



**STANDARD OPERATING PROCEDURE FOR  
APPLICATION FOR SPONSORSHIP OF HEALTH AND SOCIAL CARE RESEARCH STUDIES  
(EXCLUDING DRUG AND DEVICE STUDIES)**

SOP NUMBER:	TASC SOP029 v9
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REVIEW DATE:	19 Mar 2028

### 1. PURPOSE

This Standard Operating Procedure (SOP) describes the process to be followed when applying for sponsorship from the University of Dundee (UoD) and/or NHS Tayside (NHST) for health and social care research studies.

This SOP applies to studies not falling under the remit of the Medicines and Healthcare products Regulatory Agency (MHRA).

### 2. SCOPE

This SOP applies to any individual employed by, or holding an honorary contract with the UoD or NHST who is seeking non-commercial sponsorship of a clinical research project, following:

- successful grant application, or
- confirmation of adequate internal or external funding.

This SOP applies to both single and multi-centre UK clinical research projects.

It applies specifically to non-commercial research, defined in line with Health Research Authority (HRA) guidance as research that is not undertaken for commercial gain or marketing purposes where the research is sponsored by the UoD and/or NHST and is designed to address scientific, clinical, or public health questions, with the primary aim of improving patient care and generating new knowledge.

### 3. RESPONSIBILITIES

#### **Chief Investigator (CI):**

- To prepare documentation of a sufficient standard to enable a thorough and robust risk assessment.
- To detail recruitment strategies within the Protocol, consistent with a Quality by Design approach.
- To ensure Sponsorship is in place prior to submission to Research Ethics Committees (REC), relevant Health Boards/Trusts and others as required by the study.
- To ensure adherence to Sponsor SOPs.
- To complete and agree Data Protection Impact Assessment (DPIA) with NHST Information Governance and UoD Data Protection Officer as relevant to personal identifiable information.

Uncontrolled when printed. Please visit the [TASC website](#) for the latest version of this SOP.

- To notify Research Governance (RG) and TASC Legal of the intention to open non-UK sites, and prior to any registration on non-UK regulatory systems.

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

**Research Governance:**

- To risk assess the protocol and relevant study documentation as required to ensure NHST and UoD carry out their responsibilities as Sponsor organisations.
- To liaise with Legal team and CI regarding required contracts/agreements.
- To authorise Integrated Research Application System (IRAS) on behalf of the Sponsoring Institutions.
- Seek further opinion, where deemed necessary, in accordance with study 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, 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 Vice Principal, Faculty of Health, and RG to be informed of the outcome.

**TASC Legal team:**

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

## **4. PROCEDURE**

### **4.1 Submission requirements for Sponsorship**

All requests for the UoD and/or NHST to act as Sponsor must be submitted to [TASCGovernance@dundee.ac.uk](mailto:TASCGovernance@dundee.ac.uk)

#### **Documentation (Initial Sponsor review)**

- Evidence of funding,
  - Sufficient to deliver the trial to completion, including close-down and archiving
- Short CV of CI.
  - Evidence of role suitability and experience where applicable.
- Confirmation of independent peer review if not at grant application stage.
- Draft Protocol and Participant Information Sheet (PIS)
  - Sponsor may be contacted to provide a template or guidance.
  - 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 (OID) for each site type.
- E.g. NHS Site/Location, non-NHS site/Location, and primary care.
- Completed Schedule of Events Costing Attribution Tool (SoECAT).
- To support AcoRD compliant cost and attribution.

RG 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

Documents must always be version controlled using whole numbers only and follow Sponsor SOP on version control. Initial submitted documents must be DRAFT V1 dd-mm-YYYY.

Upon receipt of the complete document set, RG shall:

- Register the study on the Sponsor database.
- Allocate unique identifier.
- Forward the CI Declaration to be signed by CI and request it be returned to [tascgovernance@dundee.ac.uk](mailto:tascgovernance@dundee.ac.uk).

#### **4.2 Risk Assessment**

- 4.2.1 All documents pertaining to the application shall be reviewed and a documented risk assessment carried out by RG, including assessment of appropriate insurance requirements.
- 4.2.2 Once the initial sponsorship review is complete RG, if necessary, shall contact the CI/Delegate to request further information or clarification.
- 4.2.3 Once the process is complete, and all requested documentation has been received and checked, the CI shall be advised to electronically authorise the IRAS forms.
- 4.2.4 Once the CI authorisation is in place, the CI must request electronic authorisation of the IRAS Form by [tascgovernance@dundee.ac.uk](mailto:tascgovernance@dundee.ac.uk).

*Any changes made to IRAS following this signature will negate the forms. RG must be contacted, and an explanation of what changes were made must be given. The forms shall only be re-authorised once RG checks have been made to ensure sponsorship remains appropriate.*

#### **4.3 Confirming Sponsorship**

Following authorisation of IRAS, RG shall email the CI a copy of the Sponsorship letter and evidence of insurance. The CI/Delegate must follow the instructions on IRAS to process their application to NHS REC, if required, and NHS R&D.

Research projects involving human participants must obtain appropriate ethical approval prior to commencement. Where the proposed research does not fall within the remit of an NHS REC and there is a demonstrable relationship with UoD, advice and approval must be sought from the relevant Faculty Research Ethics Committee.

Where no such relationship with the University exists, the study cannot be reviewed by a Faculty REC, and alternative appropriate ethical review arrangements must be identified.

## 5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
DPIA	Data Protection Impact Assessment
IRAS	Integrated Research Application System
MHRA	Medicines and Healthcare products Regulatory Agency
NHST	NHS Tayside
OID	Organisational Information Document
REC	Research Ethics Committee
RG	Research Governance
SoECAT	Schedule of Events Costing Attribution Tool
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
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:
7	Patricia Burns (Senior Research Governance Manager)	21/10/2022	Minor clarifications/changes.
8	Patricia Burns (Senior Research Governance Manager)	15/03/2024	Requirement for a completed Schedule of Events Costing Attribution Tool (SoECAT) added to section 4.1.2.
9	Patricia Burns (Senior Research Governance Manager)	19/03/2026	Biennial review. Updated to include better definition of the studies that can be sponsored. Removed review by a Sponsorship Committee but included an escalation process where needed. Added information on requiring Faculty ethics committee

			approval to section 4.3. Vocabulary changed in line with ICH-GCP R3 updated terms.
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#### 8. APPROVALS

Approved by:	Date:
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	18 Mar 2026