STANDARD OPERATING PROCEDURE FOR MANAGEMENT OF MODIFICATION TO APPROVED RESEARCH PROJECTS

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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 28th, 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: Clinical Trials of Investigational Medicinal Product (CTIMP) modifications under Clinical Trial (CT) Regulations and non-CTIMP amendments under Health Research Authority (HRA) amendment guidance.

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

Should emergency procedures require immediate implementation, 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 by or notified to the relevant regulatory bodies, as applicable, before implementation, unless implemented as an urgent safety measure. Sponsor approval does not replace the requirement for regulatory approval/notification where applicable. To maintain an up-to-date Modification Log, in the Trial Master File (TMF), available for audit and monitoring purposes.

	To ensure the study-specific Data Protection Impact Assessment (DPIA) is reviewed and updated as required, in liaison with 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.
	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 Integrated Research Application System (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 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.
- Where applicable, Research Governance will determine whether a substantial modification is eligible for the Route B risk proportionate review pathway.

- Determine the correct regulatory classification in accordance with the amended UK Clinical Trial Trials Regulations including :
    - Substantial Modification (Route A)
    - Substantial Modification (Route B)
    - Modification of an Important Detail
    - Minor Modification.
- 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: (CTIMPs should normally proceed through Combined Review pathways, and IRAS combined submissions apply where required.
- Forward the automatic receipt of modification to CI along with the locked Modification Tool and copies of authorised modifications.
- Forward all regulatory communications from Research Ethics Committee (REC), Medicines and Healthcare products Regulatory Agency (MHRA), HRA and R&D or other, related to the modification, 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 REC, MHRA, HRA or other, 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 TMF 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 Trials of Investigational Medicinal 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
TMF	Trial Master File
UoD	University of Dundee

Route A Substantial Modification
A substantial modification likely to have a significant impact on participant safety or rights, or on the reliability or robustness of trial data, requiring full regulatory assessment.

Route B Substantial Modification
A substantial modification meeting the criteria defined in Regulation 11B of the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, which does not introduce significant new safety concerns and is eligible for a risk-proportionate MHRA review pathway.

Modification of an Important Detail
A modification which does not significantly affect participant safety, participant rights, or the reliability or robustness of trial data, but which requires notification to the relevant authorities for administrative or oversight purposes.

Minor modification or non-substantial amendment is a change that does not significantly affect participant safety, rights, or the scientific value of the trial.

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.

7	Patricia Burns (Senior Research Governance Manager)	28/05/2026	Updated to fully align with the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 and associated MHRA/HRA guidance implemented April 28th 2026, including revised modification terminology, classification framework, and incorporation of Route A and Route B substantial modification pathways.

8. APPROVALS

Approved by:	**Date:**
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	26 May 2026
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	22 May 2026