



## TAYSIDE MEDICAL SCIENCE CENTRE CONTRACTS POLICY

POLICY NUMBER:	TASC POLICY 007 v10
AUTHOR:	Euan Banyard
EFFECTIVE DATE:	14 Oct 2025
REVIEW DATE:	14 Oct 2027

### Scope

**This policy applies to contracts relating to Clinical Trials of Investigational Products (CTIMPs) and is for use by the individuals in TASC Legal responsible for preparing these contracts.** This contracts policy relies on the TASC sponsorship policy in relation to CTIMPs which is that **all such studies shall be co-sponsored.**

### 1. Purpose

The Purpose of the policy is to clarify who the “contracting party” will be for any legal agreement which relates to an Investigator-led CTIMP study sponsored by the **University of Dundee (the University)** and **Tayside Health Board (the Board)** acting as the co-sponsors.

Depending on the circumstances, the “contracting party” can be either the **University** OR the **Board** OR **both** of them together.

Legal agreements may be required with external third parties or required internally between the University and the Board. Third parties are therefore legal bodies other than the University or the Board. Third parties contracted with are likely to be other Health Boards, other Universities or companies providing funding, or supplying study drugs, services or simply collaborating on the conduct of the study.

The TASC Legal team will, on behalf of the University and the Board, take the lead on the arrangements for the negotiation, drafting and sign off of any legal agreement whether with external third parties or for internal arrangements between the University and the Board. Although it is not anticipated that a conflict of interest would arise, in such circumstances where agreements are between the University and the Board, the negotiation of these agreements will be carried out for the Board by the Board member of the TASC Legal Team and for the University by a University member.

Depending on the type of study, TASC Legal may consult with the Chief Investigator, Study Personnel, Non-Commercial R&D, Governance, Finance, the Tayside Clinical Trials Unit (TCTU) and others to ensure all stakeholders have appropriate input.

## **2. University and Board Co-Sponsored Studies**

### **i) Site Agreements (Multi Site Studies)**

Third-Parties

For governance reasons, the University and the Board (“acting as the Co-Sponsors”) will both be party to any Site Agreement with a third party acting as a Site. This document will highlight in the Division of Responsibilities section the Sponsor responsibilities allocated as between the University and the Board and will detail to whom the related activities may be delegated, either the study Chief Investigator or Principal Investigator at the third-party Site.

Tayside (the Board)

To reflect the practice with Organisation Information Documents (OIDs) (in relation to non-CTIMP studies), where the Site is Tayside, then a Site Agreement will be put in place between the University and the Board (acting as Co-Sponsors) on the one part, and on the other part, with the Board (acting as the Site).

In terms of costs passing under the Site Agreement where the Site is Tayside, these costs will be the same costs that are payable to any third-party Site for site activity, recruitment and the like. This standardises the Site Agreement template for generic review.

Any other grant co-applicant research costs, support costs, sponsor costs or the like (which are not costs linked to Tayside’s recruitment activity while acting as a Site) due to the Board (Tayside) by the University and which relate to the Board’s other study roles, and to be funded by the University where the University has been grant-funded or commercially supported, will be made over under the research collaboration agreement relevant to the study, or under a template financial appendix used for recovery of service support costs as between the Co-Sponsors.

Where Tayside is the employer of the Chief Investigator and in receipt of funding for a study, then any costs due to the University for its role in the study will be made over under a research collaboration agreement or a financial appendix for recovery of service support costs.

### **ii) Study Drug Supply Agreements, Service Agreements and Funding Arrangements**

All Study Drug Supply Agreements, Service Agreements and Funding Agreements shall generally be entered into by the institution that is the employer of the Chief Investigator (and is to be in receipt of the supply, service or funding), i.e. either the University OR the Board whichever is relevant.

## **3. Internal Sponsorship Arrangements**

The University and the Board or their respective representatives shall be the parties to Sponsor oversight arrangements. These are “internal” written arrangements made on a study-by-study basis and which provide further detail in addition to the over-arching

framework arrangements described in the Heads of Co-Sponsorship Agreement between the University and the Board.

For co-sponsored studies, these shall be: -

- i) **A Co-Sponsor Agreement & Chief Investigator Declaration** between the University, Board and Chief Investigator (providing for the allocation of responsibilities as between the University and the Board, and detailing which of these responsibilities are delegated for performance to the CI). This can include responsibilities delegated to the TCTU where relevant;
- ii) **A Drug Supply Agreement.** Where there is a study drug supply by a third party, there will usually be an Investigator-initiated Clinical Trial Agreement, a Clinical Trial Support Agreement or a Drug Supply Agreement between the third party study drug supplier and the institution acting as study lead (being the employer of the Chief Investigator);
- iii) **Funding Agreement.** These will be between the funder and the employer of the Chief Investigator.
- iv) **Service Provision and Data Sharing.** These will be between the institution contracting the service or holding the data and the third party providing the service or receiving data.

## 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:
8	Gary Clark (Contracts Manager)	13/12/2021	Minor revision to explain procedure to counteract potential conflict.
9	Euan Banyard (TASC Legal Services Manager)	13/12/2023	Review and revision to update; some clarification and expansion; no substantive changes.
10	Euan Banyard (TASC Legal Services Manager)	14/10/2025	Review and update following discussion on use of OID for single site studies/where Tayside is a site.

**APPROVALS**

<b>Approved by:</b>	<b>Date:</b>
Dr Elaine Lee, Interim Dean, School of Health Sciences, University of Dundee, on behalf of TASC Research Governance and Oversight Committee	08 Oct 2025
<b>Approved by:</b>	<b>Date:</b>
Professor Russell Petty, R&D Director, NHS Tayside	08 Oct 2025