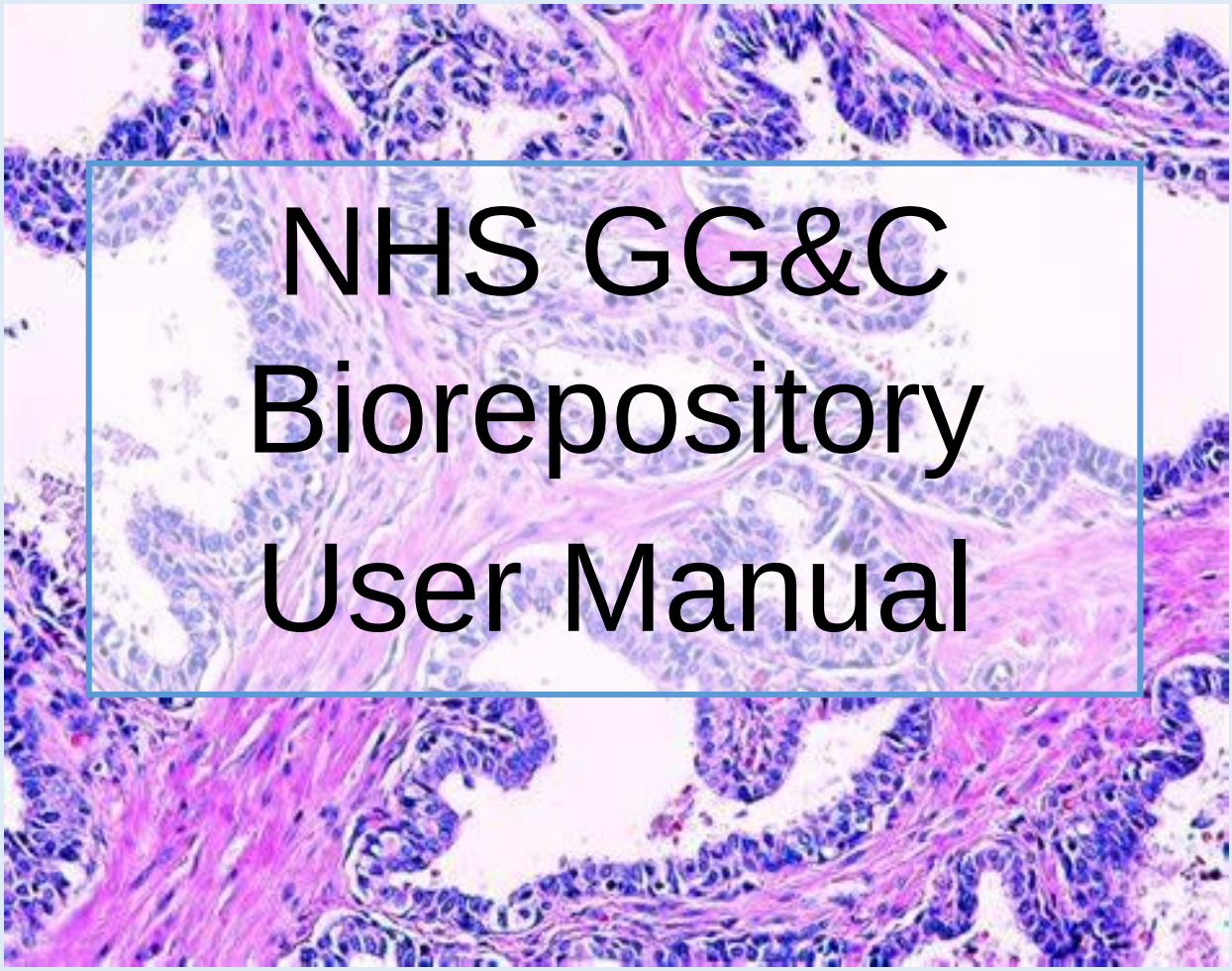


NHS GG&C Biorepository User Manual

NHSGGC Biorepository

The NHSGGC Biorepository is part of Research and Innovation in NHS GG&C. We facilitate the collection of tissue samples from patient donors for research and are ideally based in the Laboratory Medicine Building at the Queen Elizabeth Hospital site, beside Pathology. We are responsible for the governance, collection, storage and use of all human tissues in NHSGGC and its affiliated organisations. As an invaluable resource for clinical research, we provide access to a wide range of human tissue samples including surplus materials from diagnostic and surgical procedures. We ensure that all legal and ethical requirements are met for the collection, storage, use and disposal of human tissue.

We can also provide access, with appropriate governance in place, to Pathology archive specimens.

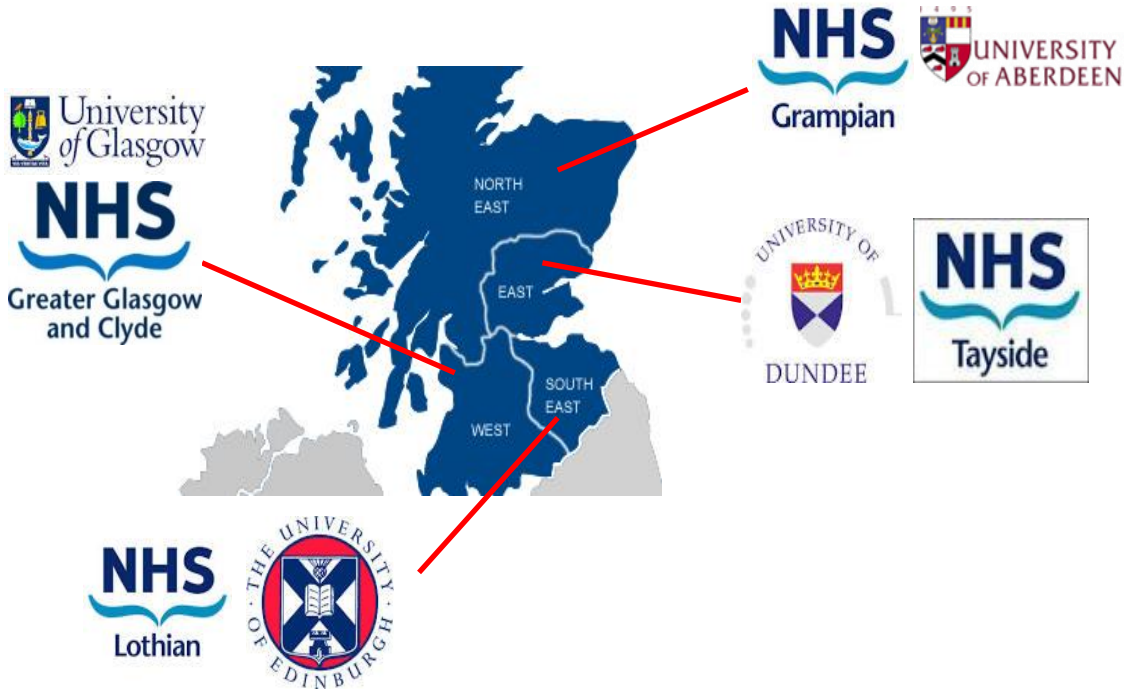
Through close collaboration with all clinical departments we source fully-consented surplus tissue and other materials in order to fulfil the need for these in research.

Each anonymised sample is accompanied by a limited set of clinical and demographic data held by the Biorepository. If necessary the scope of these data can be expanded upon through our close collaboration with the NHSGGC Data Safe Haven.

Figure 1. NHS GG&C Biorepository Laboratory

In Scotland the Biorepositories work as a network so we are one of the key operational units of the NHS Research Scotland (NRS) hub, funded by the Scottish Government Chief Scientist Office (CSO).

Biorepository Network



The 4 Biorepositories are directly responsible to their corresponding health board and work closely with their medical schools.

Network Responsibilities:

-Provide a robust, streamlined infrastructure to facilitate access to readily available human material for medical research and clinical trials.

-Create a structure for the governance of the use of human tissue in Scotland.

-Facilitate the identification of material & collections held locally and if appropriate make them available for research.

Biorepository Aims

- Facilitate patient wishes to be able to donate their samples for research
- Facilitating high quality research (international) in line with areas defined as priority for investment by the NHS in Scotland, the academic partners and the Scottish Government.
- Enhancing the capacity of the NHS in the West of Scotland and academic partners to increase their competitive grant income in particular from research councils and major funding bodies.
- Facilitating the access to human tissues to industry (mainly Biopharmaceuticals, Biotechnology and Contract Research Organisations) so to enhance the future wealth and health of the nation.

Governance/Ethical approvals and consent

The GGGC Biorepository has NHS Research Ethics Committee (REC) approval to issue samples to researchers within a defined set of research studies. If your proposed study falls within these parameters, your study will not require further REC approval.

The responsibilities placed on the NHS GGC as custodians of tissue and data is to ensure that any proposed research falls within the terms of the overarching REC approval and national regulations. It is also responsible to review the application for scientific merit or see evidence of such.

ACCESS:

How to work with the Biorepository

Initial contact –

For general queries and enquiries please contact the Biorepository using the contact details given in this document.

For any initial project queries or feasibility enquiries about a tissue collection please contact the Human Tissue Governance Manager.

Application –

For projects that require approval under our Research Tissue Bank ethics please make initial contact as above and then, once the Biorepository are aware of your planned study, please submit an online application to our web portal:

http://www.nhsgbr.org.uk

Cost Recovery –

The Biorepository operates on a cost recovery basis for works carried out. This is a requirement of the CSO and our agreement with them. Costs will be estimated according to the works carried out and in line with the National Institute of Health Research costing template. Researchers must agree to cost recovery before a project is approved.

Approvals process –

Projects that are to be approved under our Research Tissue Bank ethics undergo thorough review and feasibility checks by our Human Tissue Governance Manager prior to circulation to our Biorepository Management Group. This group comprises clinical academics, Pathologists, lay members and REC members. The process for approval is outlined in figure 2.

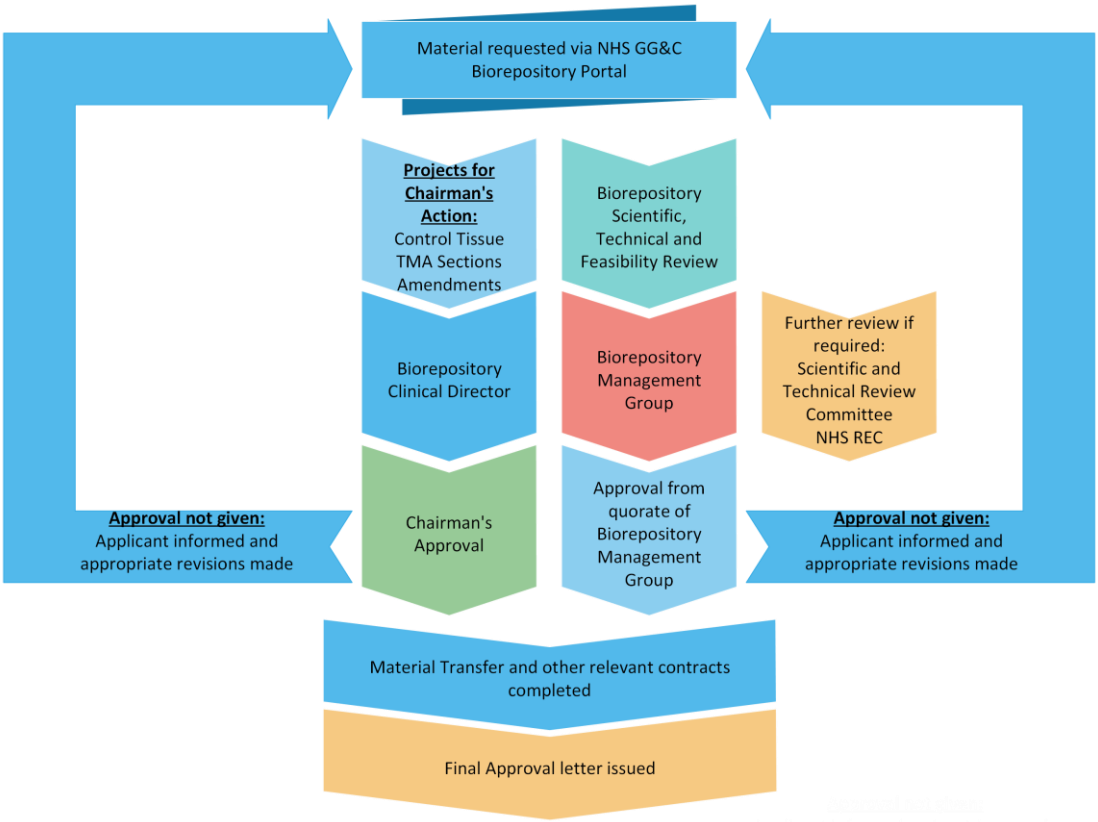


Figure 2. Route to approval.

<u>The Biorepository can also provide short term or long term storage of samples.</u>

Figure 3. Biorepository Storage Facilities

Contact details and opening hours –

Our routine working hours are 9am-5pm Monday to Friday

NHSGGC Biorepository
Level 3, Laboratory Medicine Building
Queen Elizabeth University Hospital

1345 Govan Road
Glasgow
G51 4TF

Websites –

NHSGGC : Biorepository at NHSGGC

Biorepositories and Tissue Services | NHS Research Scotland | NHS Research Scotland

NHSGGC Pathology

NHSGGC Safe Haven

Phone/email –

Biorepository.research@ggc.scot.nhs.uk

0141 354 9490

The department's email account is monitored daily, and is suitable for the receipt of patient-identifiable information. Personal or identifiable information should not be added to the subject line when emailing. Patient identifiable information should only be sent to the laboratory from secure accounts such as scot.nhs.uk or nhs.net accounts. Do NOT send patient identifiable information to the laboratory from any other email provider.

Main points of contact –

Biorepository Manager – Clare Orange clare.orange@ggc.scot.nhs.uk 0141 354 9495

Human Tissue Governance Manager – Fiona Graham Fiona.graham3@ggc.scot.nhs.uk 0141 354 9494

Clinical Director – Dr Craig Dick (Consultant Pathologist)

Complaints procedure

We endeavour to provide a good service. Our complaints policy and procedure reflects NHS Greater Glasgow and Clyde's commitment to welcoming all forms of feedback, including complaints, and using them to improve services, to address complaints in a person-centred way and to respect the rights of patients, families and staff involved. It will support our staff to resolve complaints and to conduct thorough and fair investigations so that we can make compassionate, yet evidence-based decisions, on the facts of the case.

Should you have any comments, suggestions, cause for concern or complaints about the service you receive from the Biorepository, please contact the Biorepository Manager using the contact details above.

NHSGGC Complaints Procedure

NHS Patient Confidentiality Policy

Available Tissue –

We have a number of existing collections under our Governance that are available for use under an approved application –

- TransSCOT (Colorectal cancer cohort)
- ASTERIX (Covid19 samples)

In addition we are able to support access to a wide variety of tissue samples from across a range clinical disease specialities as below:

Immunity & Inflammation	Hepatology	Oral & Dental
Cancer	Mental Health Studies	Orthopaedics
Cardiovascular	Metabolic & Endocrine	Paediatrics
Dermatology	Microbiology	Regenerative Medicine
Diabetes	Musculoskeletal	Renal
Gastroenterology	Neurology	Reproductive Health
Haematology	Ophthalmology	Respiratory

Quality Processes and Accreditation

NHSGGC Biorepository is accredited by NHS Research Scotland to operate as one of the nodal Biorepositories. Glasgow Biorepository also holds an HTA Licence for human application which enables us to support research trials that undertake the procurement of tissues and cells for human application as medicines. As part of NHSGGC R&I we also follow MHRA guidelines and all of our team are GCP trained.

Other Services –

- Access to surplus diagnostic tissue – fresh, frozen or FFPE
- Access to Pathology Archive material
- Processing to FFPE
- Sectioning
- Basic blood processing/aliquoting
- Clinical Trials support
- Tissue storage

Through the Glasgow Tissue Research Facility (GTRF) you can also access –

- TMA construction
- H&E staining
- Digital Pathology Scanning and Image Analysis

Clinical trials support

The Biorepository can provide laboratory support for clinical trials which have a tissue storage requirement. We also carry out some straightforward blood and tissue processing and support fixed tissue sample requirements in collaboration with the Diagnostic Pathology Department.

If you would like to contact us about a clinical trial please complete the Biorepository Engagement Form (Appendix 1).

Legacy collections

Previous collections can also come under our governance. Any tissue collected as part of a previously approved Research Ethics Committee approved project can be stored for the duration of that approval and for consented purposes only. The Biorepository can adopt tissue collections where the project has ended

Please contact us if you would like to find out more about adopting a legacy collection or complete the application form in Appendix 2.

Appendix 1. Biorepository/Pathology Engagement Form for Research.

Information provided in this form will be used to calculate Biorepository costs for supporting the study detailed. Information should be as full and accurate as possible and any alterations to the requirements notified as soon as possible to the Biorepository Manager.

The costs agreed on submission of this form will be used to populate the R&I finance Grant submission form if required.

Study Speciality			
Study Full Title			
Study Acronym		Sponsor	
R&I Reference No.		Eudract No.	
Chief Investigator		Project Manager	
Chief Investigator Contact details		Project Manager Contact details	
Planned Start Date		Planned Recruitment End date/duration of study	
Contract required?	Y/N	Type of contract	MTA/SLA/Collaboration Agreement/Other (please list)
Funding	Y/N/in progress	Funding Body	
Is archived Diagnostic tissue required	Y/N	For what purpose?	i.e.Screening/Primary/ Secondary/Tertiary objectives
Is the Biorepository acting as a central laboratory processing and/or storage facility	Y/N	Number of sites	
Storage required	Y/N	Processing	Y/N

If processing is required please give details	i.e. Number of aliquots, specific processing requirements/time dependent steps		
If Storage is required how long for?		Temperature dependent storage?	RT/-20/-80
Frequency of access to samples stored		Any shipment required to external sites for testing	Y/N Details (i.e. where to/how often):
Expected number and type of samples per patient Expected recruitment		Expected number and type of samples per site	
Biorepository Staff Requirements	i.e. time, WTE	Out of hours required	Y/N/Maybe (Standard hours Mon-Fri 9-5)
HTA Licence requirement i.e. TILS study	Y/N		
Additional Training Requirements	Y/N	If Yes please describe	
Additional/Specialist Equipment Requirements	Y/N	If Yes please describe	
Any specific consumable requirements	Y/N	If Yes please describe	i.e. storage vessels, specified labelling system
Laboratory Manual available	Y/N	Sample Handling Manual available	Y/N

Terms and Conditions:

All details in this form are agreed as signed below by Biorepository and Study Representative.

Any alterations or amendments to protocol and/or requirements are to be verified and approved by Biorepository Manager with an adjusted cost recovery template agreed by both parties.

Any samples stored are to be held for the above agreed time period only. After this if extended storage is required terms and costs must be agreed with the Biorepository on the understanding that this will be on a capacity and resource available basis and not guaranteed.

Following the agreed period of time for storage if an extension is not required or available then samples revert to the custodianship of the Study Sponsor and it is the responsibility of the CI to determine alternative storage. Samples stored for future use without continuing ethics will fall under the Governance of NHSGG&C Biorepository.

Completed by		Signature	
Date			
Agreed by (Biorepository)		Signature	
Cost Recovery agreed		Date	
Biorepository Manager Signature		Study PM or CI Signature	

Amendment No.	Details	Date	Signed (Biorepository)

Appendix 2. Application to store tissue collections under Biorepository Governance

Please note that if samples are to be stored out with NRS GGC Biorepository under our Governance we will ask you to undergo a site audit to ensure we are meeting NRS accreditation standards at this site.

Applicant Information

Principal Investigator:

Email:

Contact Number:

Address:

Sample Collection Information

Are the samples being transferred in from an external location?

☐ Yes (give details): ☐ No

Current sample location:

Proposed storage location: (if different to above)

Has the project / sample collection previously been approved by NHS REC?

☐ Yes ☐ No

Reference and expiry date if applicable:

Has the project/ sample collection been approved by any other REC?

☐ Yes (give details below) ☐ No

Details:

Where were the samples collected from the donors? (tick all that apply)

☐ Scotland

☐ England

☐ Wales

☐ Northern Ireland

☐ Solely Within NHS Greater Glasgow and Clyde

Are the samples currently stored in a Research Tissue Bank?

☐ Yes ☐ No

Details if applicable:

Have all donors previously consented for the long-term storage for future research?

☐ Yes ☐ No

Summary sample information

Detail the number of each sample type to be stored.

Collections	Number of samples				
	Frozen (liquid N_2)	Frozen (-80°C)	Frozen (-20°C)	Refrigerated	Ambient
Whole Blood (unseparated blood samples)					
Serum					
Plasma					
Urine					
Saliva					
Solid Tissue type:					
Solid Tissue type:					
Solid Tissue type:					

Supporting Documents

Blank copy of participant information sheet(s) ☐ Attached ☐ Unavailable

Blank copy of consent form ☐ Attached ☐ Unavailable

Ethics approval letter(s)	☐ Attached	☐ Unavailable
Material transfer / service agreements	☐ Attached	☐ Unavailable
GCP Training Certificate	☐ Attached	☐ Unavailable
Full electronic record of samples	☐ Attached	☐ Unavailable
Electronic record of consent opt-outs	☐ Attached	☐ Unavailable

Submitted by

Name:

Job title:

Contact tel:

Contact email:

Signature:

Date of submission:

Reviewed and accepted by

Name:

Job title:

Email:

Signature:

Date accepted: