SOP number	**51.030**	Version	**3.0**
Title	**Writing Sample Handling Manuals for Sites Participating in Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow**		

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SOP category	51 NHS GG&C Sponsor R&I
Staff category	

Staff Category	**R**	**A**	**C**	**I**
Lead Pharmacist Clinical Trials / R&I		X		
Project Managers	X			
Biorepository Manager	X			
Chief Investigator	X			
R&I Sponsor Research Co-Ordinators	X			
Laboratory Quality Managers			X	
Senior R&I Manager				X

1. Scope

This procedure applies to research Sponsored by NHS Greater Glasgow & Clyde (NHSGGC) or Co-Sponsored by NHSGGC and the University of Glasgow (GU). Project Managers staff category includes Project Managers from Project Management Unit, Glasgow Oncology Clinical Trials Unit, University of Glasgow and Glasgow Clinical Trials Unit.

2. Purpose

The analysis of samples collected from participants forms a key part of the clinical research process. For studies in which the protocol specifies that a central laboratory function is required, it is important to implement appropriate measures to assure the quality and integrity of samples which are collected, processed, stored and transported to the central laboratory. For samples that are processed at participating site NHS laboratories a study specific Sample Handling Manual may be required if any of the processes required differ from those employed in standard NHS sample analysis.

In order to meet this requirement a study specific Sample Handling Manual (Form 51.030C) is required for all NHSGGC Sponsored and Co-Sponsored research projects which include category 2 or 3 laboratory tests or central lab functions as defined in SOP 51.028.

The study specific Sample Handling Manual must ***only include work that is covered by the clinical study protocol***.

3. Procedures

3.1. Roles and responsibilities

The processing of clinical research samples in accordance with the study specific Sample Handling manual should be overseen by a named individual(s) who assume responsibility for the conduct of this work at the trial site. The Principal Investigator or delegate at the participating site must ensure that site personnel are appropriately trained and qualified to perform the roles and responsibilities assigned to them via the delegation log and that the site has the necessary resources to process and store the samples.

The study specific Sample Handling Manual must be written by the Chief Investigator (CI) or delegate. This process will be coordinated by the Project Manager. The manual must be jointly approved by the CI and a Sponsor representative. The CI should discuss the mode of transfer of the samples to the Laboratory with the Quality Manager/Biorepository Manager, or named individual(s) performing the Laboratory analysis.

3.2. Study Specific Sample Logs & Sample Transfer Forms

For each category 2 or 3 sample processed a study specific Sample Log (Form 51.030A) must be created for the participating sites to complete. This will document the type and number of samples, type of collection vials, processing, and storage of samples. A Sample Transfer Form (Form 51.030B) must also be created for the participating sites to complete at the time of transferring samples from site to the central laboratory. The sample logs and transfer forms must be appended to the study specific Sample Handling Manual and readily available at the participating site for monitoring purposes.

3.3. Equipment

The provision of study specific collection & storage vials, and any other equipment such as pipettes must be detailed in the study specific Sample Handling Manual.

3.4. Collection of Samples

The processes of sample collection must be detailed in the study specific Sample Handling Manual. Standard processes for inclusion are:

- All samples used for eligibility, primary, secondary or safety end-point analysis must be taken by trained site staff using Personal Protective Equipment (PPE) and techniques safe and compliant with local policies and procedures. Any potential safety issues should be dealt with by using local policies. The number and type of samples, volume, and collection vials must be detailed in a summary table within the study specific Sample Handling Manual. Appropriate vials must be provided by the study team if they differ from routine collection vials.

Additional details may be required on a study or sample specific basis.

3.5. Sample Labelling

The processes of labelling samples collected must be detailed in the study specific Sample Handling Manual. The clinical trial sample must be labelled in such a way as to allow their unequivocal identification at all times. This may necessitate the use of different labels depending on the processes deployed in collecting and processing samples. All samples must be anonymised. Study specific sample labels may be provided to the participating sites as appropriate. If so, a record of the serial numbers of study specific labels have been sent to each site must be recorded by the Project Manager for future reconciliation.

3.6. Study Specific Sample Processing at Participating Site

Any processing of samples that is required at the participating site before samples are shipped to a laboratory for analysis must be detailed in the study specific Sample Handling Manual. Site staff must receive documented training in the processes. Standard processes that may require to be included are:

- Separation of plasma/serum from blood samples
    - Plasma: detailed instructions of the centrifugation time and speed must be provided and recorded on the study specific sample logs along with the date and time of collection and processing. Details of the storage vials that the plasma must be aliquoted to and labelling must be provided.
    - Serum: Detailed instructions of the clotting time, centrifugation time and speed must be provided and recorded on the study specific sample logs along with the date and time of collection and processing. Complete separation must be obtained prior to sampling. Details of the pipette, storage vials and labelling must be provided.

- Other Samples
    - Samples such as urine, sputum etc. may be required to be aliquoted at site into study specific storage vials. For each sample processed a study specific sample log should be completed to document the type and number of samples, type of collection vials, processing, storage and transfer of samples. The sample logs should be readily available at the participating site for monitoring purposes.

- Record Retention
    - Detailed instructions on any records that require to be retained from standard processes to enable reconstruction of the trial.

3.7. Storage at Site

If samples are to be stored at participating sites for any reason, the processes must be detailed in the study specific Sample Handling Manual. Site must be requested to use a study specific storage rack where possible and sample storage conditions must be detailed in the manual. Sites must be asked if they foresee any issues with proposed sample storage during site initiation in order to mitigate them.

Standard instructions to be included are:

- Detailed instructions defining the storage conditions including temperature and monitoring required of the site staff. This will enable the Sponsor to confirm that samples have been stored in a manner to ensure that they are fit for purpose. Stability of the samples being stored over time must also be considered and documented.
- All samples must be logged in and out of the freezer/fridge or storage at the participating site on the sample log (date/time) to ensure accurate tracking of samples.
- Samples stored in participating site freezers should not remain there for more than 3 months. The study specific Sample Handling Manual must detail the frequency of shipments. This may require adjusting with the individual site based on storage space and recruitment rates.

3.8. Withdrawal of Consent

The study specific Sample Handling Manual must detail processes to be applied to samples stored at site should a participant withdraw consent. This may include destruction and may depend on what has been approved by the Research Ethics Committee.

3.9. Transport of Samples to the NHS laboratory, NHSGGC Central Laboratory or NHSGGC Biorepository

Processes for sample transfer to laboratories for analysis or further storage must be detailed in the study specific Sample Handling Manual.

- Clear instructions must be provided as to how samples are to be transferred to the respective NHS Laboratory if category 2 analysis is being undertaken at the participating site NHS Laboratories.
- Clear instructions must be provided as to how samples are to be transferred to the respective NHSGGC Laboratory undertaking a Central Laboratory Function. Packaging, courier contact details and address that the samples are to be sent to must be clearly described and transport containers provided.
- Clear instructions must be provided as to how samples are to be transferred to the respective NHSGGC Biorepository if they are any functions specified in the protocol. Packaging, courier contact details and address that the samples are to be sent to must be clearly described and transport containers provided.

All samples involved in eligibility criteria, primary, secondary and safety outcomes **must be couriered and must not be sent in the routine mail (Royal Mail services with tracking are acceptable).** The courier(s) will be specified and engaged by the Sponsor representative.

The processes for site staff to arrange courier(s) must be detailed within the study specific Sample Handling Manual. Standard processes for inclusion are:

- Site staff to contact the Project Manager or delegate to arrange transport of samples, and will not be required to contact the courier directly.
- The date and time will be arranged between the site team and Project Manager or delegate.
- A sample transport log detailing the sample id, number and types of vials, date and time must be completed by the site team and a copy sent with the sample.
- If samples have been compromised in storage the Project Manager should be promptly notified.

3.10. Non-Compliances and Potential Serious Breaches in GCP

The Study Specific Sample Handling Manual must detail the processes to be followed when incidents occur that are considered to be a noncompliance with GCP and/or potential serious breaches in GCP. Definitions of such incidents may require to be included in the Study Specific Sample Handling Manual.

3.11. Protocol Amendments

The Study Specific Sample Handling Manual must detail how any protocol amendments that affect sample handling will be distributed and implemented accordingly.

4. Referenced documents

- Form 51.030A – Site Sample Log Template
- Form 51.030B – Sample Transfer Form Template
- Form 51.030C – Sample Handling Manual Template for Participating Sites
- SOP 51.028 - NHS laboratory Samples for Research Sponsored by NHS GG& C or co-sponsored by NHS GG&C and University of Glasgow or hosted by NHS GGC.

5. Related documents

- EMA Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples (2012)
- MHRA Good Clinical Practice Guide, Chapter 13 (2012)

Document history

Version	Date	Description
1.0	24/05/2018	First release
2.0	02/11/2018	Glasgow University Project Managers added CRUK CTU PMs added Glasgow CTU (RCB) Project Managers Clarifications added on processes.
3.0	25/01/2024	Update to SOP template V2.0 Addition of RACI matrix Change of author/ approver Revision of R&D to R&I Typographical changes Update to include all research projects and not just CTIMPs