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

SOP NUMBER:	TASC SOP029 v8
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1. PURPOSE

This Standard Operating Procedure (SOP) describes the process to be followed to apply for sponsorship from University of Dundee (UoD) and/or NHS Tayside (NHST) for health and social care research studies, excluding those that fall under the remit of the Medicines and Healthcare products Regulatory Agency (MHRA).

2. SCOPE

This SOP applies to any researcher requesting sponsorship for health and social care research studies, excluding those detailed above, following successful grant application or confirmation of adequate internal funding.

3. RESPONSIBILITIES

Chief Investigator (CI):

- To ensure Sponsorship is in place prior to submission to Research Ethics Committees, 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.

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.

Sponsorship Committee:

- To review and risk assess research studies on request of Research Governance (RG) where medical, scientific, statistical or other expertise may be required.

4. PROCEDURE

4.1 Sponsor Approval Process

4.1.1 Documents sent for sponsorship review must be "draft" versions. i.e. DRAFT V1 dd-mm-yyyy. This excludes validated documents that are being used within their validation.

4.1.2 Documents must be submitted to RG by email to tascgovernance@dundee.ac.uk: The following list is an example and is not exhaustive:

- Draft Full IRAS Form (PDF)
- Protocol (templates available from Health Research Authority website)
- Copies of all documents relevant to participation
- Advert
- Participation Information Sheet
- Letter of invite
- Informed Consent Form
- Patient diary
- Questionnaires
- Letter to GP
- Draft emails
- Organisation Information Document (OID).
- Completed Schedule of Events Costing Attribution Tool (SoECAT)

4.1.3 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 Chief Investigator and request it be returned to 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.

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 Research Ethics Committee (REC), if required, and NHS R&D.

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	Organisation 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.

8. APPROVALS

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