STANDARD OPERATING PROCEDURE FOR COLLECTION, PROCESSING, STORAGE AND TRANSPORTATION OF BIOLOGICAL SAMPLES FOR CLINICAL RESEARCH

SOP NUMBER:	**Fife R&D SOP25**
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1. PURPOSE

This document describes the procedure used for the collection, processing, storage, and transportation of biological samples in NHS Fife.

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

2. APPLICABILITY

This SOP applies to all staff who collect, process, store and/or transport biological samples from a participant in a clinical research study.

It is the responsibility of the Chief/Principal Investigator (CI/PI) to ensure that study specific samples are collected, processed, stored, and transported according to the study protocol, sample processing instructions and/or lab manual.

4. POLICY

4.1 All biological samples required for research purposes in NHS Fife must be collected, processed, stored and analysed in a demonstrable manner and **ALL** relevant information regarding the sample life history must be recorded in order to ensure a full audit trail of each sample (from the point of collection to disposal) can be produced for the purposes of monitoring/audit/inspection.

4.2 Samples must be collected only when all the appropriate approvals are in place, and consent has been obtained from the patient. This includes screening and baseline tests.

4.3 Samples must be collected and processed at the appropriate time points indicated in the study protocol.

4.4 Samples must be collected in accordance with Chapter 7 of the NHS Fife Infection Control Manual: Safe Infection Control Practice in Specimen Handling (available via NHS Fife StaffLink).

4.5 All staff must receive the appropriate training to carrying out any procedures relating to collection, processing, transportation and storage of biological samples (See R&D SOP42 – Training for Research Staff) and must be listed on the Delegation of Duties (Doc Ref 13-01), where appropriate.

4.6 All equipment used for sample processing e.g., aliquoting, centrifugation, incubation and/or refrigeration, must be serviced and calibrated at least annually and servicing and calibration records must be uploaded and stored on Q-Pulse (see R&D WI26).

4.7 Freezers and fridges used for sample storage must have continuous temperature monitoring performed and any temperature excursions managed (see NHS Fife SOP46)

5. PROCEDURE

5.1 Study set up for Collection, Processing, Storage and Transportation of Biological samples

5.1.1 When setting up a study involving collection and analysis of biological samples it is important to consider the following:

- Sample Type – are samples being collected for routine (standard care) analysis or for specific study related analysis?
- Will the local NHS Fife laboratories be involved? Is an Analytical Plan required (see R&D SOP29)? If it does, a 'Research Team – Laboratory Analytical Plan' workflow must be added and completed on EDGE and signed off by the appropriate Lab Manager.
- Storage - If the samples are to be stored for any length of time then consideration must be given to where they will be stored, how they will be transported (including any restrictions on timelines between collection and processing to storage which are detailed in the protocol), storage conditions (during transport and at destination) and associated storage and transportation costs.

5.2 Sample Labelling

5.2.1 Once samples are processed, they must be pseudonymised in accordance with the study protocol and any data protection and ethical requirements for ensuring anonymity to the study subjects. As a minimum, samples must be labelled with the following, unless otherwise specified in the study protocol:

- Study Identifier.
- Patient Initials.
- Patient ID number.
- Study Time Point and date.

5.2.2 The date/time format used should be dd/mmm/yyyy unless otherwise defined in the study protocol.

5.2.3 Appropriate freezer resistant labels and/or indelible marker pens must be used that comply with the storage conditions. Note any instructions on positioning sample labels that are detailed in the protocol.

5.2.4 High-risk samples must be labelled in accordance with NHS Fife guidelines (See Laboratory Services Handbook available via StaffLink).

5.3 Processing Samples

5.3.1 When processing biological samples staff must:

- wear protective clothing. This may be in the form of a uniform, a laboratory coat, or a disposable apron.
- wash their hands before handling biological samples according to the procedure described in the Chapter 2 of the NHS Fife Infection Control Manual: Standard Infection Control Precautions.
- wear disposable gloves and goggles when there is a risk of contamination. Gloves and goggles must always be worn when aliquoting.
- complete the Equipment Usage Log (Doc Ref 25-03) to document any sample processing performed (see relevant equipment Work Instructions).

5.3.2 Record the details of any sample processing on the Sample Tracking and Processing Log (see Doc Ref 25-01), unless a study specific form is provided.

5.3.3 Sample processing details will vary for individual studies, but may include:

- study identifier
- patient identifier (initials/study ID number)
- date and time of sample collection
- time on wet ice
- time & speed in centrifuge
- time in dry ice
- time in liquid nitrogen
- time placed in fridge or freezer.

5.4 Aliquoting Serum Plasma Samples

5.4.1 Centrifuge the whole blood. Refer to NHS Fife R&D WI12 - Use of Centrifuge.

- remove the blood from the centrifuge and place into a storage rack next to the centrifuge.
- ensure that the collection tubes for the serum plasma are labelled correctly and are placed in the rack ready for aliquoting.
- carefully unscrew the top off the separated blood tube ensuring that the serum plasma and blood don't mix together again. Pipette out the serum plasma from the blood cells by squeezing the pipette together at the top, enabling a suction effect, avoiding any air bubbles in the plasma. The blood tube can be tilted slightly to make pipetting easier.
- place the serum plasma into the labelled collection tube, taking care not to over fill the tube as this may cause it to crack once frozen and ensure that the cap or lid of the tube is securely closed to avoid any leakage or spillage.
- Discard the whole blood tube and pipette in an orange lidded sharps disposal container.

5.5 Sample Storage

5.5.1 Samples must be stored in an appropriate labelled container so that loose individual samples are not lost or misplaced. Containers may include poly bags, fibreboard specimen boxes, racks, or plastic boxes.

5.5.2 When samples are placed in a fridge or freezer the Inventory Log (Doc Ref 25-02) for that fridge or freezer must be updated with the sample details and the location of the samples. This will avoid searching for samples with open doors and allows an accurate record to be maintained of contents in the event of any freezer failure. When samples are removed from a fridge or freezer the log must be updated to reflect this.

5.5.3 Where possible, samples must not be allowed to accumulate and remain in the freezers for longer than 6 months. This must be discussed with the study Sponsor during study set-up and any requirements for long term storage of samples agreed in advance.

5.6 Sample Transport

5.6.1 Staff transporting biological samples in their own vehicles must have business class insurance for the car they are using.

5.6.2 All employees must use dangerous goods boxes (available from the R&D Support Officer) when transporting biological samples and comply with the guidance in Appendix 1. Further advice and guidance are available from NHS Fife Health & Safety Services (Fife.safety-fife@nhs.scot).

5.6.3 If samples are collected for routine “standard care” analysis they should be processed and transported to local laboratories in line with local standard procedures.

5.6.4 Where study specific samples are being analysed by the local NHS Fife Lab then these must be identified as research study samples in accordance with the Analytical Plan agreed with the Lab Services Manager.

5.6.5 If a sample or an aliquot of a sample is sent for analysis to an external centre, these must be collected, packaged, and transported as described in the protocol. If the protocol is unclear, then the Sponsor must be contacted to establish the mode of transport. The sample details and destination should be recorded on the sample log. Confirmation of receipt from the receiving laboratory should be obtained.

5.6.6 If a courier is needed to transport samples, the courier’s details and accompanying paperwork should be retained in the Investigator Site File to provide evidence of transport including collection and delivery sign off.

5.6.7 Temperature sensitive samples should use a “tag” system to supply evidence that samples have not exceeded the agreed temperature during transit.

5.6.8 Where samples are being transported in dry ice then staff must have completed the appropriate IATA training and must follow R&D WI20 – Transporting Samples in Dry Ice.

5.7 Requesting and Transporting Tissue Blocks

If the study requires tissue blocks or slides to be transported out with the NHS Fife Cellular Pathology Lab, then the process for this must be documented in an Analytical Plan (see R&D SOP29) agreed with the relevant Lab Services Manager and to ensure that specimens sent for testing out with the department are handled in an appropriately controlled manner.

5.8 Long Term Storage

If the study protocol and patient consent allow it, samples may be retained at the end of a study. Tissue samples (i.e., any sample containing cellular material) should be stored securely in a temperature-controlled environment and be link-anonymised (i.e., labelled without any patient identifiable information).

If there is a requirement to store samples from NHS Fife locally as part of a tissue collection, advice must be sought from the R&D Research Coordinator and either NHS Lothian NRS Bioresource, via the Lothian Tissue Governance Manager (rie.tissuegovernance@luht.scot.nhs.uk) or the NHS Tayside Biorepository (http://www.tissuebank.dundee.ac.uk/?page=main) (see R&D SOP41 - Obtaining Approval for Research Involving Human Tissue Samples in NHS Fife).

6. ASSOCIATED DOCUMENTS

Doc Ref 25-01 - Sample Tracking and Processing Log
Doc Ref 25-02 - Fridge/Freezer Sample Inventory Log
Doc Ref 25-03 - Equipment Usage Log

R&D SOP29 – Preparing an Analytical Plan for Laboratories Associated with Clinical Research).
R&D SOP41 - Obtaining Approval for the Provision and Use of Human Tissue Samples for Research in NHS Fife.
R&D SOP46 - Temperature Monitoring of R&D Fridges & Freezers

R&D WI12 - Use of Centrifuge
R&D WI20 - Transporting Samples in Dry Ice
R&D WI26 - Management of Equipment

7. ABBREVIATIONS

CI	Chief Investigator
GCP	Good Clinical Practice
PI	Principal Investigator
R&D	Research and Development
SOP	Standard Operating Procedure

8. REFERENCES

(Please contact the Quality & Performance Team (fife.researchquality@nhs.scot) if you are unable to access these via StaffLink)

NHS Fife Infection Control Manual:
https://app.joinblink.com/#/hub/5d4d08ce-f3a8-4857-8d08-cef3a838571c.

NHS Fife Laboratory Services Handbook:
https://app.joinblink.com/#/hub/1920d3fb-528e-4272-96a6-ecb0162db19b.

9. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Julie Aitken R&D Trials Facilitator	02/02/2015	New
2	Julie Aitken R&D Trials Facilitator	08/06/2018	Minor changes for clarity only
3	Julie Aitken R&D Quality & Performance Lead	02/06/2020	Reformatted in line with current SOP template and text refreshed throughout for clarity. Reference to R&D SOP29 added.
4	Julie Aitken R&D Quality & Performance Lead	09 Nov 2023	Reference to NHS Fife WI13 replaced by NHS Fife SOP46. The need to consider restrictions on timelines between collection, processing and storage during the set-up stage has been highlighted. Date format for labelling samples has been specified. Need to have Business Class insurance when transporting samples has been clarified. Need for staff to complete IATA training and reference to Fife R&D WI20 added. Need for completion of an Analytical Plan when local labs involved and reference to SOP29 added. Further guidance on packaging and transporting samples added to Appendix 1. Point of contact for further guidance from NHS Fife Health & safety services added.

10. APPROVAL

APPROVED BY	Date
Professor Frances Quirk, Assistant Director RIK, NHS Fife Signature: 	09 Nov 2023

APPENDIX 1

Dangerous Goods Awareness for Staff Transporting Small Quantities of Clinical Waste and/or Clinical Specimens

This guidance has been provided to ensure legal compliance with the above, and in particular to ensure that staff are aware of the key issues in order to comply with the relevant legislation.

There are 9 different classes of goods considered dangerous for transport. The groups which staff may carry are Class 6.2, Infectious Substances and covers small amounts of clinical waste (including sharps boxes*) or specimens. As staff are likely to only carry small amounts, a number of the legal requirements are removed, making compliance much simpler. However, there are still things that must be in place to ensure staff are fulfilling these legal obligations.

Key points to note:

1. Items must be packed in the UN approved rigid leak-proof package. The UN approved container should have the designation 'UN3373' (as below) visible on the outside of the container and it should have some absorbent material (cotton wool or absorbent pad) inside it should one of the samples leak during transit.

   Example of UN3373 label

2. Items must be stowed in the vehicle out of direct sunlight and away from foodstuffs. The container should be securely restrained in the vehicle so that in the event of an accident (or similar) it cannot 'fly about' either the boot or the cabin of the vehicle, potentially injuring the driver and passengers and disgorging its contents and then potentially covering the interior of the vehicle and its occupants in biological material(s).

3. Clinical waste sacks must be placed inside a rigid package as described above

4. Leaking packages must not be transported

5. If a package does leak, the load compartment must be cleaned and disinfected (Refer to Infection Control Manual section 2.6)

6. If staff are using their own vehicle for this work, they must have Business Class Insurance in place.

7. If questioned by an enforcing officer (Police / VOSA or HSE) about the clinical waste or specimens being carried, the transport boxes must contain the following information *for enforcing officers:*

   The driver of this vehicle is an employee of NHS Fife. Under the exemptions within Chapter 1.1.3.6 of ADR this vehicle may be carrying limited amounts of UN 3291 (Infectious Substances) and/or UN3373 (Biological Substance, Category B).

   * A sharps container once finally closed and locked is a compliant dangerous goods container in its own right, which may be carried in the boot of a car. One which is only temporarily closed is not and must be carried in a UN container as in 1 above.