STANDARD OPERATING PROCEDURE FOR SPONSORSHIP OF CLINICAL TRIALS

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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.

Research Governance (RG):

- To risk assess the protocol and relevant study documentation to assist in decision on sponsorship
- To provide Sponsor Green Light draft to the Monitor for completion at Site Initiation Visit, including obtaining signature form Clinical Trial Pharmacy
- To provide signed Green Light Form to trial team and monitoring team when all conditions met.

Clinical Trial Pharmacist:

- To sign Green Light Form as provided by the Monitor, when satisfied all conditions have been met as per Good Clinical Practice (GCP), Clinical Trial Pharmacy SOPs and Approvals.

TASC Legal team:

- To arrange contracts/agreements where required.

Sponsorship Committee:

- To review and risk assess research projects and confirm or decline sponsorship
- To ensure potential risks have been mitigated both to trial participants and to trial integrity
- To decide on sponsorship on a case-by-case basis.

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
- Investigational Brochure (IB) or Summary of Product Characteristics (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, RG shall register the trial on the Sponsor Tracker and provide a unique Sponsor identification number.

4.2 Risk Assessment

4.2.1 Should the proposed research fall under MHRA Clinical Trial/Medical Device legislation, the Research Governance Manager (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 Quality Assurance (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 RG 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 take into account the identified risks.

4.3 Insurance

4.3.1 If the trial falls out with the terms of the UoD clinical research insurance policy the RGM will contact the UoD Insurance Manager.

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 Committee

4.4.1 Study Protocol and any other required documents shall be forwarded to the Sponsorship Committee, who will communicate to the RGM any queries or required changes. RG will liaise with the study team to resolve.

4.4.2 The Sponsorship Committee members are requested to vote within a reasonable number of working days, 7-14 preferably, but members' other commitments must be taken into account. The vote will remain open until there are no unresolved queries. Research Governance retain the right to call on external experts.
Voting options are:

- Vote 'Yes' to Approve for Sponsorship
- Vote 'No' to Not Approve for Sponsorship
- Abstain - due to conflict of interest.

4.4.3 The minimum number of votes for committee approval is 3 medically qualified members and one non-medically qualified member to vote 'Yes'.

4.5 Sponsorship Approved

Following confirmation of sponsorship from the Sponsorship Committee, 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

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

4.7 Contracts and Agreements

4.7.1 The TASC Contracts Manager will draw up/approve any agreements detailed in the Risk Assessment and will ensure that all 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, if required. The RGM may refer the trial back to the Sponsorship Committee for risk assessment and review of sponsorship, depending on the nature of the 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 Committee votes against approval in current draft, the CI will be advised to either amend the trial, as detailed by the Sponsorship Committee, and resubmit or advised that the trial will not receive approval.

Should the Sponsorship Committee decline Sponsorship, the Investigator may appeal the decision and the RGM may organise a meeting between the CI and the Sponsorship Committee as required.

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
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

8. APPROVALS

Approved by:	Date:
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	14 Mar 2024