TISSUE AND DATA ACCESS POLICY

Purpose and Scope

To provide an overview of the access procedure for the Lothian NRS BioResource managed by the Tissue Governance Unit.

Responsibilities

All Tissue Governance staff
All researchers wishing to access the Lothian NRS BioResource.

References

Human Tissue Act 2004, Human Tissue (Scotland) Act 2006
General Data Protection Regulation (GDPR) Data Protection Act 2018
Caldicott Principles
The Human Tissue Authority (HTA) Codes of Practice
National Cancer Research Institute (NCRI) document "Samples and Data for Research: Template for Access Policy Development" June 2009.
National Guiding Principles for Governance of NHSScotland Tissue for Research.
NIHR – National Institute for Health Research

Definitions

MTA – Material Transfer Agreement TMA – Tissue Microarray
NRS – NHS Research Scotland FFPE – Formalin fixed paraffin embedded
REC – Research Ethics Committee

Documentation

QP-TGU-A-ACCESSR – Request for Access to the NRS BioResource
QP-TGU-A-TISSREQ - Procedure for dealing with Requests for Access to Tissue Samples Held by the NRS BioResource
TGU-A-GOVCOMS - Terms of Reference and membership of Tissue Governance Committee Lothian NRS BioResource.
QP-TGU-A-COMPROC, "Procedure for Making a Complaint to the Lothian NRS Bioresouce".
Samples and Data for Research: Template for Access Policy Development" National Cancer Research Institute (NCRI) June 2009
National Guiding Principles for Governance of NHS Scotland Tissue for Research – CSO (Chief Scientist Office) Scotland. September 2012

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Authorising signatures

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Quality checked:	**Vishad Patel**	**Date:**	18-Jun-2021

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1 INTRODUCTION

The Lothian NRS BioResource holds ethical approval from the East of Scotland REC, reference number 20/ES/0061 to operate as a Research Tissue Bank. This permits the BioResource to provide samples and linked anonymised clinical data to researchers who satisfy the Tissue Governance committee that their application is ethically and scientifically appropriate. The relevant Tissue Governance Committee will then make a decision on whether approval should be given or not. The term Tissue Governance Committee will be considered to be synonymous with "Access Committee". (See QP-TGU-A-GOVCOMS - Terms of Reference and membership of Tissue Governance Committees Lothian NRS BioResource)

Overview:

1.1 The BioResource (Tissue Bank) consists primarily of diseased and normal surgical surplus tissue samples from consented donors. These are held within a variety of collections. Data may be linked to the tissue samples for specific projects.

1.2 The contents of the BioResource are open to applications from any researcher, including commercial organisations and institutions from overseas, seeking to utilise material collected under the approval of the BioResource for bona fide research purposes, including basic and translational research.

1.3 The BioResource has an open and broad access policy which aims to provide fair access to all in order to maximise public benefit and advance biomedical knowledge.

1.4 Applications may be submitted at any time by a research investigator and will be considered in the order in which they are received on an *ad hoc* basis.

1.5 If researchers apply for access to materials from a collection that has been collected for a specific project, the primary use may restrict the secondary use.

1.6 The target time for responding to applicants is ten working days.

2 APPLICATION AND APPROVALS PROCESS

2.1 See document QP-TGU-A-TISSREQ Procedure for dealing with Requests for Access to Tissue Samples Held by the NRS BioResource.

2.2 Applications to obtain materials from the BioResource should be submitted electronically on form QP-TGU-A-ACCESSR, to the BioResource/Tissue Governance Manager.

2.3 Submissions should contain sufficient detail and include name, contact details, institute or organisation, outline of study and methodology to be used, type and quantity of materials required, whether any previous ethical approval has been granted and details of funding. If associated data is required, this must be requested in detail.

2.4 Applicants will also be asked to indicate whether they have a named local NHS collaborator, eg pathologist where required, as a co-applicant or whether they require support from the BioResource to help implement this where possible.

2.5 Applications are sent round the committee electronically. The Tissue Governance committee will make an assessment of the overall application taking cognisance of the ethical and scientific ethos of the Laboratory Medicine terms of reference and make a decision as to whether approval should be given or not. Applications may also be discussed at face to face meetings, particularly if there are any issues to be resolved.
(TGU-A-GOVCOMS - Terms of Reference and membership of Tissue Governance Committees Lothian NRS BioResource).

2.6 Where a project has been previously peer reviewed and there is an abundance of material available, approval may be given by the Tissue Governance management without the need for the request to be sent round the full committee.

2.7 If and when approval is received for a given project, this approval to collect and/or use material collected under the ethical approval or governance of the BioResource is dependent on the applicant agreeing to the conditions of access stated on the form QP-TGU-A-ACCESSR, Request for Access to the NRS BioResource. See section 9.

3 SURPLUS DIAGNOSTIC SAMPLES WITHIN LABORATORY MEDICINE

3.1 The BioResource is the central portal to access surplus diagnostic material held within Laboratory Medicine such as FFPE tissue, blood, and bodily fluids.

3.2 The BioResource holds ethical approval to release tissue samples and linked patient data from this material for research purposes in an anonymised manner once they have fulfilled their primary (diagnostic) purpose.

3.3 Anyone wishing to access these samples must submit an application as in 2.2.

3.4 Diagnostic archival FFPE blocks are rarely issued to researchers. Sections, with appropriate approval by a pathologist, will be released as an alternative to whole blocks. This ensures sufficient residual material remains for unforeseen diagnostic or legal purposes.

3.5 Retrieval of samples and section cutting will be carried out by BioResource staff where possible and issued to researchers in a de-identified fashion.

3.6 Diagnostic fluid samples from Laboratory Medicine, such as blood, serum, plasma and other bodily fluids, can only be released for research at the point where they would normally routinely be surplus and/or disposed of by the clinical laboratories.

3.7 All surplus diagnostic samples must be released to researchers in a de-identified manner.

4 TISSUE MICROARRAYS

4.1 The BioResource accepts applications from researchers wishing to have tissue microarrays (TMAs) constructed. Researchers wishing to construct TMAs should approach the Tissue Governance / BioResource Manager for initial discussions, and apply through the normal route (See 2.2)

4.2 A selection of TMA blocks exist within the BioResource, and can also be applied for through the normal route. (See 2.2)

5 DATA

5.1 Samples may be provided with linked anonymised clinical data where required.

5.2 Specific clinical information required with samples should be requested on the application form as in 2.2.

5.3 No requests for patient identifiable data will be considered and the Caldicott principles will apply.

5.4 Donor anonymity will be upheld at all times. No sample shall be supplied by the BioResource which could result in the original donor being identified.

6 PRIORITISATION OF ACCESS

6.1 Tissues Requests will be assessed on a case by case basis and as far as possible will be handled in a "first come first served" manner.

6.2 Where demand for material exceeds its availability, access will be prioritised based on scientific and technical merit (as assessed by the Tissue Governance Committee).

6.3 As the amount of material available is limited, should this issue arise it will be suggested that applicants collaborate. If applicants are not willing to collaborate then both applications will be considered as usual. However, it is very unlikely that access to the BioResource will be granted for two very similar studies.

7 EXCLUSIONS

While no research institution will be excluded from applying for tissue or data, samples will not be released for use into termination of pregnancy, reproductive cloning, or to tobacco companies.

8 APPEAL AND COMPLAINTS PROCESS

8.1 Where a request has been rejected, a reason will have been given for this. If a researcher wishes to appeal the decision, they should write to the Tissue Governance / BioResource Manager indicating that they wish to appeal.

8.2 The researcher should provide documented evidence addressing any issues raised and request reconsideration of their application. The appeal will be considered and a decision issued within 10 working days.

8.3

Complaints from researchers who are recipients of tissue samples should be handled as described in document QP-TGU-A-COMPROC, "Procedure for Making a Complaint to the Lothian NRS Bioresource".

9 CONDITIONS OF ACCESS TO THE BIORESOURCE

9.1 Before a request to the BioResource is approved, applicants must agree to the terms set out in the BioResource User Agreement on form QP-TGU-A-ACCESSR – "Request for Access to the NRS BioResource" and return the signed copy to the Tissue Governance / BioResource Manager

9.2 Where samples and/or data are to be transferred outwith NHS Lothian and/or the University of Edinburgh a MTA must be in place, and help with this will be given by the Tissue Governance team.

9.3 In summary, the BioResource will require a commitment in the following areas:

9.3.1 Any charges incurred by the BioResource will be met.

9.3.2 The title of each research project will be made available on the list of active research projects supported by the BioResource

9.3.3 The materials supplied by the BioResource must only be used for the purposes specified in the application.

9.3.4 Onward transfer of the materials will not be permitted without prior written approval of the BioResource.

9.3.5 If the research carried out using materials provided by the BioResource is published, appropriate acknowledgement of the contribution of the BioResource should be made.

9.3.6 Unused materials must be withdrawn from research use if the user is notified that the donor has withdrawn consent for the use of their material for research purposes.

9.3.7 If any samples remain following the research, the samples are returned to the BioResource or disposed of as instructed.

9.3.8 The recipient will not attempt to identify donors.

9.3.9 Requestor understands that the samples are released to them with no warranties on their fitness for purpose.

10 COST RECOVERY

10.1 All BioResource services are subject to cost recovery. Costs are recovered for staffing, consumables, equipment servicing/maintenance and overheads. **No patient samples are sold for profit.**

10.2 The BioResource will make a charge per sample to cover its costs. The costing structure is based on the National Costing model derived from the NIHR Industry Costing Template. This model determines reimbursement costs based on the staff time associated with the task

10.3 The national costing model is not definitive/comprehensive. Therefore, costs may vary on a project-specific basis.

10.4 Academic work will be charged on a “per project” basis and commercial work charged on a “per case” basis as outlined in the National Costing Model (Policy for the cost of tissue provision and associated services within the Scottish Biorepository network)

10.5 The cost of TMA projects will be calculated on a project-specific basis. There will be a flat rate hourly fee for the construction of the TMA. The related sample acquisition cost for each TMA project will vary dependent on the number of cores per TMA and pathologist input.

10.6 Charges may be incurred to cover time for acquisition of data. This will be judged on a project-specific basis.

10.7 To avoid doubt, all costs are in respect of activities undertaken or outlays incurred by the BioResource in supply of the material, but no charge is made in respect of the material itself.

Document Review History

Review date	Version	New Version	Reviewed by
02-Dec-2013	1.0	1.1	Frances Rae

Summary of changes

1.1 Added
1.7 removed and inserted under "References"
2.8 removed as covered in 9.2
8.3 removed "Alternatively, if the researcher cannot satisfactorily address any issues, they are free to amend their original request and resubmit. This will also be considered and a decision issued within 10 working days.
9.2 Removed "signed by the applicant"
9.3.9 added "Requestor understands that the samples are released to them with no warranties on their fitness for purpose".
10.5 Removed "If the requested information is complex or detailed"

Review date	Version	New Version	Reviewed by
22-Oct-2015	1.1	1.2	Frances Rae

Summary of changes

1.1 Ethics information updated
3.1 Wording changed to "Archives of Laboratory Medicine"
4.2 added in.
7 Exclusions changed to remove cosmetics industry
10.4 "Pathologist time" added in

Review date	Version	New Version	Reviewed by
12-Feb-2019	1.2	1.3	Frances Rae Craig Marshall Hannah Monaghan

Summary of changes

2.5 Applications are sent round the committee electronically. The Tissue Governance committee will make an assessment of the overall application taking cognisance of the ethical and scientific ethos of the Laboratory Medicine terms of reference and make a decision as to whether approval should be given or not.

10.4 Academic work will be charged on a "per project" basis and commercial work charged on a "per case" basis as outlined in the National Costing Model (Policy for the cost of tissue provision and associated services within the Scottish Biorepository network)

10.7 To avoid doubt, all costs are in respect of activities undertaken or outlays incurred by the BioResource in supply of the material, but no charge is made in respect of the material itself.

Review date	Version	New Version	Reviewed by
18-Jun-2019	1.3	1.4	**Frances Rae**

Summary of changes

Section 2 “Approvals” added to Application process title.
Section 8 “Complaints information added to “Appeals” section.
2.5 “Applications may also be discussed at face to face meetings, particularly if there are any issues to be resolved” added

Review date	Version	New Version	Reviewed by
18-Jun-2021	1.4	1.5	**Craig Marshall**

Summary of changes

Introduction: Lothian NRS Bioresource REC reference number changed from “15/ES/0094” to “20/ES/0061”

Section 3.6 “surplus and/or” added