STANDARD OPERATING PROCEDURE FOR IMPLEMENTATION AND MAINTENANCE OF A QUALITY ASSURANCE SYSTEM IN CLINICAL RESEARCH LABORATORIES

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AUTHOR:	Valerie Godfrey
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1. PURPOSE

This Standard Operating Procedure (SOP) specifies the requirements for the Quality Management System for University of Dundee (UoD) clinical research laboratories that analyse samples from Clinical Trials of Investigational Medicinal Products (CTIMP) to ensure the purpose and objectives of Good Clinical Practice (GCP) principles are satisfied. It offers guidance to researchers of non-CTIMPs.

2. SCOPE

This SOP applies to Research and Sponsor staff participating in CTIMPs sponsored or co-sponsored by UoD and/or NHS Tayside. It does not include laboratory activities for diagnostic purposes or for the routine clinical care of patients.

3. RESPONSIBILITIES

Sponsor Office:

- To oversee laboratories in relation to the analysis or evaluation of human samples collected as part of a clinical trial.
- To plan a programme of internal audits (processes and facilities) to ensure compliance with GCP for laboratories.

UoD Laboratory staff:

- To have GCP training commensurate with role and record this in their training records .
- To ensure the laboratory is fit for purpose.
- To provide an Analytical Plan in advance of participant recruitment.
- To securely report and store study laboratory results.
- To ensure any Corrective Actions/Preventative Actions arising from audit are completed.

***Chief Investigator (CI)/Principal Investigator (PI*):**

- To ensure an Analytical Plan is in place.

4. PROCEDURE

By following the information provided in the "European Medicines Agency's (EMA) Reflection Paper for laboratories that perform the analysis or evaluation of clinical trial samples (2012)", laboratories should be able to maintain quality systems which will comply with GCP.

4.1 Organisation and Personnel

Each laboratory should have a staff organisational chart.

The CI/PI will contact the laboratory-designated Analytical Plan Manager (APM) before the start of a new study. The APM will receive the Study Protocol and ensure that an Analytical Plan (AP) is completed accordingly (refer to the TASC SOP on APs).

Breaches of GCP, TASC SOPs or study protocols will be reported to the TASC Research Governance team following the TASC SOP on Reporting Breaches in Clinical Research.

The TASC Quality Assurance (QA) Manager or delegate will audit laboratories for GCP compliance according to the TASC Laboratory Audit Schedule and report to Sponsor and the TASC Laboratory QA Committee.

The TASC Laboratory QA Committee will affect continual improvement through annual review of audit findings and dissemination of updates to current practice and regulations to relevant parties.

4.2 Facilities

UoD clinical research laboratories should be of suitable size to ensure segregation of activities and have adequate secure storage areas to permit the orderly retention of materials and equipment.

4.3 Laboratory SOPs and Guidelines

SOPs and guidelines should include, but not be limited to the following:

- Maintenance, servicing, calibration and use of equipment.
- Validation of equipment, methods and computerised systems.
- Inclusion of adequate Quality Control (QC) functions.
- Manuals (may be used to supplement procedures written by the laboratory).

Version control must be used and superseded documents must be retained for reconstruction purposes.

4.4 Samples

Informed Consent

The CI/PI must ensure written informed consent has been given by the research participant before analysis of samples. The CI/PI will confirm this on the AP. The lab must be informed if consent for sample processing is withdrawn to ensure that samples in storage are destroyed and no further data is generated. The disposal will be implemented and recorded according to the laboratory's written instructions.

Sample Identification and Chain of Custody
TASC SOP on Chain of Custody for Samples in Clinical Research must be followed.

Sample Storage
Fridge and freezer temperatures must be recorded either manually or electronically. If temperatures go out with the desired range, this must be recorded and appropriate action taken to ensure that the integrity of the stored samples is maintained. Equipment for monitoring temperatures should be subject to periodic calibration and the results documented. Fridge/Freezer maintenance records should be kept. Relevant storage stability data should be available for samples stored prior to analysis.

Sample Analysis
Analysis must be carried out in accordance with the laboratory's SOPs and guidelines, and the AP. All deviations required for operational reasons must be documented by the laboratory staff. All data must be recorded as specified in the AP. Repeat analyses should only be undertaken in accordance with clearly defined criteria in written documentation. It is never acceptable to selectively report data.

4.5 Data Management and Integrity

Computerised systems used for the capture, processing, reporting and storage of data should be developed, validated and maintained in ways which ensure the validity, integrity and security of the data. Computerised systems must be password protected and access controlled. An audit trail must be able to determine the date on which the analysis or evaluation was performed and the identity of the person who conducted the work. Source data must be identifiable, traceable and available.

Manually transcribed data must be checked and signed and dated as such. Automatic transfer (data flow) and/or analysis of data should be periodically checked and recorded as checked. There should be paper/electronic trails for any modifications, deletions and duplications.

Electronic data systems must be reliably backed up and the recovery process tested.

Reports
Reports should be provided to the study team. The way in which data will be reported by the laboratory should be documented in the AP. Regardless of how data is reported, it must be accurate, legible and complete. Any modifications or corrections to reports once issued must be signed, dated and the reason documented.

4.6 Equipment, Materials and Reagents

Equipment
Laboratory staff will ensure that equipment is validated, i.e. the process whereby documented evidence demonstrates that a system has been developed, implemented, operated and maintained, in a controlled manner. Validation will assure that the system consistently meets its specification and is suitable for its intended purpose. Equipment will be serviced and calibrated according to risk-based requirements and records must be kept.

Staff must be trained in the use of equipment and this will be recorded in their training records. Faulty or long-term unused equipment will be clearly labelled as out of use.

Materials and Reagents
Laboratory staff will ensure that materials and reagents are labelled, stored at the correct temperatures, kept in secure and suitable storage conditions and used before their expiry dates. Reagents must be identified by title with a record of concentration, date of opening/constitution, and expiry date. Batch numbers and expiry dates of purchased kits and reagents must be recorded. Laboratory staff must keep a record of the preparation and dispatch of reagents or sample processing kits that they send to other laboratories. Regular Quality Control (QC) checks of lab kits before dispatch should be recorded.

4.7 Quality Control

Method Validation
Methods must be validated before use with defined acceptance criteria where appropriate. The validation of methods should be documented and, on completion, this documentation should be archived.

Standards and QC Materials
Laboratory staff will analyse and check QC samples at intervals specified in the relevant SOP or instructions. Test sample results will not be reported prior to satisfactory QC results being obtained. QC and calibration data must be recorded.

4.8 Sub-Contracting

Laboratories can sub-contract work to other laboratories for specialist services but GCP compliance of the contracted lab must be assured and documented and the Sponsor must be informed before any work commences. A sample and data transfer agreement must be put in place prior to transfer of any samples.

4.9 Quality Assurance

Laboratory audits, which may be on-site or remote, will be performed as per TASC SOP for performing Quality Assurance audits. The frequency, duration and content of each laboratory audit will be a risk-proportionate decision which can vary dependent on the history and nature of the work carried out by the laboratory.

Summary reports of audit activity will be prepared by the TASC QA Manager for annual review by the TASC Laboratory QA Committee, UoD Research Governance & Policy Sub-Committee and NHS Tayside Care Governance Committee.

4.10 Archiving

Archiving of laboratory data will be carried out according to each individual laboratory's local arrangements and in accordance with TASC SOP for Archiving Clinical Studies.

5. ABBREVIATIONS & DEFINITIONS

AP	Analytical Plan
APM	Analytical Project Manager

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
EMA	European Medicines Agency
GCP	Good Clinical Practice
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
UoD	University of Dundee

6. ASSOCIATED DOCUMENTS & REFERENCES

European Medicines Agency Reflection Paper for laboratories that perform the analysis or evaluation of clinical trial samples (28 Feb 2012).

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
9	Valerie Godfrey (TASC QA Manager)	03/02/2023	Scheduled review, text refreshed and wording in section 4.4 and 4.8 updated.
10	Valerie Godfrey (TASC QA Manager)	03/02/2025	No changes required at this scheduled review.
11	Valerie Godfrey (TASC QA Manager)	28/04/2026	Updated in accordance with the new Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

8. APPROVALS

Approved by:	Date:
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	23 Mar 2026
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	20 Mar 2026