SOP number	**17.041**	Version	**2.0**
Title	**GCRF Management of Samples**		

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SOP category	17 NHS GG&C Clinical Research Facility – Clinical

Staff category

Staff Category	R	A	C	I
Nursing	X			
Administration	X			
Principal Investigator	X			
Clinical Research Fellow	X			
GCRF Manager		X		
GCRF Associate Director				X
Senior R&I Manager				X

1. Scope

This SOP applies to all samples collected for research participants to be processed and/or stored at Glasgow Clinical Research Facility (GCRF) sites.

2. Purpose

The purpose of this SOP is to describe the safe management of samples i.e. processing, storage and equipment, within GCRF sites.

It is the responsibility of each PI to ensure samples are processed, stored and shipped in accordance with study protocol.

3. Procedures

3.1. Training

All staff must be trained before processing samples within GCRF laboratory.

- A formal laboratory workshop is conducted for all GCRF clinical staff as part of the induction period. Staff may be required to work within the GCRF laboratories before completing the workshop, in this instance the sample processing competency must be signed off.

- External staff will be expected to complete GCRF laboratory safety and competency will be signed off as part of their ongoing induction to the facility.

3.2. Processing

NHS GG&C Personal Protective Equipment (PPE) Policy must be followed when working in the laboratory. Appropriate PPE must be worn when processing samples and must be removed before exiting the laboratory.

Study specific processing instructions should be detailed in the protocol, laboratory or sample handling manual. The manual should also detail how the samples are correctly labelled.
Each sample processed must be detailed on a study specific sample log. This log may be provided by Sponsor, in the event it is not provided Form 17.041A Sample Log must be used. Sample logs are stored in the *Sample Log files* within laboratory in alphabetical order. The Samples Logs must be provided for monitoring and audit purposes, a file note must be created in the Investigator Site File detailing logs are kept in the laboratory until all samples have been shipped.

3.3. Sample labelling

All samples must be labelled to identify the research participant and study using one of the following:

- Labels provided by sponsor.
- Study Specific Labels generated by GCRF.
- Handwritten on sample container with freezer proof marker pen.

All labels must detail the research participant study identification number, study acronym/ID, date and visit number. Participant initials may also be used if indicated in laboratory manual.

3.4. Storage

Samples must be stored according to instructions in study protocol, laboratory or sample handling manual. All samples must be securely sealed before being placed in a fridge or freezer. Form 17.041B Fridge and Freezer Planner must be completed once samples have been stored.
To ensure tracking of samples all must be logged in and out on the Sample Log Form 17.041A.

If for any reason samples must be moved internally the fridge/freezer planner Form 17.041B and study specific Sample Log Form 17.041A must be updated.

3.5. Shipment

Samples should not remain in GCRF freezers any longer than 6 months unless agreed with the sponsor. GCRF Nurse Managers will regularly spot check the sample logs and notify study teams when samples are coming up to the 6 month period.
When samples are due for transfer instructions as detailed in protocol, lab or sample handling manual must be followed. Shipment details of samples must be recorded on Sample Log Form 17.041A.

3.6. Sample disposal

Sample disposal will only occur following clear written instructions from the sponsor or Chief Investigator.

4. Referenced documents

- Form 17.041A – Sample Log
- Form 17.041B – Fridge and Freezer Planner
- NHS GG&C Personal Protective Equipment Policy

5. Related documents

None

6. Document history

Version	Date	Description
1.0	20/12/19	First release
2.0	18/08/2023	Update to SOP template v2.0 Addition of RACI matrix