STANDARD OPERATING PROCEDURE FOR OBTAINING APPROVAL FOR THE PROVISION AND USE OF HUMAN TISSUE SAMPLES FOR RESEARCH IN NHS FIFE

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1. PURPOSE

This document describes the procedure in NHS Fife for obtaining approval for the provision and use of human tissue samples for research projects or for donation of tissue to a research biorepository.

The aim of this SOP is to protect the rights, welfare and safety of participants and potential participants involved in projects which use their tissue (throughout this SOP, "tissue" is understood to include the associated data that may be linked with it).

It is the responsibility of all researchers using this SOP to ensure they are using the latest version of it. The latest version is available via NHS Fife StaffLink, EDGE and the R&D section of the NHS Fife website (www.nhsfife.org/research). For guidance, contact the R&D Department via fife.randd@nhs.scot.

2. APPLICABILITY

This SOP applies to all staff involved in the provision and/or use of human tissue and all staff involved in the review of requests submitted to the NHS Fife Tissue Governance Group (TGG).

3. POLICY

3.1 Human tissue is defined as material that has come from a human body and consists of or includes human cells.

3.2 As part of the Accreditation Scheme for the Collection and Storage of NHS Tissue in Scotland, the NRS network of biorepositories has been charged with overseeing the governance of collections of surplus or prospectively collected tissue derived from NHS patients that are intended for research, and acts as a central resource through which requests for access to these patient samples and human tissue for research should be notified and channelled.

NHS Fife acts as a Satellite Tissue Collection site and all collections of tissue for research purposes from NHS Fife patients must be registered with, and managed by, an NRS Biorepository.

3.3 The NHS Fife TGG has been established to provide assurance to the NHS Fife Research Governance Group that appropriate governance procedures are in place concerning requests from researchers to:

- Create a collection of tissue that is not being routinely collected for clinical purposes.
- Use tissue from a collection that has not been routinely collected for clinical purposes.

The NHS Fife TGG is accountable to the NHS Fife Medical Director and comprises:

- Tissue Governance Lead, NHS Fife
- Tissue Governance Manager, NHS Lothian or NHS Tayside
- Assistant R&D Director, NHS Fife
- R&D Research Coordinator, NHS Fife
- Research active clinician within a clinical area relevant to the tissue request
- Pathologist, NHS Fife
- Clinical Technical Services Manager, NHS Fife

Responses from a quorum consisting of 4 members of the TGG are required before any application can be approved and a majority decision is required.

3.4 The NRS Biorepositories holds approval from a Research Ethics Committee (REC) to collect, store and distribute samples and associated data from NHS Fife patients to staff who satisfy the NHS Fife TGG that their application is both ethically and scientifically appropriate. Occasionally, for certain projects (e.g., research involving animals, research where procedures are to be performed or samples collected in addition to routine care) the NRS Biorepository and NHS Fife TGG may require that staff seek formal NHS Research Ethics Committee (REC) and/or R&D Approval before sanctioning their request to collect or provide tissue or data. Guidance on the need for separate REC and/or R&D Approval is available from the TGG.

3.5 There are a number of different scenarios in which tissue may be sought for research purposes and each of these has different Local Management Review and Approval requirements:

a) Research project with NHS Fife Local Management Approval (see Section 4.1).

b) Research project with Local Management Approval from another Health Board requesting access to archived tissue held in NHS Fife (see Section 4.2).

c) Research project with Local Management Approval from another Health Board requesting provision of freshly collected tissue from NHS Fife patients (see Section 4.3).

d) Request from NHS Fife staff to collect and provide tissue samples to an NRS biorepository (see Section 4.4).

e) Request to use and/or process tissue from a collection held in NHS Fife which is registered with an NRS Biorepository (see Section 4.5).

f) Request from an accredited biorepository or commercial accredited tissue provider for NHS Fife to provide specific tissues direct to that accredited biorepository or commercial tissue provider for storage as part of their collection and provision by them to a 3rd party(ies) (see Section 4.6).

4. PROCEDURE

4.1 Research Project with NHS Fife Local Management Approval

For these projects, all procedures for the provision and use of tissue will be covered by the research governance and review processes for these projects (see R&D SOP11 - Process of Review for Local Management Approval).

4.2 Research Project with Local Management Approval from another Health Board – Requesting Access to Archived Tissue Held in NHS Fife

4.2.1 For these projects, NHS Fife Local Management Approval is **not required**, however the NHS Fife R&D Department requires evidence that the study has had relevant regulatory review and approval.

4.2.2 The R&D Approvals Team must request a copy of the following documentation:

- Approval letter from the Research Ethics Committee confirming the study has had a favourable review.
- Copy of the Local Management Approval Letter from the requesting Health Board
- Confirmation of any funding available to reimburse NHS Fife's Pathology Department for their work.

4.2.3 The R&D Approvals Team must review the documentation provided and draft an acknowledgment letter (Doc Ref 41-01) confirming that there are no objections to the samples being released.

4.2.4 This acknowledgement letter must be reviewed and signed by the NHS Fife Medical Director (or delegate) before being sent by the R&D Approvals Team to the person requesting the tissue. Copies of the acknowledgement letter must also be sent to the NHS Fife Pathology Department and the NHS Fife R&D Business Accountant (where funding is available).

4.2.5 The Pathology Department will review each request for archived tissue on an individual patient basis, to determine if there might be a requirement to use the tissue for future diagnostic purposes. Prior to releasing the samples, the Pathology Department will also require a copy of the relevant, signed patient consent forms, if consent is in place, or proof of ethical approval that the samples can be used as diagnostic surplus and are consent exempt.

4.2.6 For samples where funding is available, the R&D Approvals Team will advise the R&D Business Accountant who will arrange to raise the appropriate invoice.

4.3 Research Project with Local Management Approval from another Health Board – Requesting Provision of Freshly Collected Tissue from NHS Fife Patients

For these projects, NHS Fife Local Management Approval is required and the R&D Approvals Team must advise the research team on the process for applying for this approval (see R&D SOP11 - Process of Review for Local Management Approval).

4.4 Request from NHS Fife Staff to Collect and Provide Tissue Samples to an NRS Biorepository

See also Section 4.5 which details the process for requests to use and process tissue from a collection held in NHS Fife which is registered with a biorepository

4.4.1 All NHS Fife and St Andrews University staff must register tissue collections for research purposes with either the NHS Lothian NRS Bioresource, via the Lothian Tissue Governance Manager (rie.tissuegovernance@luht.scot.nhs.uk) or with the NHS Tayside Biorepository (http://www.tissuebank.dundee.ac.uk/?page=main).

The individual biorepository will provide guidance on the registration process.

4.4.2 Where REC and/or NHS Fife Local Management Approval have not been obtained, the biorepository will advise the Lead Applicant if further approvals are required.

4.4.3 The completed registration application will be circulated electronically to the NHS Fife TGG by the biorepository for their consideration. If any member of the NHS Fife TGG is also a co-applicant on the registration application, they will be unable to take part in the review process and a suitable replacement group member will be identified by the Assistant R&D Director to review that application.

4.4.4 Depending on the responses received from members of the TGG, the request for approval to collect tissue will either be:

- approved
- approved pending confirmation of the study specific REC Favourable Opinion/R&D Approval (if deemed appropriate by the TGG)
- further clarification sought prior to approval, providing a satisfactory response is received or
- rejected

4.4.5 The TGG will aim to review requests and issue a response within 10 working days of receipt of all required information. In order to facilitate the process, responses will be sent via email with a follow-up letter then issued. In exceptional circumstances, where the application has urgent implications for patient care, efforts will be made to expedite the process.

4.4.6 If successful, applicants requesting permission to collect tissue samples will be contacted by the R&D Approvals Team to confirm approval.

4.4.7 Following approval of a request to collect tissue, the Lead Applicant or delegate should provide the Lothian Tissue Governance Manager with:

- Regular updates regarding the number of samples stored, used in research, distributed and disposed of. These updates will be requested by the biorepository every 6 months following the date of approval.
- Notification of any significant change to the details provided at registration, such as contact details or location of storage.

4.5 Request to Use and/or Process Tissue from a Collection Held in NHS Fife which is Registered with an NRS Biorepository

4.5.1 Applicants wishing to use tissue samples from collections stored in NHS Fife should submit a request to the appropriate biorepository.

Applicants submitting a request relating to samples from other Health Boards in addition to NHS Fife need only complete one request form and should indicate the number of samples required from each Health Board.

4.5.2 Prior to submitting a request, applicants are advised that they must have the support of an NHS Fife Clinician and Pathologist so that the NHS Fife TGG can ensure material of the appropriate type and quality is provided. Applicants requiring assistance with enlisting the help of an NHS Fife Pathologist or Clinician (e.g., an external requestor with no local co-applicant) can contact the NHS Fife TGG.

4.5.3 Submissions should contain sufficient detail regarding their purpose in order to allow a full and proper assessment of the scientific and technical merit of the project and the anticipated benefit to be made.

4.5.4 Details of the request will be circulated electronically to the NHS Fife TGG by the NRS Biorepository for their consideration. If any member of the TGG is also a co-applicant on the Request Form they will be unable to take part in the review process and a suitable replacement group member will be identified by the Assistant R&D Director to review that application.

4.5.5 If the NHS Fife Pathology Department is required to perform any form of manipulation of samples (e.g., embedding, cutting sections, staining, extracting nucleic acid etc) these requirements should be detailed in the request. Applicants will be expected to cover any associated costs which will be advised by the NHS Fife Clinical Technical Services Manager.

4.5.6 Depending on the responses received from members of the NHS Fife TGG, the Tissue Request will either be:

- approved
- approved pending confirmation of the study specific REC Favourable Opinion/R&D Approval (if deemed appropriate by the NHS Fife TGG)
- further clarification sought prior to approval, providing a satisfactory response is received or
- rejected

4.5.7 The NHS Fife TGG will aim to review requests and issue a response within 10 working days of receipt of all required information. In order to facilitate the process, responses will be sent via email with a follow-up letter then issued. In exceptional circumstances, where the application has urgent implications for patient care, efforts will be made to expedite the process.

4.5.8 If successful, applicants requesting tissue samples will be contacted by the R&D Approvals Team to make arrangements to receive the tissue or other samples that have been requested.

4.5.9 If and when approval is received from the TGG for a given project, access to material is dependent on the Lead Applicant abiding by the terms and conditions laid down by the TGG.

4.5.10 Following approval of a request to use tissue, the Lead Applicant or delegate should provide the TGG with:

- Regular updates regarding the number of samples stored, used in research, distributed and disposed of. These updates will be requested by the TGG every 6 months following the date of approval.
- Notification of any significant change to the details provided in the application, such as contact details or location of storage.

4.6 Request from an NRS Accredited Biorepository or Commercial Tissue Provider for NHS Fife to Provide Specific Tissues Direct to that Biorepository or Tissue Provider for Storage as Part of their Collection and Provision by them to a 3rd Party(ies)

4.6.1 For these requests, NHS Fife Local Management Approval is **not required.** However, the NHS Fife R&D Department requires evidence that the study has had relevant regulatory review and approval.

4.6.2 The R&D Approvals Team must request a copy of the following documentation:

- Approval letter from the Research Ethics Committee to confirm the study has had a favourable review.
- Participant recruitment paperwork.
- Confirmation that the biorepository has a current accreditation (not applicable to commercial tissue providers/banks).
- Supply Agreement.

4.6.3 The R&D Approvals Team must review the documentation provided and arrange for any Supply Agreement to be reviewed and signed by the NHS Fife Medical Director (or delegate).

4.6.4 The R&D Approvals Team will then provide a letter acknowledging the request and receipt of the required documentation and a signed copy of any Supply Agreement to the person requesting the tissue.

4.6.5 Copies of the acknowledgement letter must also be sent to the NHS Fife Pathology Department and the NHS Fife R&D Business Accountant (where funding is available).

4.6.6 If the biorepository is a commercial organisation, an appropriate contract must be put in place confirming the roles and responsibilities of the parties and the financial arrangements.

4.6.7 Prior to releasing the samples, the Pathology Department will also require a copy of the signed patient consent forms for each tissue sample requested.

4.6.8 For samples where funding is available, the R&D Business Accountant will arrange to raise the appropriate invoice.

4.7 Obtaining Written Informed Consent for Donation of Surplus Tissue and Data

4.7.1 Consent for donation of surplus tissue and data must be obtained by a member of the patient's clinical care team, a research nurse or other appropriately trained member of staff.

4.7.2 Any member of staff involved in obtaining written informed consent from patients must be employed by NHS Fife or hold an Honorary Clinical contract, Honorary Research contract or Letter of Access from NHS Fife.

4.7.3 All staff involved in obtaining consent must review and adhere to the policies and procedures prescribed by the relevant accredited biorepository or commercial tissue provider.

4.7.4 Consent for donation of surplus tissue and data must be obtained and documented using the recruitment paperwork submitted by the biorepository or commercial tissue provider for review by the NHS Fife R&D Department.

When obtaining consent for the collection and provision of tissue samples to an NRS Biorepository (see Section 4.4), the procedures prescribed by the relevant biorepository must be followed. unless otherwise advised by the TGG or unless study specific documents have been approved by a REC.

4.7.5 NRS Biorepositories have REC approval for the release of anonymised, unconsented data.

If consent is not being obtained then approval must be obtained from the NHS Fife Caldicott Guardian or Public Benefit and Privacy Panel for Health (PBPP) before identifiable data can be accessed.

5. ASSOCIATED DOCUMENTS

R&D SOP11 - Process of Review for Local Management Approval.

Doc Ref 41-01 - Template Acknowledgment Letter for Requests for Release of Archived Tissue.

6. ABBREVIATIONS

NRS	NHS Research Scotland
PBPP	Public Benefit and Privacy Panel for Health (PBPP)
R&D	Research and Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TGG	NHS Fife Tissue Governance Group

7. REFERENCES

Letter from Chief Medical Officer regarding Accreditation Scheme for the Collection and Storage of NHS Tissue in Scotland
http://www.sehd.scot.nhs.uk/cmo/CMO(2011)07.pdf

8. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Julie Aitken R&D Trials Facilitator	30 Mar 2017	New
2	Julie Aitken R&D Trials Facilitator	05 July 2019	Reformatted in line with current SOP template and updated to reflect current practice.
3	Aileen Yell R&D Research Coordinator	21 Sept 2021	Updated to cover NHS Tayside Biorepository in addition to NHS Lothian Bioresource.

9. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research & Development Director, NHS Fife Signature: 	21 Sept 2021