STANDARD OPERATING PROCEDURE FOR RISK ASSESSMENT OF CLINICAL RESEARCH ON BEHALF OF THE SPONSOR

SOP NUMBER:	TASC SOP064 v6
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1. PURPOSE

To describe the process for risk assessment to be applied to each Clinical Trial of an Investigational Medicinal Product (CTIMP), Clinical Investigation of a Medical Device and other selected studies sponsored and/or co-sponsored by the University of Dundee and NHS Tayside**,** following the awarding of a grant or confirmation of adequate funding.
This SOP ensures compliance with the UK Clinical Trials Regulations, including the principles of risk-proportionate regulation, participant safety, data integrity, and efficient trial delivery.

2. SCOPE

This Standard Operating Procedure (SOP) applies to all staff involved in sponsor oversight and risk assessment activities on behalf of the Sponsor(s) for:

- CTIMPs conducted under the UK clinical trials regulatory framework
- Clinical investigations of medical devices
- Other sponsor-approved health research studies

This SOP applies from initial application for Sponsorship through the full lifecycle of the study, including Modifications.

The assessment of Reference Safety Information (RSI) for the Investigational Medicinal Product (IMP) is outside the scope of this SOP and shall be subject to a separate risk assessment undertaken by Sponsor Pharmacovigilance

3. RESPONSIBILITIES

Research Governance Managers are responsible for:

- Preparing, approving, and maintaining a live, proportionate Risk Assessment throughout the study lifecycle, ensuring the risk assessment reflects:
    - Trial complexity
    - Investigational medicinal product risk
    - Participant population
    - Trial design and operational delivery

- Liaising with:
    - Chief Investigator
    - Quality Assurance Manager
    - Sponsor Legal Team
    - Other specialist services as required

Ensuring identified risks are mitigated appropriately and to inform:

- Monitoring Plan
- Audit schedule
- Safety oversight arrangements

4. PROCEDURE

4.1 Sponsor Receipt of Documents and Initial Risk Assessment processes

4.1.1 Document receipt

On receipt of the draft documents, the study shall be:

- Entered onto the Sponsor Master Tracker
- Assigned a unique Sponsor Reference number

Documents may include, but not be limited to:

- Protocol
- Full Integrated Research Application System (IRAS) Dataset
- Participant facing documents
- Informed Consent Forms/Assent Forms
- Investigator Brochure (IB) and/or Summary Product Characteristics (SmPC).
- IMP documentation
- Any additional documents relevant to study conduct and oversight

Research Governance shall keep in communication with the study team and supporting departments, (e.g. QA) to inform the initial and ongoing Risk Assessment.

4.1.2 Risk Assessment Methodology

The Risk Assessment template(s) shall be used to:

- Identify inherent and operational risks
- Assess likelihood of occurrence and potential impact on:
    - Participant safety
    - Data reliability
    - Regulatory compliance

Determine whether additional mitigation measures are required.

Risk assessment must be proportionate, in line with UK CT Regulations, and shall directly inform:

- Monitoring needs and approach

- Safety oversight mechanisms
- Sponsor audit strategy

4.1.3 Risk Mitigation and Document Review

Where risks are identified, Research Governance shall:

- Liaise with the CI or delegate to request updates to study documentation
- Ensure mitigations are clearly documented and implemented prior to Sponsorship approval
- Document said mitigations within Risk Assessment

4.1.4 Finalisation of Risk Assessment – Non-CTIMPs

For non-CTIMPs, the Risk Assessment must be finalised prior to sponsor authorisation within IRAS.

4.1.5 Finalisation of Risk Assessment -CTIMPs

For CTIMPs:
For studies proposed for Sponsorship after 28 April 2026, Research Governance shall finalise the Risk Assessment in advance of:

- Submission via IRAS for combined review
- Notification or authorisation to the MHRA as application under the CT Regulations

The Risk Assessment shall be signed by:

- Chief Investigator
- Senior Research Governance Manager

A fully signed copy shall be:

- Provided to the CI for filing in the Trial Master File
- Retained in the Sponsor File

For studies proposed for Sponsorship prior to March 2026, Research Governance shall finalise the Risk Assessment in advance of :

- Sponsor Green Light

The Risk Assessment shall be signed by:

- Chief Investigator
- Senior Research Governance Manager

A fully signed copy shall be:

- Provided to the CI for filing in the Trial Master File
- Retained in the Sponsor File

4.2 Risk Assessment of CTIMP Modification

On receipt of proposed Modification, Research Governance shall:

- Document a proportionate risk assessment using Risk Assessment template

The outcome of the risk assessment shall be used to:

- Classify the modification (substantial, important detail, or minor)
- Determine whether regulatory and/or ethics approval is required

- Define any necessary risk mitigation measures, including participant re-consent, or enhanced oversight including changes to Monitoring Plan or Sponsor audit schedule

The Modification Risk Assessment shall be signed by:
Chief Investigator
Senior Research Governance Manager

A fully signed copy shall be:
Provided to the CI for filing in the Trial Master File
Retained in the Sponsor File

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
IB	Investigator Brochure
IRAS	Integrated Research Application System
QA	Quality Assurance
SmPC	Summary Product Characteristics
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre

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:
3	Patricia Burns (Senior Research Governance Manager)	17/02/2022	Updated - minor changes: i.e. designation 'senior' has been removed.
4	Patricia Burns (Senior Research Governance Manager)	17/02/2024	Clarification of process for Appraisal of Amendment with Risk Assessment (section 4.2).
5	Patricia Burns (Senior Research Governance Manager)	17/02/2026	Scheduled review. Reference to Sponsor Committee removed from section 3. Vocabulary changed in line with ICH-GCP R3 updated terms.
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