TAYSIDE MEDICAL SCIENCE CENTRE CONTRACTS POLICY

POLICY NUMBER:	TASC POLICY 007 v9
AUTHOR:	Euan Banyard
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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.

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)** or **Tayside Health Board (**the **Board)** or, both the **University** and 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 will consult with the Chief Investigator, Study Personnel, Non-Commercial R&D, Governance, Finance, TCTU and others to ensure all stakeholders have appropriate input.

2. University Single-Sponsored Studies

Where a legal agreement is required with a third party for a University single-sponsored study, i.e. where the University is acting as the Sponsor alone, the University will be the contracting party to any agreement.

Therefore, the agreement will be between the University and the third party.

Examples of the type of issues requiring a legal agreement include: -

(i) Site arrangements for the conduct of the study;

(ii) Study drug supply;

(iii) Service provision;

(iv) Funding support;

(v) Data sharing and material transfer.

3. Board Single-Sponsored Studies

Where a legal agreement is required with a third party for any Board single-sponsored study, i.e. where the Board is acting as the Sponsor alone, the Board will be the contracting party to any such agreement.

Examples of the type of legal agreements are similar to those included in section 2 above.

4. University and Board Co-Sponsored Studies

i) Site Agreements (Multi Site Studies)

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.

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.

5. 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 single sponsored University studies, these shall be: -

i) A Sponsor to NHS Delegation between the University and Board (of the sponsor responsibilities delegated to the Board to perform, for example, pharmacy or monitoring);

ii) A Sponsor to Chief Investigator Delegation between the University and Chief Investigator (of the sponsor responsibilities delegated to the CI, for example, applying to the MHRA for a Clinical Trial Authorisation);

iii) A Drug Supply Agreement. Where there is a study drug supply by Tayside Pharmaceuticals (an internal division of the Board), there will be a Drug Supply & Technical Agreement between the University/University's representative (as represented by the study Chief Investigator) and the Board/Board's representative (as represented by Tayside Pharmaceuticals).

For single sponsored Board studies, these shall be: -

i) A Sponsor to Chief Investigator Delegation between the Board and Chief Investigator;

ii) A Drug Supply Agreement. Where there is a study drug supply by Tayside Pharmaceuticals (an internal division of the Board), there will be a Drug Supply & Technical Agreement between the Board acting as study drug supplier (as represented by Tayside Pharmaceuticals) and the Board acting as study lead (as represented by the Chief Investigator) notwithstanding that this agreement may be legally unenforceable. The document serves to evidence the governance arrangements and agree the cost of supply for the purposes of internal financial arrangements.

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);

ii) A Drug Supply Agreement. Where there is a study drug supply by Tayside Pharmaceuticals (i.e. the Board), there will be a Drug Supply & Technical Agreement between the Board acting as study drug supplier (as represented by Tayside Pharmaceuticals) and the institution acting as study lead - in most cases the University - (as represented by the Chief Investigator).

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.

APPROVALS

Approved by:	**Date:**
Dr Linda Martindale, Dean, School of Health Sciences, University of Dundee, on behalf of TASC Research Governance and Oversight Committee	07 Dec 2023
Approved by:	**Date:**
Professor Russell Petty, R&D Director, NHS Tayside	07 Dec 2023