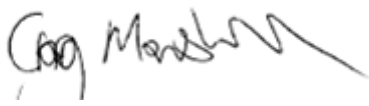
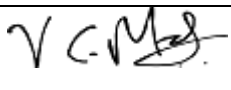
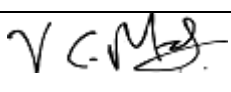
EoS REC – East of Scotland Research Ethics Committee.

Documentation

QP-TGU-A-ACCESSR – Request for Access to Bioresource
QP-TGU-A-TDACPOL - Tissue and Data Access Policy

COPY	2	Tissue Governance shared drive
Location of Copies		ACCORD website

Authorising signatures

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Authority for issue:		Date:	23-May-2024
Quality checked:		Date:	23-May-2024

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Authority for Issue	Vishad Patel	Date	23-May-2024
Quality checked	Vishad Patel	Date	23-May-2024

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1 INTRODUCTION

This document describes the terms of reference and membership of the Tissue Governance committee acting on behalf of the Lothian NRS BioResource. This committee will act as the Access Committee and make decisions on whether applications are approved or not and the terms Tissue Governance Committee and Access Committee will be considered to be synonymous.

2 OVERVIEW

- 2.1 All requests to the BioResource are reviewed by the Tissue Governance Committee who will scrutinise each request for the appropriateness of the science and ethics. The exception to this will be where a request has been previously peer reviewed, in which case, if there is an abundance of tissue available, it may be reviewed by the Tissue Governance management alone.
- 2.2 The Lothian NRS BioResource has an open access policy and all bona fide requests from legitimate researchers including commercial entities will be considered. (See Tissue and Data Access Policy - QP-TGU-A-TDACPOL)
- 2.3 If tissue has been collected for a specific study, the research group who collected it will be respected as the first end user, and during the period of study, access will be restricted.
- 2.4 The Tissue Governance committee is responsible to the Executive Medical Director for NHS Lothian.
- 2.5 The Tissue Governance Committee mainly operates electronically, and all requests are sent round by email. Applications may also be discussed at face-to-face meetings, particularly if there are any issues to be resolved.

3 HAZARDS AND PRECAUTIONS

N/A

4 PROCEDURE

- 4.1 All requests for tissue and data should be submitted to the Tissue Governance Manager or Tissue Governance Officer on form QP-TGU-A-ACCESSR.
- 4.2 The Tissue Governance Manager or Tissue Governance Officer will conduct an initial review of the application and refer back to the applicant with any queries, issues or amendments, within 10 working days were possible.

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- 4.3 Once all parties are agreed that the application is ready for submission, the request will be sent to the Tissue Governance Committee for review by means of email by the Tissue Governance Manager or Tissue Governance Biomedical Science Officer.
- 4.4 A response from committee members should be made in a timely fashion, with a target of 10 working days. In the event of a researcher being asked to supply additional information, the clock will be stopped.
- 4.5 The review process must respect the conditions of donor consent where relevant and all use of tissue and data must come under the terms of the RTB ethical approval granted by the East of Scotland REC, reference number 20/ES/00061 (previously 15/ES/0094).
- 4.6 The review process should assess the quality of the science, protocol and monitor any risk.
- 4.7 Restriction of access must be handled in a transparent manner and any refusal to supply tissue samples must be accompanied by an explanation eg in the event of rare or precious samples where the fulfilment of the request would deplete the resource.
- 4.8 In the case of requests for archival pathology samples there must be sufficient tissue remaining in the block to maintain the patient record.
- 4.9 Where an applicant requesting tissue is also a member of the Tissue Governance Committee, they will be deemed to have a conflict of interest and will be excluded from the review process for that request.

5 MEMBERSHIP OF TISSUE GOVERNANCE COMMITTEE

5.1 Core membership of Tissue Governance Committee

- Clinical Lead of the Lothian NRS BioResource
- Consultant Pathologist and deputy to the Clinical Lead.
- Consultant Pathologist University of Edinburgh.
- Consultant Clinician NHS Lothian
- Tissue Governance Manager
- Tissue Governance Officer/ Biomedical Science Officer

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- This core committee meets approximately monthly to discuss all issues concerning the BioResource and Tissue Governance, including ethics.
- Members listed in section 5.2 below participate as required whenever their area of expertise is thought to be an advantage to any parts of the agenda.
- Minutes of this meeting are submitted to the Executive Medical Director for review upon request.

5.2 Membership of Tissue Governance Committee reviewing requests for tissue and data:

- Tissue Specific committees consist of the core members (5.1) plus the following members co-opted on where relevant according to specialty.
- Lead Consultant Pathologist or senior scientist of the specialty.
- Surgeon, Oncologist or another clinician or scientist.
- Lothian Research Safe Haven manager.
- Research Governance from NHS Lothian and Research Governance from the University of Edinburgh where appropriate.

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Document Review History

Review date	Version	New Version	Reviewed by
06-May-2013	1.0	1.1	Frances Rae
Summary of changes			
5.2 Designation of committee members added as requested by HIS for clarification as part of post panel analysis.			
Review date	Version	New Version	Reviewed by
24-Oct-2015	1.1	1.2	Frances Rae
Summary of changes			
Names of individuals removed. Title of BioResource changed.			
Review date	Version	New Version	Reviewed by
14-Feb-2019	1.2	1.3	Frances Rae Craig Marshall
Summary of changes			
5.1 “Consultant Pathologist University of Edinburgh” added 5.2 “Lothian Research Safe Haven manager and Research governance from NHS Lothian and Research Governance from the University of Edinburgh where appropriate” added.			
Review date	Version	New Version	Reviewed by
18-Jun-2019	1.3	1.4	Frances Rae
Summary of changes			
Clarification in the introduction and throughout the document that the Tissue Governance Committee is the same as the Access Committee of the BioResource.			
Review date	Version	New Version	Reviewed by
23-May-2020	1.4	1.5	Frances Rae
Summary of changes			
4.8 added “Where an applicant requesting tissue is also a member of the Tissue Governance Committee, they will be excluded from the review process for that request”.			
Review date	Version	New Version	Reviewed by
23-May-2022	1.5	1.6	Craig Marshall
Summary of changes			

Author	Craig Marshall	Date	23-May-2024
Authority for Issue	Vishad Patel	Date	23-May-2024
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2.4 and 5.1 were amended to replace “Director of Public Health and Health Policy” with Executive Medical Director”

5.1 ‘Tissue Governance Officer’ changed to Tissue Governance Officer/ Biomedical Science Officer

Added:

4.2 The Tissue Governance Manager or Tissue Governance Officer will conduct an initial review of the application and refer back to the applicant with any queries, issues or amendments, within 10 working days were possible.

4.3 Once all parties are agreed that the application is ready for submission.....

5.1 ‘Consultant Clinician NHS Lothian’

Review date	Version	New Version	Reviewed by
23-May-2024	1.6	1.7	Craig Marshall

Summary of changes

5.2 – ‘Tissue Specific committees consist of the five core members (5.1)’ – ‘five’ removed

5.2 - Lothian Research Safe Haven manager. - Removed

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