STANDARD OPERATING PROCEDURE FOR NON-COMMERCIAL SPONSORSHIP OF CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

SOP NUMBER:	TASC SOP028 v13
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1. PURPOSE

This Standard Operating Procedure (SOP) describes the process for obtaining non-commercial co-sponsorship from University of Dundee (UoD) and NHS Tayside (NHST) for Clinical Trials of Investigational Medicinal Products (CTIMPs) conducted under the UK Clinical Trials Regulations (as amended and implemented in 2026) and ICH Good Clinical Practice (GCP) (as adopted in the UK).

This SOP applies specifically to non-commercial CTIMPs, defined as trials co-sponsored by UoD and NHST, that are not undertaken for commercial gain or marketing, and are designed to address scientific, clinical, or public health questions in the interests of patient care and to generate new knowledge. This includes trials involving licensed and unlicensed Investigational Medicinal Products (IMPs).

2. SCOPE

This SOP applies to any individual employed by, or holding an honorary contact with, the UoD or NHST who is seeking non-commercial sponsorship for a CTIMP following a successful grant application or by confirmation of adequate internal or external funding.

The SOP applies to both single-centre and multi-centre UK CTIMPs conducted in the UK including combined IMP and medical device trials where the IMP is the primary regulated intervention.

Note:
UoD/NHST shall not undertake the role of local Sponsor for global CTIMPs.
For global CTIMPs sponsored outside the UK, the Organisations may, on a case-by-case basis, consider acting as the UK Legal Representative, subject to contractual agreement and compliance with MHRA requirements.

NHST/UoD as Co-Sponsors do not accept responsibility for any non-UK registrations without prior approval

3. RESPONSIBILITIES

Chief Investigator (CI):

- To prepare documentation of a sufficient standard to enable a thorough and robust risk assessment.
- To ensure an Inclusivity and Diversity Plan is developed and maintained, setting out how the trial will support inclusive participation, address barriers to access, and minimise the risk of excluding groups historically underserved by research.
- To detail recruitment strategies within the protocol, consistent with the principles set out in ICH E6(R3) as part of a proportionate, Quality by Design approach.
- To complete a Data Protection Impact Assessment (DPIA) and obtain appropriate review before commencing the trial.
- To ensure sponsorship is in place prior to submission to Research Ethics Committee (REC), Medicines and Healthcare Products Regulatory Agency (MHRA) and relevant Health Boards/Trusts.
- To ensure that participant recruitment does not commence until Sponsor Green Light has been issued, and NHS R&D permission has been obtained for each participating location before recruitment begins at that location.
- To notify Research Governance and TASC Legal of the intention to open non-UK location, and prior to any registration on non-UK regulatory systems.

Research Governance:

- To undertake a proportionate risk assessment of the Protocol and associated trial documentation to support decisions relating to sponsorship and oversight.
- To liaise with the UoD Insurance provider (UMAL) via university representative, to ensure appropriate cover for trial.
- To provide R&D Director/Delegate, and others as appropriate with the Protocol and Investigator Brochure (IB), Reference Safety Information or Summary Product Characteristics (SmPC) to support decisions relating to sponsorship and oversight.
- To liaise with Quality Assurance (QA) Manager on a trial-by-trial basis to ensure Good Clinical Practice (GCP) audits of co-sponsored CTIMPS including facilities, processes and vendors are carried out in accordance with the TASC Audit Programme and TASC Quality Policy.
- To provide Pharmacovigilance Monitor with IB/SmPC to enable risk assessment of the Reference Safety Information and ensure its suitability for the specific clinical trial.
- To provide Lead Monitor with final Sponsor Risk Assessment to inform development of Monitoring Plan and to ensure that monitoring activities outlined in the Monitoring Plan are proportional to, and compliant with, the identified risks.
- To delegate Sponsor specific tasks to suitably qualified and experienced individuals or organisations where required, and where that delegate is willing and able to accept them.
- To ensure completion of Sponsor Green Light form at the Lead Location Initiation/Green Light Visit, with documented confirmation that the IMP is available at location and IMP related documentation is complete, accurate, and compliant with regulatory requirements, where Tayside Pharmacy responsible for IMP.

- To formally approve and sign the completed Green Light Form once satisfied that all Sponsor requirements have been met and to issue a copy of the approved form to the trial and Monitoring teams.

Permission to begin recruitment at external locations shall be delegated to CI and trial team.

TASC Legal team:

- Responsibility for the negotiation and management of contracts and agreements Contractual discussions and agreement development may occur prior to submission of the project to Research Governance for Sponsorship consideration or in parallel during the Sponsorship review process.

4. PROCEDURE

4.1 Submission requirements for Sponsorship

All requests for the UoD/NHS to act as Co-Sponsors for a CTIMP must be submitted to TASCgovernance@dundee.ac.uk

Documentation (Initial Sponsor review)
The following documents must be provided to enable assessment in line with UK CTIMP Regulations as updated and Combined Review requirements administered via Integrated Research Application System (IRAS)

- Online request to accept sponsorship through IRAS Gateway.
- Evidence of funding
  - sufficient to deliver the trial to completion, including close-down and archiving.
- Short CV of CI
  - Evidence of role suitability and CTIMP experience where applicable.
- Confirmation of independent peer review if not at grant application stage.
- Copy of GCP training certificate for CI
  - This must be aligned to the UK Clinical Trial Regulations, including the current UK regulatory framework for CTIMPs.
- IB or SmPC or Investigational Medicinal Product Dossier (IMPD)
  - Reference Safety Information (RSI) must be clearly identified to enable risk assessment for suitability for trial.
- Draft Protocol using Health Research Authority (HRA) template, incorporating:
  - Trial classification
  - Safety reporting strategy aligned with MHRA requirements.
    A risk-adapted and proportionate monitoring approach may be proposed within the Protocol, consistent with the principles of proportionality set out in the UK Clinical Trials Regulations and ICH-GCP.
- Participant Information Sheet (PIS), which must adhere to the specific guidance and template available from Sponsor or HRA website,
  - To include explicit reference to data use, retention and sharing.
- Informed Consent Form

  - To include where applicable, consent for future use of data and/or samples
  - To include provision for electronic or remote consent if proposed.
- Outline Organisational Information Document for each location type
  - e.g. NHS Location, non-NHS Location, and primary care.
- Completed Schedule of Events Costing Attribution Tool (SoECAT)
  - To support AcoRD-compliant cost and attribution.

Research Governance may request any documentation necessary to assess regulatory, ethical, or operational readiness, including but not limited to:

  - Recruitment materials (e.g. adverts and posters)
  - Letter of invite, if separate from PIS
  - Participant diary
  - Questionnaires or participant-reported outcome measures
  - Letter to General Practitioners (GP)
  - Draft emails to participants and/or text messages
  - Data Management Plan
  - Emergency Contact card if required by Protocol.

Documents must always be version controlled using whole numbers only and follow Sponsor SOP of version control. Initial submitted documents must be DRAFT V1 dd-mm-yyyy.
On receipt of the application and all trial documents, Research Governance shall ensure registration of the trial on the Sponsor Tracker and record the unique Sponsor identification number.

4.2 Risk Assessment

Research Governance shall:

- Document the Risk Assessment.
  - Seek further opinion, where deemed necessary, in accordance with trial oversight and governance requirements. If no response is received by provided deadline, it will be assumed that the recipient has no objections or comments.
- Contact the Vice-Principal of Faculty of Health where approval for Sponsorship may depart from established governance practice or introduce reputational, legal, or financial risk.
  - No response will be assumed as negative response in which case the process will be discontinued and research team informed.
  - An appeal can be made by CI to the Vice-Principal and Research Governance to be informed of the outcome.
- Submit the completed Insurance questionnaire to the UoD Insurance function via the designated email address, for assessment of adequacy of insurance cover for the trial to confirm whether appropriate, or trial-specific cover is required, or determine if cover cannot be provided,
  - Inform the CI or delegate of this outcome and to determine if risk assessment continues or is abandoned
  - The trial shall not commence without evidence of cover.

- Liaise with the TASC QA Manager during the sponsorship process to ensure overall systems remain appropriate during trial design and set up.
- Ensure the finalised Risk Assessment is reviewed and approved by the CI and signed prior to Sponsor authorisation.
    - The signed document will then be returned to Research Governance for signature.
    - A copy will be provided to the CI/delegate for retention in the Trial Master File (TMF).
    - Provide a copy of the finalised Risk Assessment to the Lead Monitor to inform the risk-based Monitoring Plan, in accordance with ICH GCP E6(R2).

4.3 Sponsorship Decision

Co-sponsorship will be confirmed by the NHS R&D Director or delegated representative following review and assessment and evidenced by a formal co-sponsorship letter.

4.4 Sponsorship Approved

Following confirmation of sponsorship, Research Governance shall:

- Inform the CI of the decision.
- Ensure the Risk Assessment is signed by the CI and Sponsor representative.
- Issue the Confirmation of Co-sponsorship letter, as signed by R&D Director/Delegate.
- Provide the CI with evidence of Insurance.
- Submit IRAS forms.
- Inform the Monitoring team that sponsorship has been confirmed.

4.5 Following REC, MHRA and lead R&D approval

Research Governance shall ensure Green Light at lead location is completed.

4.6 Contracts and Agreements

4.6.1 A signed copy of the Sponsor/CI Delegation of Responsibilities Agreement shall be retained in the Sponsor File and a copy forwarded to the CI. The TASC Contracts Manager will draw up/approve any agreements and ensure are signed and returned in a timeous manner.

4.6.2 The original copy of the fully executed Agreements will be retained by TASC Legal and a copy sent to the CI for filing in the TMF. These documents will be archived within the Sponsor File at the time of archiving.

4.7 Modifications

The review of sponsorship arrangements for all research projects will be ongoing for the duration of the trial.

The CI is responsible for submitting details of all proposed modifications to Research Governance for review, classification, and Sponsor approval prior to submission to the NHS Research Ethics Committee (REC), NHS R&D offices, or the MHRA, as applicable. Research Governance shall retain evidence of risk assessment for each modification.

4.8 Data Protection Impact Assessment

The CI shall complete the DPIA to ensure compliance with the General Data Protection Regulation (GDPR) and liaise with the Data Protection team at UoD and/or NHST as appropriate.

4.9 Sponsorship Declined

Where sponsorship is declined, the CI will be informed of the decision and provided with the justification.
The CI may be advised to amend the proposed trial and resubmit for further consideration or will be informed that Sponsor approval will not be granted.
The CI may appeal to the R&D Director and Vice-Principal, Faculty of Health.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
DPIA	Data Protection Impact Assessment
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GP	General Practitioner
HRA	Health Research Authority
IB	Investigational Brochure
IMP	Investigational Medicinal Products
IMPD	Investigational Medicinal Product Dossier
IRAS	Integrated Research Application System
MHRA	Medicines and Healthcare Products Regulatory Agency
NHST	NHS Tayside
PIS	Participant Information Sheet
QA	Quality Assurance
REC	Research Ethics Committee
RSI	Reference Safety Information
SmPC	Summary of Product Characteristics
SoECAT	Schedule of Events Costing Attribution Tool
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
TMF	Trial Master File
UoD	University of Dundee

6. ASSOCIATED DOCUMENTS & REFERENCES

None

7. DOCUMENT HISTORY

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

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
8	Patricia Burns (Senior Research Governance Manager)	21/10/2022	Minor updates - taking into account IRAS Gateway.
9	Patricia Burns (Senior Research Governance Manager)	26/07/2023	Minor updates to voting process to take into account potential delays in responses.
10	Patricia Burns (Senior Research Governance Manager)	15/03/2024	Requirement for a completed Schedule of Events Costing Attribution Tool (SoECAT) added to section 4.1
11	Patricia Burns (Senior Research Governance Manager)	14/10/2024	Amended in line with updated Heads of Agreement between NHS Tayside and University of Dundee. Section 3 has been updated to state that CI must notify Sponsor of the intention to open non-UK sites and Research Governance (RG) will provide TASC Legal with a completed copy of the Risk Assessment.
12	Patricia Burns (Senior Research Governance Manager)	28/04/2026	Updated in accordance with the new Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2026.
13	Patricia Burns (Senior Research Governance Manager)	20/10/2026	No procedural changes made at scheduled review. IMP and RSI added to abbreviations list.

8. APPROVALS

Approved by:	Date:
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	15 Oct 2026
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	15 Oct 2026