TAYSIDE MEDICAL SCIENCE CENTRE QUALITY POLICY

POLICY NUMBER:	TASC POLICY 003v10
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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

This Quality Policy describes the procedures adopted by TASC in order to ensure the safety of participants, integrity of data and to comply with:

- Principles of Good Clinical Practice (GCP)
- The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004 No 1031)
- The Medical Devices Regulations 2002 (SI 2002 No 618)
- UK Policy Framework for Health & Social Care Research (2017)
- General Data Protection Register and Data Protection Act (2018)
- Human Tissue (Scotland) Act 2006
- TASC policies and Standard Operating Procedures (SOPs).

This policy applies to researchers and TASC staff who participate in Clinical Trials of Investigational Medicinal Products (CTIMPs) and Medical Device Clinical Investigations that are sponsored or co-sponsored by UoD and/or NHST. This policy demonstrates “good practice” for all other staff who may work on non-CTIMPs or Medical Device Clinical Investigations to follow while carrying out clinical research activities.

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.

Please visit the TASC website for the latest version of this Policy

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-based programme of GCP audits of processes, facilities and studies within TASC.

5. Audit of external facilities/service providers (vendors) to TASC are carried out as required.

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 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.

- Continually work to build quality improvements and efficiencies in to 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 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-based 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 described as overseeing the progress of a clinical trial and ensuring that it is conducted, recorded and reported in accordance with the protocol, SOPs, GCP and regulatory requirements. The frequency of monitoring visits is scheduled by the Sponsor risk assessment. Monitoring responsibilities may be transferred in writing to appropriate groups and organisations. Such delegation of monitoring responsibilities must be made using a formal agreement or contract.

10. Education

A 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, GDPR and the Data Protection Act. A Data Protection Impact Assessment is carried out as part of the Sponsor risk assessment for studies sponsored by UoD and/or NHST.

12. Biological Samples

Research activities may involve handling, processing, analysing and disposing of human samples. To ensure integrity and avoid contamination or loss, samples must be subject to a documented chain of custody. Samples to be retained at the end of study for future research will be registered with Tayside Biorepository.

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 Drug Storage & Supply Sites that are external to the 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

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
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.

Approved by	Date
Professor Linda Martindale, Dean, School of Health Sciences, University of Dundee, on behalf of TASC Research Governance Oversight Committee	17 Apr 2024
Approved by	**Date**
Dr Steve McSwiggan, Senior R&D Manager, on behalf of Professor Russell Petty, Tayside R&D Director, NHS Tayside	17 Apr 2024

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APPENDIX 1

TASC Quality Management System