STANDARD OPERATING PROCEDURE FOR AMENDMENTS TO HEALTHCARE RESEARCH PROJECTS

SOP NUMBER:	TASC SOP063 v4
AUTHOR:	Patricia Burns
ISSUE DATE:	09 Sept 2022
EFFECTIVE DATE:	09 Sept 2022
REVIEW DATE:	09 Sept 2024

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 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 the proposed amendment and ensure amendment type and category is appropriate. To sign and lock the Amendment Tool when approved.

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 re 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 on 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 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 relevent 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.
- Obtain Sponsor Committee opinion prior to authorisation for any proposed amendment that potentially increases risk to participant safety or trial integrity.
- Determine whether sponsorship and insurance remain valid.
- Confirm the type and category of amendment and 'Lock for submission'.
- Return the locked Amendment Tool to the CI/Delegate.
- Retain DPIA.

4.3 CI/Delegate:

Once the CI/Delegate receives the locked PDF from Research Governance, they must follow the instructions on the Amendment Tool and on the Integrated Application System (IRAS) to submit the amendment to the relevant review bodies.

Research Governance must be forwarded the Research Ethics Committee (REC), Medicines and Healthcare products Regulatory Agency (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
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

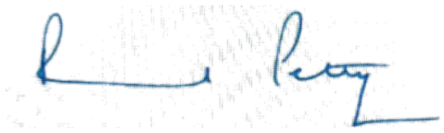
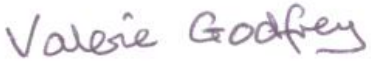
6. ASSOCIATED DOCUMENTS & REFERENCES

None.

7. DOCUMENT HISTORY

Version Number:	Reviewed By (Job Title)	Effective Date:	Details of editions made:
1	Patricia Burns (Senior Research Governance Manager)	15/04/2019	New.
2	Patricia Burns (Senior Research Governance Manager)	09/09/2020	IRAS Amendment Tool active. SOP updated in line with changes.
3	Tracy Petrie (Quality Assurance Support Officer)	29/01/2021	Uploaded to new TASC SOP template which shows the new TASC website in the footer. Physical scan converted to electronic pdf as a requirement for upload to new TASC website.
4	Patricia Burns (Senior Research Governance Manager)	09/09/2022	Updated to include Research Registers and DPIA.

8. APPROVALS

Sign		Date
APPROVED BY:	Professor Russell Petty, R&D Director, NHS Tayside	
Signature		08 Sep 2022
APPROVED BY:	Dr Valerie Godfrey, TASC QA Manager, Chair of Clinical Research Guidelines Committee	
Signature		08 Sep 2022