STANDARD OPERATING PROCEDURE FOR AMENDMENTS TO HEALTHCARE RESEARCH PROJECTS

SOP NUMBER:	TASC SOP063 v5
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1. PURPOSE

This document describes the procedures for the management of amendments to research projects after original approvals from all relevant review bodies.

2. SCOPE

This Standard Operating Procedure (SOP) applies to all research projects sponsored or co-sponsored by the University of Dundee (UoD) and/or NHS Tayside (NHST) through the Research Governance Office, TASC, including Clinical Trials of Investigational Products (CTIMP) and Research Registers.

It is relevant to Chief Investigators (CI) and all study staff who are involved in the management of amendments.

Should emergency procedures require to be implemented immediately, Research Governance must be informed, and this SOP then followed without delay.

3. RESPONSIBILITIES

Chief Investigator:	To ensure that all proposed amendments are approved by the Sponsor and relevant approving bodies prior to implementation. To keep an up-to-date Amendment Log, in the Trial Master File, available for audit and monitoring purposes. To ensure a study specific Data Protection Impact Assessment (DPIA) is updated if required and agreed with Data Protection/Information Governance Officers responsible for the review.
Research Governance:	To review on behalf of the Sponsor, the proposed amendment and ensure amendment type and category are appropriate.

4. PROCEDURE

4.1 CI/Delegate to:

- Alert TASCgovernance@dundee.ac.uk that an amendment is being proposed.
- Liaise with any nurse, lab and/or other support departments to ensure capacity and capability.
- Liaise with NHS R&D regarding impact on costings.
- Confirm with funding body that the amendment is required and establish funding arrangements.
- Liaise with TASC Legal team regarding impact on contracts or agreements and determine whether notification or agreement is required from other stakeholders to ensure compliance with contractual obligations.
- Following provisional confirmation that financial and logistical impact has been addressed, all relevant study documents must be updated, and the Amendment Tool, available on the Integrated Application System (IRAS), completed.
- Forward all relevant study documents and Amendment Tool to TASCgovernance@dundee.ac.uk.
- The name and email address of the Sponsor's authorised representative required on the Amendment Tool must be completed by Research Governance. Research Governance are responsible for locking the form. If the Amendment Tool is not signed and locked by Research Governance, it will not be an authorised amendment.
- In liaison with the relevant Data Protection/Information Governance Officers (UoD and/or NHST) a DPIA for the study must be in place and up to date. An agreed copy must be sent to TASCgovernance@dundee.ac.uk.

4.2 Research Governance to:

- Review proposal against original risk assessment, liaising with CI/Delegate and update Risk Assessment as required.
- Determine whether sponsorship and insurance remain valid.
- Confirm the type and category of amendment and 'Lock for submission.'
- Submit locked amendment tool plus all relevant updated documents to IRAS.

- Forward the automatic receipt of amendment to CI along with the locked Amendment Tool.

- Forward any communications from Research Ethics Committee (REC), Medicines and Healthcare products Regulatory Agency (MHRA), Health Research Authority (HRA) and R&D or other, related to the amendment, by email to CI and Trial Manager (where there is one).

4.3 CI/Delegate to:

- Liaise with REC, MHRA, HRA where relevant and R&D in relation to any queries related to the application until they are resolved.

- Forward to Research Governance the REC, HRA (when required), MHRA and R&D approvals and the final document set.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Product
DPIA	Data Protection Impact Assessment
HRA	Health Research Authority
IRAS	Integrated Application System
MHRA	Medicines and Healthcare products Regulatory Agency
NHST	NHS Tayside
REC	Research Ethics Committee
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:
4	Patricia Burns (Senior Research Governance Manager)	09/09/2022	Updated to include Research Registers and DPIA.
5	Patricia Burns (Senior Research Governance Manager)	15/05/2024	Updated to include that Research Governance on behalf of the Sponsor shall submit Amendments through IRAS.

8. APPROVALS

Approved by:	**Date:**
Dr Steve McSwiggan, Senior R&D Manager for Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	13 May 2024