STANDARD OPERATING PROCEDURE FOR PERFORMING QUALITY ASSURANCE AUDITS

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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 principles of Good Clinical Practice (GCP), current regulations and relevant Standard Operating Procedures (SOP) to ensure participant safety and integrity of data.

The Quality Management System in TASC includes a programme of audit schedules. The purpose of this SOP is to describe the procedure for planning and carrying out audits in TASC and planning and carrying out audits of external service providers to TASC (vendors).

2. SCOPE

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).

3. RESPONSIBILITIES

Sponsor: to ensure that clinical research is conducted, managed safely and effectively in compliance with the principles of GCP, TASC SOPs, study protocols and regulations.

TASC QA Manager: to conduct audits of clinical research processes, facilities and studies against the relevant standards.

Auditees: to ensure that relevant documentation (paper and electronic) and facility access is available for audit.

4. PROCEDURE

4.1 The individual carrying out the audit must be appropriately trained and qualified 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 with the external party in writing.

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

4.4 The frequency of audit shall vary depending on the risk. The frequency of each type of audit - process, facility, study specific - is planned by the TASC QA Manager. Schedules are documented and agreed with the R&D Director or Senior R&D Manager. Additional or unscheduled audits may be carried out if:

- Concerns are raised regarding research practice.
- 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 senior management.

4.5 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 required for the audit may be requested and collated at this time.

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

4.7 The audit agenda will include 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.

4.8 The Audit Report will be issued to the auditee (and any other interested parties). Findings (non-conformances) and observations (i.e. an opportunity for improvement or a potential non-conformance) will be detailed in an Action Plan. Findings should be rectified by the auditee within an agreed timescale and Corrective Actions/Preventative Actions (CAPA) recorded. Persistent failure to rectify findings will be reported to TASC senior management.

4.9 Serious and significant findings detected at audit must be escalated to the TASC Senior Research Governance Manager at the earliest opportunity.

4.10 The TASC QA Manager or delegate will ensure that actions are followed up to completion, close the audit, sign, and date the Audit Report. Audit Reports and any other associated documents will be securely filed by the TASC QA team. The Audit Report and an Audit Statement will be provided to the auditee. For Study Specific Audits, a copy of the Audit Statement should be filed in the Trial Master File and Sponsor File.

4.11 Trends from findings are reported annually to the UoD Research Governance & Policy sub-Committee and the NHST Care Governance Committee.

Note: Monitoring and auditing of clinical trials are separate, 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, Good Clinical Practice (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.

8. APPROVALS

Approved by:	Date:
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	01 Aug 2024