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
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 E – 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
QP-TGU-A-IMPEXPT – NHS Lothian Tissue Governance Policy on Import and Export of Human Tissue Samples.
QF-TGU-A-TCBREG – Registration Form for Research Tissue Banks of Human Tissue Collections.

Authorising signatures

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Staff Review Form for Standard Operating Procedures

Author	Vishad Patel	Date	14-Feb-2021
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I have read and understood the above Standard Operating Procedure

Name	Signature	Date

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1 INTRODUCTION

Human tissue includes any bodily part or fluid that contains 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 patient 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@nhslothian.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.

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 Lothian NRS BioResource/Tissue Governance team.

3.1.2 Management approval where appropriate (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 unless the necessary approvals are in place eg Caldicott, Information Governance, Research Safe Haven.

3.3.3 The patient details pertaining to the samples should be kept on a secure database with the appropriate approvals in place.(See 3.3.2)

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.

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, taxi or courier at ambient temperature wrapped in bubble wrap and in a padded envelope or box.

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 Fresh tissue samples should be packaged and transported in a manner appropriate for the transport of such material, adhering to any guidance requirements or arrangements provided by the recipient.

3.6.12 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 Tissue Governance contact 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.

3.7.3 If samples are to be retained beyond the original study that they were collected for and/or provided for, then the collection must be registered with Tissue Governance. It is the responsibility of the research group to do this. (QF-TGU-A-TCBREG – Registration Form for Research Tissue Banks of Human Tissue Collections).

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 E – 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.

Document Review History

Review date	Version	New Version	Reviewed by
04-Mar-2011	1.0	1.1	Frances Rae

Summary of changes
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.

Review date	**Version**	**New Version**	**Reviewed by**
04-Mar-2012	1.1	1.1	Frances Rae

Summary of changes
No changes apart from review date.

Review date	**Version**	**New Version**	**Reviewed by**
08-Jan-2013	1.1	1.2	Frances Rae

Summary of changes
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.

Review date	**Version**	**New Version**	**Reviewed by**
15-Jan-2015	1.2	1.3	Frances Rae

Summary of changes
3.3.4 added in **"**No patient identifiable data should be held outwith the NHS without prior approval from the Caldicott Guardian".

Review date	**Version**	**New Version**	**Reviewed by**
30-Oct-2015	1.3	1.4	Frances Rae

Summary of changes
3.9 added "Security of premises"

Review date	**Version**	**New Version**	**Reviewed by**
14-Feb-2019	1.4	1.5	Frances Rae Craig Marshall

Summary of changes

Introduction: "**plasma and serum**" removed

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 unless the necessary approvals are in place eg **Caldicott, Information Governance, Research Safe Haven**.

3.3.3 The patient details pertaining to the samples should be kept on a secure database with the **appropriate approvals in place**.(See 3.3.2)

3.6.11 added

3.7.3 added

Review date	Version	New Version	Reviewed by
14-Feb-2021	1.5	1.6	Vishad Patel

Summary of changes

Email address change rie.tissuegovernance@nhslothian.scot.nhs.uk

3.7.1: The Research Ethics Committee and the R&D department or DI **and Tissue Governance contact** should be notified of the completion of a study

"**DI**" removed