TAYSIDE MEDICAL SCIENCE CENTRE COMMERCIAL RESEARCH POLICY

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1. Introduction

This document together with specified procedure instructions represents the Commercial Research Services (CRS) of Tayside Medical Science Centre (TASC) in relation to commercially sponsored trials. TASC was formally established on 1st January 2010. The Centre combines the research strengths of the University of Dundee with NHS Tayside and is part of the eastern node of NHS Research Scotland (NRS).

2. Purpose of this Policy

The purpose of this policy is to set out how TASC Commercial Research Services manages and conducts itself in relation to commercially sponsored clinical trials.

3. Commercial Research Services Strategy

Our Vision

To bring as many commercial research opportunities as possible to NHS Tayside and support our research community in improving the health of Tayside's population.

To do this we must ensure that our internal and external customers view CRS as

- A centre of choice in all areas of local strength
- The most efficient, robust and transparent research site in Scotland
- A helpful, supportive and pragmatic R&D department.

Mission statement

To promote, facilitate and regulate sustainable commercially sponsored clinical research in Tayside for the benefit of the people of Tayside.

Commercial Research Team Core Values:

1. Patient Safety First
2. Excellent Customer Service

3. Promote world class clinical research in Tayside
4. Committed to Delivery
5. Financial sustainability and transparency
6. Strong working relationships with all stakeholders.

4. Roles and Responsibilities of Commercial Research Services

With regards to commercial research undertaken within Tayside the Commercial Research Services Policy ensures that:

1. We are an ethical, transparent and robust service.
2. We negotiate clinical study terms and conditions that are acceptable to both NHS Tayside and commercial sponsors.
3. We cost and price commercial trials in a robust and transparent way.
4. We manage any income and ensure costs recovered are disbursed appropriately and transparently.
5. We effectively minimise and manage any related risks to either NHS Tayside/University of Dundee.
6. We conduct ourselves in a responsible and professional manner with all stakeholders.
7. We regularly review our processes and policies and update them as required.

5. Confidentiality

All confidentiality agreements should be reviewed by the commercial research team within R&D and should be signed off at institutional level to protect our investigators.

6. Feasibility Process

It is critical to ongoing and future business that the feasibility process is followed accurately. By following the process this enhances our reputation as an active research site. We aim to bring all feasibilities to the attention of our Investigators within 48 hours of receipt and to respond to sponsor with a detailed feasibility inclusive of Confidentiality Disclosure Agreement (CDA) within their specified timelines.

7. Clinical Trial Agreements

Tayside's policy is to use the latest version of the standard Scottish version Association of the British Pharmaceutical Industry (ABPI) model clinical trial agreement (mCTA) for all Industry - Led clinical trials. This agreement has been agreed with the Department of Health, Chief Scientist Office of Scotland and many of the major pharmaceutical companies.

8. Approving Industry-Led Clinical Trials

The facilitation of enhanced start up processes and the approval of commercially sponsored trials are major functions of our team and therefore a key aspect to the delivery of our goals. The Chief Scientist Office (CSO) national target for local approval of commercial studies is to approve within 10 calendar days of receipt of a full document set.

9. Costing and Pricing of Industry-Led Clinical Trials

Tayside's policy for the costing and pricing of all Industry Sponsored Research is to use the NIHR interactive Costing Tool (iCT). This has been endorsed by the Department of Health, Chief Scientist Office of Scotland, and Industry. The nationally agreed performance by results (PBR) multiplier has been agreed for all Scottish sites of 1.2.

10. Income Distribution from Industry-Led Clinical Trials

The TASC Policy on Income Disbursement for Industry-Led Commercial Trials was introduced to provide study teams with a simple, efficient, and transparent process of how monies from trials would be disbursed. This joint policy also gives parity across both institutions. This policy has been active since 1st April 2010 for all new Industry-Led commercial clinical trials.

11. Managing Commercial Study Amendments

Commercial Amendments are an important aspect of our business. They may affect the way the trial is conducted and they may have financial or contractual implications for CRS. The target to complete an amendment review is within 35 calendar days of receipt of the full document set.

12. Single site or multi-centred research in Scotland

In Scotland, all multi-centred industry sponsored clinical research is coordinated by the NRS Permissions Coordinating Centre (NRSPCC). NRS PCC will generate a unique NRS ID number for tracking and audit purposes and will allocate a Study Wide Reviewer/Generic Reviewer to carry out a full governance review and negotiate the study budget and contract on behalf of all UK participating sites.

If Tayside is the only UK site participating in a study this does not go through NRSPCC instead we generate a local ID similar to the NRS ID e.g. CRS19/IRASID and carry out the study review locally.

13. Version Control of Documents

The use of whole number e.g. V1 should be used for all documents. If the sponsor uses a different policy then then we will mirror the pharmaceutical company system.

14. **Set Up Fees for Industry Sponsored Research**

Set up fees are reviewed on a yearly basis via the National Institute for Health Research (NIHR) Industry Costing group. A comparison with other UK research sites is conducted on a yearly basis in an effort to ensure the UK remains competitive globally in setting up and delivering commercial trials.

15. University of Dundee Requirements in relation to Industry sponsored Clinical Trials

All contractual agreements with sponsors are with NHS Tayside and therefore the Board has agreed a number of commitments to maintain this policy which are as follows:

It has been agreed that the Board shall ensure that:

1. The Board has obtained valid written confirmation of all regulatory approvals and other applicable permissions necessary, including but not limited to, an approval from the Medicines and Healthcare products Regulatory Authority and a favourable opinion from the relevant NHS Research Ethics Committee (REC).
2. The University has insurance cover for the participation of all University Staff.
3. The Sponsor has and maintains adequate insurance cover.
4. A Project Registration Form (PRF) has been completed and signed evidencing:-
    a. that the price agreed with the Sponsor for the participation of University Staff is adequate to cover the full economic cost (fEC) of the time commitment of the University Staff.
    b. that the University Principal Investigator, if applicable, has agreed to the price payable to the University and to the disbursement thereof.
5. The University Principal Investigator, if applicable, has accepted his/her responsibilities under the Clinical Trial Agreement and there is written evidence to this effect.
6. Financial due diligence has been carried out with regard to the party responsible for payment to the Board.
7. A duly authorised officer of the Board signs all legally binding agreements in accordance with the Code of Corporate Governance, having taken the above into account.

The Board agrees that in relation to (1) to (3) above these obligations will be met prior to giving R&D Approval in relation to a Clinical Trial.

Following R&D approval of a Clinical Trial, the Board shall ensure that a copy of the R&D approval, fully executed mCTA, study protocol, completed and signed PRF and disbursement sheet for the Clinical Trial are sent to Research Finance Services at University of Dundee. CRS will support the entry of this information onto the University's IRIS Database for use by the University's Finance Office.

Abbreviations

ABPI	Association of the British Pharmaceutical Industry
CDA	Confidentiality Disclosure Agreement

CRS	Commercial Research Services
CSO	Chief Scientist Office
fEC	Full economic cost
iCT	Interactive Costing Tool
mCTA	Model Clinical Trial Agreement
NIHR	National Institute for Health Research
NRS	NHS Research Scotland
NRSPCC	NRS Permissions Coordinating Centre
PBR	Performance by results
PRF	Project Registration Form
R&D	Research & Development
REC	Research Ethics Committee
TASC	Tayside Medical Science Centre

DOCUMENT HISTORY

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

Version Number:	**Reviewed By (Job Title):**	**Effective Date:**	**Details of editions made:**
7	Julie Johnston (Head of Commercial Research Services)	26/03/2023	Scheduled review date: Organisational chart in section 4 updated. Section 16 updated to include revised list of documents sent to University of Dundee. Abbreviations updated to include iCT.
8	Julie Johnston (Head of Commercial Research Services)	26/03/2025	Scheduled review date: Organisational chart in section 4 updated. Section 13 updated in line with current UK working practices.

APPROVALS

Approved by:	**Date:**
Professor Linda Martindale, Dean, School of Health Sciences, University of Dundee, on behalf of TASC Research Governance and Oversight Committee	25th Mar 2025
Approved by:	**Date:**
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	25th Mar 2025

APPENDIX 1

Commercial Research Services – Organisational Chart