STANDARD OPERATING PROCEDURE FOR SPONSORSHIP OF CLINICAL TRIALS

SOP NUMBER:	TASC SOP028 v11
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1. PURPOSE

This Standard Operating Procedure (SOP) describes the process to obtain sponsorship from University of Dundee (UoD) and/or NHS Tayside (NHST) for the following projects:

- Clinical Trial of an Investigational Medicinal Product (CTIMP),
- Clinical investigation or other study of a medical device,
- Combined trial of an investigational medicinal product and an investigational medical device,
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

2. SCOPE

This SOP applies to any researcher employed by the UoD or NHST requesting sponsorship for the above listed projects following successful grant application or confirmation of adequate funding.

3. RESPONSIBILITIES

Chief Investigator (CI):

- 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 complete a Data Protection Impact Assessment (DPIA),
- To wait for confirmation of Sponsor Green Light before commencing recruitment.
- To notify Sponsor of the intention to open non-UK sites, and prior to any registration on non-UK regulatory systems. Note: the Sponsor does not accept responsibility for any non-UK registrations without prior Sponsor approval.

Research Governance (RG):

- To risk assess the Protocol and relevant study documentation to assist in decision on sponsorship,
- To contact University of Dundee Insurance provider (UMAL) via University representative to ensure appropriate cover for trial,

- To provide R&D Director, Clinical Trial Pharmacist, TASC Legal representative and others as appropriate with the Protocol and Investigator Brochure (IB), Reference Safety Information or Summary Product Characteristics (SmPC) as relevant to the trial,
- To delegate specific tasks to named individuals or organisations where required, and where that delegate is willing and able to accept them,
- To liaise with Quality Assurance (QA) Manager about each trial, 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 TASC Legal with final Sponsor Risk Assessment for contract and agreement purposes,
- To provide Lead Monitor with final Sponsor Risk Assessment for Trial Monitoring Plan and to ensure that the plan complies with identified risks,
- To provide Sponsor Green Light draft form to the Monitor for completing at the Tayside Site Initiation/Green Light Visit, including obtaining an approval signature from the Clinical Trials Pharmacist to confirm that the IMP is on site and IMP documentation is in order,
- To sign the completed Green Light Form once satisfied that all conditions have been met and give to trial team and Monitoring team.

The Green Light occurs when the Sponsor and Tayside Clinical Trials Pharmacist are satisfied with the conditions for IMP release. Permission to begin recruitment at external sites shall be delegated to CI and trial team as per permissions required.

Clinical Trial Pharmacist:

- To sign Green Light Form as provided by the Monitor, when satisfied all conditions have been met as per GCP, Tayside Clinical Trials Pharmacy SOPs and trial Approvals.

TASC Legal team:

- To arrange contracts/agreements where required.

4. PROCEDURE

4.1 Applying for Sponsorship

The following must be sent to TASCgovernance@dundee.ac.uk

- Online request to accept Sponsorship through Integrated Research Application System (IRAS) Gateway,
- Evidence of funding,
- Short CV of CI,
- Evidence of peer review if not at grant application stage,
- Copy of GCP training certificate for CI,
- IB or SmPC or Investigational Medicinal Product Dossier (IMPD),

- Draft Protocol using Health Research Authority (HRA) template,
- Participant Information Sheet (PIS), which must adhere to the specific guidance and template available from HRA website, the HRA recommended wording for General Data Protection Regulations (GDPR) compliance must be used,
- Informed Consent Form which must adhere to the specific guidance and template available from the HRA website (search for online consent guidance tool),
- Outline Organisational Information Document for each site type,
- Completed Schedule of Events Costing Attribution Tool (SoECAT).

This list is not exhaustive. The Sponsor may request any documents relevant to the trial e.g.

- Advert
- Letter of invite, if separate from PIS
- Patient diary
- Questionnaires
- Letter to GP
- Draft emails to participants
- Emergency Contact card if required by Protocol.

Documents must always be version controlled using whole numbers only. Initial submitted documents must be DRAFT V1 dd-mm-yyyy.
On receipt of the application and all study documents, Research Governance Manager (RGM) shall register the trial on the Sponsor Tracker and provide a unique Sponsor identification number.

4.2 Risk Assessment

4.2.1 The RGM shall document the Risk Assessment.

4.2.2 The RGM, shall provide advice and guidance on any amendments required, prior to review by the Sponsorship Committee and liaise with the investigator to ensure study documents identify and mitigate potential risks to trial participants and trial integrity.

4.2.3 The RGM will liaise with the TASC QA Manager during the process to ensure overall systems remain appropriate during trial design and set up.

4.2.4 The Risk Assessment will be provided to the CI for agreement and signature and returned to RGM for Sponsor representative to sign. A copy of the signed Risk Assessment will be retained in the Trial Master File (TMF).

4.2.5 When finalised, a copy of the Risk Assessment will be provided to the Lead Monitor to inform the Monitoring Plan which must consider the identified risks.

4.3 Insurance

4.3.1 The trial shall not commence without evidence of cover as provided by the University insurance provider

4.3.2 The UoD Insurance Manager will inform the RGM:

- If UoD insurance is sufficient for the trial,
- If trial-specific insurance requires to be sought,
- If the UoD cannot provide insurance for the trial.

4.3.3 The RGM will inform the CI or delegate of this outcome and confirm whether the risk assessment is to continue whilst insurance cover is organised, or whether the trial is to be abandoned at this stage.

4.4 Sponsorship Decision

4.4.1 Study Protocol and any other required documents shall be forwarded to advisors for review - for example experienced trial CIs, Statistician, Pharmacist, who will communicate to the RGM any queries or required changes. RGM will liaise with the study team to resolve. Research Governance retain the right to call on external advisors

4.4.2 The advisors are requested to respond within a reasonable period, 14 days, however the discussion will remain open until there are no unresolved queries.

4.4.3 Co-sponsorship of CTIMPs will be authorised by the NHS R&D Director after review and risk assessment by TASC Research Governance.

4.5 Sponsorship Approved

Following confirmation of sponsorship, the RGM shall:

- Inform the CI of the decision,
- Ensure the Risk Assessment is signed by the CI and Sponsor representative,
- Issue the Confirmation of Sponsorship letter,
- Provide the CI with evidence of Insurance,
- Submit IRAS forms,
- Inform the Monitoring team that sponsorship has been confirmed.

4.6 Following REC, MHRA and lead R&D approval

RGM shall provide the Monitoring team with the draft Green Light form for the monitor to take and complete at the Site Initiation/Green Light Visit. At the visit, the monitor will arrange authorisation by Clinical Trials Pharmacy and return the signed form to RGM for final sign-off.

4.7 Contracts and Agreements

4.7.1 The TASC Contracts Manager will draw up/approve any agreements and ensure that agreements are signed and returned in a timeous manner.

4.7.2 The original copy of the fully executed Agreements will be filed in the Sponsor File and a copy sent to the CI for filing in the TMF.

4.7.3 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.

4.8 Amendments

The review of sponsorship arrangements for all research projects is ongoing while the project is active. It is the CI's responsibility to forward details of all amendments to the RGM for review, classification and approval, prior to submission to NHS REC, R&D or the MHRA. RGM shall retain evidence of risk assessment for each amendment.

4.9 Data Protection Impact Assessment

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

4.10 Sponsorship Declined

If Sponsorship is declined, the CI will be advised to either amend the trial, as detailed by the documented risk assessment, and resubmit or advised that the trial will not receive approval, and be provided with the justification for this decision

The CI may appeal the decision and the RGM may organise a meeting between the CI and the NHS R&D Director.

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 Regulations
GP	General Practitioner
HRA	Health Research Authority
IB	Investigational Brochure
IRAS	Integrated Research Application System
IMPD	Investigational Medicinal Product Dossier
MHRA	Medicines and Healthcare Products Regulatory Agency
NHST	NHS Tayside
PIS	Participant Information Sheet
QA	Quality Assurance
REC	Research Ethics Committee
RG	Research Governance
RGM	Research Governance Manager
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 RG will provide TASC Legal with a completed copy of the Risk Assessment.

8. APPROVALS

Approved by:	Date:
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	11 Oct 2024