# TAYSIDE MEDICAL SCIENCE CENTRE QUALITY POLICY

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| POLICY NUMBER: | TASC POLICY 03 v11 |
| AUTHOR: | Valerie Godfrey |
| EFFECTIVE DATE: | 22 Apr 2026 |
| REVIEW DATE: | 22 Apr 2028 |

## 1. Background

This document sets out the Quality Management System for clinical research projects and activities that are overseen by Tayside Medical Science Centre (TASC). TASC was formally established in January 2010 to combine the research strengths of the University of Dundee (UoD) with those of NHS Tayside (NHST) within a single organisational framework.

## 2. Purpose and Scope

To ensure that implementation and maintenance of quality assurance is applied to clinical research projects carried out in Tayside, in accordance with The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, the Principles of Good Clinical Practice (GCP), the UK Policy Framework for Health & Social Care Research 2017 (as updated), General Data Protection Regulation (2018) and any other regulations and guidelines as applicable to the project. TASC policies and Standard Operating Procedures (SOPs), relevant to the project, will be followed.

## 3. TASC Quality Policy

This Quality Policy, underpinned by the commitment of senior management (R&D Director and Senior R&D Manager), sets out the principles and standards that clinical research staff are expected to uphold.

1 The TASC Quality Assurance (QA) Manager has responsibility for the implementation and maintenance of the Quality Management System.
2 The TASC Quality Policy is reviewed regularly, updated as required and any changes communicated to all personnel concerned.
3 There is a procedure to control documents that lie within the scope of the TASC Quality Management System.
4 There is a risk-proportionate programme for GCP audits of processes, facilities and studies within TASC.
5 Audit of external facilities/third party service providers (vendors) to TASC are carried out as required in accordance with contractual discussions and agreements.

6 The TASC QA Manager regularly updates TASC senior management and the TASC Research Governance Oversight Committee on issues and developments relating to the TASC Quality Management System and will seek their advice and approval as necessary.

7. The TASC QA Manager provides an annual summary report to the TASC Laboratory QA Committee, UoD Research Governance & Policy Sub-Committee and NHST Care Governance Committee and will review and action any feedback if required.

## 4. TASC Quality Objective

TASC aims to:

- Ensure that clinical research is fulfilled in a professional manner consistent with the principles of GCP and regulatory requirements.

- Create a vibrant quality culture that provides clinical research staff with the support that they require for GCP and regulatory compliance and to ensure the rights, safety and well-being of participants are adhered to.

- Enable research work that is accountable, consistent, reliable and respected in the medical and scientific community including stakeholders, collaborators and funders.

- Ensure recruitment strategies and study activities described within the study protocol are consistent with the principles set out in ICH E6(R3) as part of a proportionate, Quality by Design approach.

- Continually work to build quality improvements and efficiencies into procedures through a planned programme that includes auditing and monitoring with regular reviews of findings. Any required corrective or preventive actions are implemented within stated timelines.

## 5. Organisation of TASC

TASC is composed of functional groups which reflect the wide variety of activities and facilities required for the governance of clinical research studies.

The TASC Quality Management System Organisational Chart is shown in Appendix 1.

## 6. Documentation

The TASC QA Manager has overall responsibility for the maintenance and version control of TASC policies and SOPs. Current versions of policies and SOPs are available on the TASC website.

There are 3 levels of documentation:

1 TASC policies - the TASC Research Governance Oversight Committee is responsible for the ratification of new and reviewed TASC policies.
2 TASC SOPs – the TASC Clinical Research Guidelines Committee is tasked with the development and approval of new and reviewed TASC SOPs.
3 TASC Doc Refs – documents and templates associated with specific TASC SOPs.

## 7. Audit

Audit is a QA activity that is a systematic examination conducted by trained and experienced QA staff who are independent of the study, process or facility being audited. There is a TASC audit programme planned by the TASC QA Manager and agreed by senior management. Audits are scheduled via a risk-proportionate assessment to determine frequency. Study Specific, Process and Facility audits are carried out to check compliance with study protocols, TASC SOPs, GCP and regulatory requirements.

## 8. External Audits and Inspections

Study teams, functional groups and facilities may also be subject to audit and inspection from external parties and the Medicines and Healthcare products Regulatory Agency (MHRA) respectively. Staff involved are expected to fully cooperate. Audit and inspection findings will be dealt with by the appropriate staff and committees to provide resolution within agreed timelines. TASC QA staff may also audit vendors on behalf of TASC to ensure that vendors are fit for purpose and compliant with GCP and relevant regulations as applicable.

## 9. Monitoring

Monitoring is a Quality Control (QC) process. Monitoring activities must be risk-based, proportionate and documented in a Monitoring Plan as informed by the Sponsor risk assessment. Monitoring may include centralised monitoring.

## 10. Education

A TASC Research Education programme is in place to ensure researchers and supporting staff are aware of current regulations relating to clinical research. This programme includes delivery of NHS Research Scotland (NRS) GCP training and a wide range of Research Education courses including GCP for Laboratories.

It is the line manager's responsibility to ensure staff have the appropriate qualifications, skills, knowledge and training for the duties they perform,

Each member of staff is responsible for the quality of their work and must keep a training record with evidence of appropriate training for their role.

## 11. Data

Clinical research activities involve collecting, storing, analysing and destroying data which must be done in compliance with GCP and GDPR. A Data Protection Impact Assessment is carried out for studies sponsored by UoD and/or NHST.

## 12. Biological Samples

Research activities may involve handling, processing, analysing and disposing of human samples. Sponsor is expected to have oversight of laboratory selection and the work undertaken. To ensure integrity and avoid contamination or loss, samples must be subject to temperature control and a documented chain of custody. Samples to be retained at the end of study for future research will be registered with Tayside Biorepository or returned to the owner as documented.

## 13. Investigational Medicinal Product (IMP)

The Clinical Trials Pharmacist and appropriately trained pharmacy staff must comply with the principles of GCP and Good Manufacturing Practice (GMP Annexe 13) when receiving, preparing, dispensing, delivering and disposing of IMP. Environmental and drug accountability records will be kept. For sponsored studies, Clinical Trials Pharmacy staff will ensure that any Drug Storage & Supply Sites that are external to a central pharmacy are secure and GCP compliant.

## 14. Equipment and Facilities

Equipment must be fit for purpose and capable of achieving the accuracy required for measurements. Equipment will be calibrated, serviced and maintained with up-to-date records available. Staff must be trained accordingly. Facilities must be safe, fit for purpose and secure.

*Note: Financial audits and Health and Safety inspections are not addressed in this policy.*

## Abbreviations

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| CTIMP | Clinical Trial of an Investigational Medicinal Product |
| GCP | Good Clinical Practice |
| GDPR | General Data Protection Regulation |
| GMP | Good Manufacturing Practice |
| IMP | Investigational Medicinal Product |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| NHST | NHS Tayside |
| NRS | NHS Research Scotland |
| QA | Quality Assurance |

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

**Document History**

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

| Version Number | Edited by (job title) | Effective Date | Details of editions made |
|---|---|---|---|
| 9 | Valerie Godfrey (TASC QA Manager) | 21/04/2022 | Minor changes to update Committee and School names. Removal of reference to AHSP on page 1 as this is no longer appropriate. |
| 10 | Valerie Godfrey (TASC QA Manager) | 22/04/2024 | Refreshment of text throughout. Section 10, previously Training, is now Education. |
| 11 | Valerie Godfrey (TASC QA Manager) | 22/04/2026 | Scheduled review. Updated the reference in section 2 to "The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025". Vocabulary changed in line with ICH-GCP R3 updated terms. |

| Approved by | Date |
|---|---|
| Dr Elaine Lee, Interim Head of Division, University of Dundee,<br>on behalf of TASC Research Governance Oversight Committee | 14 Apr 2026 |
| **Approved by** | **Date** |
| Professor Russell Petty, Tayside R&D Director, NHS Tayside | 15 Apr 2026 |

**APPENDIX 1**

**TASC Quality Management System**