STANDARD OPERATING PROCEDURE FOR PERFORMING QUALITY ASSURANCE AUDITS

SOP NUMBER:	TASC SOP020 v10
AUTHOR:	Valerie Godfrey
EFFECTIVE DATE:	04 Aug 2026
REVIEW DATE:	04 Aug 2028

1. PURPOSE

Sponsors of clinical trials must have Quality Assurance (QA) mechanisms in place to ensure that clinical research is carried out according to the study protocol, relevant Standard Operating Procedures (SOPs), the principles of Good Clinical Practice (GCP) and applicable regulatory requirements to ensure participant safety and integrity of data.

QA should be applied throughout the study and includes implementation of risk-based strategies to identify potential or actual causes of serious non-compliance to enable their corrective actions and preventive actions (CAPA).

2. SCOPE

The Quality Management System in Tayside Medical Science Centre (TASC) includes a programme of audit schedules that includes Study-Specific, Process, Facility and Laboratory audits. This SOP applies to personnel associated with and managing clinical research activities and studies sponsored or co-sponsored by the University of Dundee (UoD) and/or NHS Tayside (NHST). It also applies to external service providers (vendors) to TASC.

3. RESPONSIBILITIES

Sponsor: Ensure that the auditors are qualified by training and experience to conduct audits properly and are independent of the clinical trial/processes being audited.

TASC QA Manager: Ensure the auditing of clinical research processes and facilities is conducted in accordance with a risk-based audit plan.

Provide Audit Reports.

Follow up audit findings to resolution and close audits off.

Issue Audit Statements as evidence of audit.

Auditee(s): Ensure the relevant documentation (paper and electronic) and facility access is available for audit.
Agree appropriate and proportionate actions to audit findings in an agreed timeline.

Document actions to audit findings to the satisfaction of the auditor or delegate.

4. PROCEDURE

4.1 The individual carrying out the audit must be appropriately trained and experienced and this must be demonstrated in their training records.

4.2 External companies may be employed to carry out audits at Sponsor's request. Such a transfer of responsibilities must be formally agreed in writing with the external party .

4.3 The audit may be conducted at site or remotely, e.g. via MS Teams.

4.4 The frequency and scope of each routine audit will be a risk-based decision guided by TASC QA's local risk assessment and in accordance with Sponsor requirements.

4.5 Audit Plans are prepared annually for Laboratories as locations and staff tend to change regularly, and biannually for the other long-standing processes and facilities associated with TASC. Audit Plans are live documents and may be changed at any time. Changes with reasons for change should be documented.

4.6 Audit Plans for Study Specific, Process and Facility Audits will be documented and agreed with the R&D Director (or delegate). Additional or unscheduled audits may be carried out if:

- Concerns are raised regarding practice, including external service providers.
- Monitoring has highlighted concerns.
- Information provided to TASC, UoD or NHST is causing concern.
- The Medicines and Healthcare products Regulatory Agency (MHRA) or other regulatory/inspection body have indicated that they are to conduct an inspection.
- Instructions are received from TASC R&D Director (or delegate) or Senior Research Governance Manager.

4.7 A date and time for the audit will be agreed in advance with the auditee(s). The scope and objective of the audit will be explained and any relevant documents (e.g. Work Instructions, organograms) required for the audit may be requested at this time.

4.8 Audit checklists will be prepared or updated by the TASC QA Manager. Consideration will be given to previous or systematic findings.

4.9 An audit agenda will be provided starting with an opening meeting, followed by document review, discussion with auditees and a closing meeting whereby any findings can be outlined. The audit agenda is flexible so it can be adapted to the requirements of the audit as they arise.

4.10 After the audit, an Audit Report will be issued to the auditee, Senior Research Governance Manager and any other relevant parties as applicable. Findings (non-compliances) and observations (opportunities for improvement or a potential non-compliance) will be detailed in an Action Plan.

4.11 Findings should be rectified by the auditee within an agreed timescale and CAPA recorded. Persistent failure to rectify findings will be escalated to the R&D Director or delegate.

4.12 Potential serious breaches and any other significant findings must be escalated to the TASC Senior Research Governance Manager at the earliest opportunity.

4.13 The TASC QA Manager or delegate will ensure that any required actions are followed up to completion and will close the audit and sign, and date the Audit Report. Audit Reports and any other associated documents will be kept electronically by the TASC QA team.

4.14 An Audit Report and Audit Statement will be provided to the auditee. The MHRA will not routinely request audit reports. For Study Specific Audits, the Audit Statement should be filed in the Trial Master File to show evidence of audit taking place.

4.15 Audit findings will be collated and reported to the TASC Laboratory QA Committee, TASC Research Governance & Oversight Committee, University Research and Innovation Committee and the NHST Care Governance Committee.

Note: Monitoring and auditing of clinical trials are different activities. A definition for each is given below and examples of differences between the 2 roles are given in Doc Ref 091 (Audit versus Monitoring Guide).

Monitoring *is the act of overseeing the progress of a clinical trial and of ensuring that it is conducted, recorded and reported in accordance with the protocol, SOPs, GCP and applicable regulatory requirements. Monitoring is an ongoing activity throughout the conduct of the trial.*

Audit *is a systematic and independent examination of trial-related activities and documents to determine whether the trial-related activities were conducted, recorded and reported in accordance with the protocol, SOPs, GCP and applicable regulatory requirements. Audit is an assessment of compliance with these standards at a given moment in time.*

5. ABBREVIATIONS & DEFINITIONS

CAPA	Corrective Action/Preventative Action
GCP	Good Clinical Practice
MHRA	Medicines and Healthcare products Regulatory Agency
NHST	NHS Tayside
QA	Quality Assurance

SOP Standard Operating Procedure
TASC Tayside Medical Science Centre
UoD University of Dundee

6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 091: TASC Monitoring versus Auditing Guide

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:**
08	Valerie Godfrey (TASC QA Manager)	04/08/2022	No changes made at scheduled review.
09	Valerie Godfrey (TASC QA Manager)	04/08/2024	Minor changes to text in section 1 for clarity.
10	Valerie Godfrey (TASC QA Manager)	04/08/2026	Minor changes throughout to highlight risk proportionality in auditing. Reporting lines updated in 4.12 to Senior Research Governance Manager and 4.15 to University Research and Innovation Committee.

8. APPROVALS

Approved by (job title)	**Date**
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	29 July 2026
Dr Valerie Godfrey (TASC Quality Assurance Manager) on behalf of TASC Clinical Research Guidelines Committee	27 July 2026