SOP number	**51.028**	Version	**5.0**
Title	**NHS Laboratory samples for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow or hosted by NHSGGC.**		

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Released by Signature	Julie Brittenden Date

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			
Chief Investigator	X			
Sponsor Research Co-Ordinators	X			
Innovation Contracts Manager	X			
Biorepository Manager			X	
Laboratory Quality Managers			X	
Senior R&I Managers				X

1. Scope

This procedure applies to research Sponsored by NHS Greater Glasgow & Clyde (NHSGGC), Co-Sponsored by NHSGGC and the University of Glasgow (GU) and hosted as a participating site on behalf of external sponsors. Project Managers staff category includes Project Managers from NHSGGC Project Management Unit, Glasgow Oncology Clinical Trials Unit, University of Glasgow and Glasgow Clinical Trials Unit.

2. Purpose

Laboratory sample analysis contributes significantly to research data, including essential safety information, eligibility criteria and primary or secondary outcomes. It is therefore essential that research samples are processed correctly, by trained and qualified laboratory staff. The laboratory may receive, prepare and store samples prior to shipping to a central laboratory for analysis, or may perform the analysis themselves. Training should be appropriate to the nature of the test and the activities undertaken.

All laboratories undertaking activities relating to eligibility criteria, primary, secondary or safety end-points for Clinical Trials of Investigational Medicinal Products (CTIMPs) must operate to International Standards commensurate with Accreditation (ISO 15189:2022), Good Clinical Laboratory Practice and Good Clinical Practice standards.

3. Procedures

3.1. CTIMPs and non-CTIMPs where NHSGGC are a Participating Site

Prior to study commencement each Laboratory test detailed within the study protocol should be reviewed by the R&I Sponsor Research Co-ordinator to ensure that the participating site can comply with the Sponsor's requirements. Laboratory tests that have to be undertaken within NHSGGC on behalf of an external Sponsor must be costed and contracted as appropriate.

- Where the Laboratory tests are considered standard care and the external Sponsor only requires copies of reference ranges for NHSGGC Laboratories, no further action is required. These would be considered Category 1 Tests as below.
- Where the Laboratory tests are additional to standard care or involve any additional processes by NHSGGC Laboratories, the Quality Manager of the NHSGGC Laboratory must be contacted by the R&I Co-ordinator for advice regarding costs, contracts and capacity. These would be considered Category 2 or 3 Tests as below.

3.2. Categorisation of Laboratory Tests for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC & University of Glasgow

During protocol development, each Laboratory test detailed within the study protocol must be classified according to the following criteria, by the Project Manager (PM) and Chief Investigator (CI). Form 51.028A must be completed for each test listed within the protocol and this must be filed in the laboratory section of the Sponsor TMF, and the Laboratory Master Research File**:**

Category 1: Standard test i.e. validated and in use in clinical practice within NHS
Category 2: Standard test, with specific requirements or
Category 3: Nonstandard test, research tests

Where an amendment to the protocol is made, which changes the Laboratory tests required, Form 51.028A should be reviewed and updated accordingly.

3.3. Processing of Laboratory Samples

3.3.1. Category 1 – Standard tests performed at local NHS laboratories

These samples may be processed by the local NHS laboratories in the same manner as those which are part of clinical care practices within NHS. For studies Sponsored by NHSGGC or Co-Sponsored by NHSGGC & University of Glasgow, NHS laboratories must be fully accredited, audited and inspected in line with standard processes, (e.g. ISO 15189, 2022) in order to process these samples. If for any reason the NHS laboratory does not hold accreditation this should be risk assessed and documented in the study risk assessment document (Form 51.004B) during study set-up.

Where samples conform to routine processes,

- Form 51.028A will be filed in the Sponsor TMF and no further action is needed.
- The NHS Laboratory Quality Manager(s) for the laboratories will be required to be updated periodically about these studies via the Sponsor Lab Oversight Group.

3.3.2. Category 2 – Samples for Standard tests, with specific requirements at NHS laboratories

Examples of Category 2 include specific requirements for sample labelling/identification, reporting of results and storage of the sample/data or may be adjustments to existing laboratory procedures which might otherwise compromise compliance with the protocol (for example; phoning results may be a standard procedure, but for a clinical trial sample, may result in unblinding of the study team).

In cases where specific requirements for processing research samples exist which differ from routine processes:

- The respective NHS Laboratory Quality Manager **will** be required to be informed directly about the study. For studies Sponsored or Co-Sponsored by NHSGGC and GU, this will be communicated to the NHS participating site via site initiation processes. When NHSGGC are a participating site the R&I Sponsor Research Co-ordinator or Innovation Contract Manager will identify laboratory costs as per SOP 51.010 which will need to be approved by R&I Finance. Laboratory support will need to be in place before local management approval is issued.
- The accredited NHS Laboratory will be expected to notify Sponsor if the specific requirements may affect the quality assurance of the assay and results.
- A study specific **laboratory manual** provided by the Sponsor will detail the specific requirements for the samples within the laboratories. The study specific Laboratory manual should be filed within the Laboratory Master Research File for NHSGGC laboratories. External participating NHS laboratories should follow local processes.

Study specific bar code labels may be provided to identify research samples which have specific requirements in order that these can be identified by the Laboratory.

3.3.3. Category 3 – Non-standard Research tests at NHS Laboratories

In cases where non-routine care research tests are performed within NHS laboratories:

- The respective NHS Laboratory Quality Manager **will** be required to be informed directly about the study. For studies Sponsored or Co-Sponsored by NHSGGC and GU, this will be communicated to the NHS participating site via site initiation processes. When NHSGGC are a participating site the Research Co-Ordinator or Innovation Contracts Manager will identify laboratory costs as per SOP 51.010 which will need to be approved by R&I Finance. Laboratory support will need to be in place before local management approval is issued. A named person within the NHS Laboratory will be expected to be responsible for the quality assurance of the assay and results.
- A study specific **laboratory manual** provided by the Sponsor will detail the specific requirements for the samples within the laboratories. The study specific Laboratory manual should be filed within the Laboratory Master Research File for NHSGGC laboratories. External participating NHS laboratories should follow local processes.

3.3.4. NHSGGC Laboratories acting as 'Central' Laboratories

NHSGGC laboratories may act as central laboratories as specified within the protocol for the purpose of storing samples and/ or performing analysis. The respective laboratory procedures should be adhered to whenever possible. The NHSGGC Laboratory team will be expected to be responsible for the quality assurance of the assay and results.

- The respective NHSGGC Laboratory Quality Manager **will** be required to be informed directly about the study by the Research Co-Ordinator or Innovation Contracts Manager for NHSGGC Sponsored or Co-Sponsored studies or PM.
- A named person within the NHS Laboratory will be expected to be responsible for the quality assurance of the assay and results.
- A study specific **laboratory manual** provided by the Sponsor/Co-Sponsor will detail the specific requirements and activities to be undertaken for the samples within the laboratories. The study specific Laboratory manual should be filed within the Laboratory Master Research File for NHSGGC laboratories.
- Research Co-ordinator or Innovation Contracts Manager will ensure that the appropriate contracts, Service Level Agreements or formal engagement of local laboratories are in place and documented.

3.3.5. Laboratories external to NHSGGC

All non-NHSGGC laboratories will be subject to vendor assessment (SOP 51.015) and contracts with the exception of those at the University of Glasgow (when study is co-sponsored with GU). Studies Co-Sponsored by NHSGGC and the University of Glasgow that utilise University Laboratories will be assessed and documented for suitability during the study-specific risk assessment process. Research Co-ordinator or Innovation Contracts Manager will ensure that the appropriate contracts, Service Level Agreements or formal engagement of external laboratories are in place and documented.

3.4. Trial Specific Laboratory Manuals

3.4.1. Study-specific "Sample Handling Manual" for Sites Participating in Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC/GU

This is required for studies which use category 2 and 3 tests from above and/or are undertaking any form of central laboratory function. The processes for participating site staff to undertake sampling, labelling and transporting all samples to the NHS laboratories is described in SOP 51.030.

3.4.2. Study-specific "Laboratory Manual" for NHS Laboratories

This is required for studies which use category 2 and 3 tests from above and/or are undertaking any form of central laboratory function, and is detailed in SOP 51.029.

3.5. The Laboratory Master Research File

A Laboratory Master Research File (LMRF) for each NHSGGC laboratory involved in Research is set-up and maintained following SOP 56.002 and Form 56.002L. One copy of the LMRF will be held by Sponsor (held within R&I) and the other by the respective Laboratory. The Sponsor copy of the file will be updated by the Project Management Unit (PMU) team to form a reference to all NHSGGC Sponsored/Co-Sponsored studies involving laboratory samples. The PMU team will send copies of the appropriate documents to the Quality Manager for the respective lab to file. The Quality Managers will hold the copies for their lab in order to have a reference to all NHSGGC Sponsored/Co-Sponsored studies involving laboratory samples. External PMs will send the appropriate documents to the R&I Co-ordinator and Quality Managers for filing.

3.6. Training of Laboratory Staff

There is no requirement to obtain CVs and GCP certificates from lab staff unless there is a specific reason to do so.

Where specific requirements for processing research samples exist which differ from routine processes, these should be subject to documented training. This information may be included in laboratory procedures or a study specific laboratory manual provided by the Sponsor. Evidence of training may be in the form of study specific SOP or laboratory manual training records.

Quality Managers within each laboratory must understand the role of the research sample (its role in determining patient safety and eligibility, and in endpoint analysis) to ensure that samples are processed in accordance with GCP, applicable legislation and guidance, and good laboratory practice.

- Quality Managers must receive applicable GCP training, preferably training that has a laboratory perspective (chapters covered in the EMA Reflection paper).

Where research samples are contributing to study endpoints and the assays performed are specific to the research study, named laboratory staff processing these samples must have:

- Appropriate GCP training to perform their delegated role. Where possible this should be laboratory specific GCP training and would include chapters covered in the EMA Reflection paper.

3.7. Training Records

The laboratory should ensure that all staff processing 'routine care' research samples are qualified and trained to do so. Evidence of competency to conduct the required test/operate particular instruments must be available for all staff.

Training for all staff in procedures specific to research samples must be recorded. The Laboratory Quality Managers who are responsible for the overall management of research samples must be able to provide evidence of training of all staff if required and must be prepared to provide a copy of their own CV and associated training to illustrate the knowledge required for the management and oversight of research samples within the laboratory.

3.8. NHSGGC R&I & Laboratories Clinical Trial Group

The NHSGGC R&I & Laboratories Clinical Trial Group includes representation from NHSGGC Laboratories & NHSGGC Sponsor team and

- Ensures that laboratory research samples for MHRA –regulated trials within NHSGGC are analysed in accordance with the EMA reflection paper.
- Ensures that non-MHRA regulated projects that require substantial NHSGGC lab resource to validate assays and analyse samples that impact patient care within clinical research and innovation are conducted within the appropriate regulatory frameworks

The group reports directly to the NHSGGC Laboratory Quality Management & Compliance Group, and will inform the Glasgow Health Science Partnership Regulatory Affairs Group of any significant audit findings, deviations or non-compliances.

4. Referenced documents

- Form 51.028A - Categorisation of Laboratory tests
- SOP 51.029 - Writing Study Specific Laboratory Manuals for Research Sponsored by NHSGGC or Co-sponsored by NHSGGC and the University of Glasgow
- SOP 51.030 - Writing Study Specific Sample Handling Manuals for Research Sponsored by NHSGGC or Co-sponsored by NHSGGC and the University of Glasgow
- SOP 56.002 – Project Management Trial Set-up
- Form 56.002L – Laboratory Master Research File
- SOP 51.015 – Assessment of Vendors
- ISO 15189:2022, Medical laboratories Requirements for quality and competence
- EMA Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples (2012) Form 51.004B - Risk Assessment Tool
- SOP 51.010 - Preparation and Review of Grant Applications and Costs

5. Related documents

- MHRA Good Clinical Practice Guide, Chapter 13 (2012)

6. Document history

Version	Date	Description
1.0	24/05/2018	First release
1.1	01/06/2018	Typo corrected.
2.0	02/11/2018	Title updated to cover hosted CTIMPs. Glasgow University Project Managers added CRUK CTU PMs added Glasgow CTU (RCB) Project Managers Wording added to cover participating site activities. Clarifications on roles to undertake duties added. Reorganisation of order or section 5.3.2
3.0	08/01/2019	New Governance structure included in Section 5.8.
4.0	25/01/2024	Update to SOP template V2.0 Addition of RACI matrix Change of author & approver Revision of R&D to R&I Update to ISO15189 reference Update to include research as a whole and not just CTIMPs Update to name of R&I & Laboratories Clinical Trial Group and reflect the ToR of that group.
5.0	03/05/2024	Further clarification on roles