STANDARD OPERATING PROCEDURE FOR MANAGEMENT OF MODIFICATIONS TO APPROVED RESEARCH PROJECTS

SOP NUMBER:	TASC SOP063 v6
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1. PURPOSE

This document describes the procedures for the management of modifications to research projects following approval by the relevant review bodies, in accordance with the UK Clinical Trials Regulations, including the amended framework effective April 2026.

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, including Clinical Trials of Investigational Products (CTIMPs) and Research Registers.

It is relevant to Chief Investigators (CI) and all study staff who are involved in the identification, preparation, submission, and implementation of modifications.

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

3. RESPONSIBILITIES

Chief Investigator:	To ensure that no modification is implemented without Sponsor prior approval, and that all modifications are approved or notified to the relevant regulatory bodies, as applicable, before implementation, unless implemented as an urgent safety measure. To maintain up-to-date Modification Log, in the Trial Master File, available for audit and monitoring purposes.

	To ensure the study specific Data Protection Impact Assessment (DPIA) is reviewed and updated as required, in liaison Information Governance Officers.
Research Governance:	To review proposed modifications on behalf of the Sponsor. To confirm the appropriate classification and regulatory pathway for the modification (e.g. modification requiring approval or notifiable modification). To ensure regulatory compliance prior to submissions.

4. PROCEDURE

4.1 CI/Delegate to:

- Notify Research Governance of a proposed modification by emailing TASCgovernance@dundee.ac.uk at the earliest opportunity.
- Liaise with any nurse, lab, and/or other support departments to ensure capacity and capability implications.
- Liaise with NHS R&D to assess any impact on costings or service support.
- Confirm with funding body that the modification is required and clarify and revise funding arrangements.
- Liaise with TASC Legal team regarding impact on contracts, agreements, or indemnities and confirm whether notification or approval from external stakeholders is required to ensure compliance with contractual obligations.
- Update all relevant study documents following provisional confirmation that financial and logistical impacts have been addressed,
- Complete the relevant IRAS Modification functionality in line with current regulatory requirements
- Submit the completed modification documentation to TASCGovernance@dundee.ac.uk for Sponsor review.

The Sponsor's authorised representative details required within the Integrated Research Application System (IRAS) will be completed by Research Governance. Research Governance is responsible for finalising and authorising the submission.
A modification is not authorised unless it has been reviewed and approved (or notified where applicable) by Research Governance.

- 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. A copy to be provided to TASCgovernance@dundee.ac.uk.

4.2 Research Governance to:

- Review the proposed modification against the original risk assessment, liaising with CI/Delegate and update as required.
- Confirm whether sponsorship and insurance remain valid.
- Determine the correct regulatory classification:
    - Modification requiring approval or,

  - Notifiable modification in accordance with UK Clinical Trials Regulations.
- Finalise and authorise the modification for submission via IRAS.
- Ensure the submission of the authorised modification and all supporting documentation via the appropriate regulatory pathway (including combined review where applicable).
- Forward the automatic receipt of amendment to CI along with the locked Amendment Tool and copies of authorised amendments
- Forward all regulatory 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 applicable).

4.3 CI/Delegate Post-Submission Responsibilities:
Following submission, CI/Delegate must:

- Respond to and resolve any regulatory or governance queries raised by the REC, MHRA, HRA where relevant and NHS R&D.
- Ensure that no modification is implemented until the required approvals or acknowledgements have been received, unless implemented as an urgent safety measure.
- Forward to Research Governance the REC, HRA (when required), MHRA and R&D approvals and the final document set.
- Ensure that approved modifications are implemented consistently across all participating sites/locations and documented appropriately.

4.4 Implementation and Record Keeping
All approved or notified modifications must be:

- Retained in Trial Master File and Investigator Site File (where applicable).
- Communicated to relevant study staff.
- Implemented in accordance with the approved conditions and regulatory timelines.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Product
DPIA	Data Protection Impact Assessment
HRA	Health Research Authority
IRAS	Integrated Research 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.
6	Patricia Burns (Senior Research Governance Manager)	28/04/2026	Updated in accordance with the new Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

8. APPROVALS

Approved by:	Date:
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	23 Mar 2026
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	20 Mar 2026