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

SOP NUMBER:	TASC SOP064 v4
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REVIEW DATE:	17 Feb 2026

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.

2. SCOPE

This Standard Operating Procedure (SOP) applies to all staff responsible for risk assessment on behalf of the Sponsor(s) as above on confirmation of adequate and appropriate funding.

3. RESPONSIBILITIES

Research Governance Managers (RGM):

- To review all documents relevant to the proposed study.
- To prepare and maintain Live Risk Assessment for each research project.
- To liaise with the Chief Investigator (CI), TASC Quality Assurance (QA) Manager, members of the Sponsor Committee, Clinical Trials Pharmacist, Legal team and any other as relevant to the project for mitigation of risk.

4. PROCEDURE

4.1 Sponsor Receipt of Documents

4.1.1 On receipt of the draft documents, the study shall be entered onto the Sponsor Master Tracker and a Sponsor number shall be issued.
Documents may include, but not be limited to:

- Protocol
- PDF Full Integrated Research Application System (IRAS) Dataset
- Participant related information
- Informed Consent Form
- Others as relevant to the study

- Investigator Brochure (IB)/Summary Product Characteristics (SmPC).

The Research Governance team shall keep in communication with the study team and supporting departments, for example QA, for input into the Risk Assessment to help inform the QA strategy in terms of audit planning.

4.1.2 The Risk Assessment template shall be used to identify risk and the likelihood of occurrence and impact. Based on the likelihood of occurrence and impact of risk, the assessment will include if any additional mitigation is necessary to reduce this.

4.1.3 The RGM shall follow up with the Investigator or delegates regarding updates to study documentation required to further mitigate/manage identified risks.

4.1.4 Finalisation of the Risk Assessment for non CTIMPs will occur prior to Sponsor authorisation on IRAS and submission to the competent authority and/or Research Ethics Committee.

4.1.5 For CTIMPs, the RGM will finalise the Risk Assessment and request CI signature prior to their own. A copy of the fully signed Risk Assessment will be forwarded to the CI for retention in the Trial Master File and will also be kept in the Sponsor File.

4.2 Appraisal of Amendment with Risk Assessment

4.2.1 The Amendment Tool will be used to appraise the proposed amendment and will be reviewed, along with updated document set, against the specific area in the original Risk Assessment. The Amendment Tool defines the classification of the amendment, however the Sponsor as represented by Research Governance, retains the right to overrule the decision and justify this as required.

4.2.2 If approved, the Risk Assessment will be completed and retained by Sponsor and the Amendment Tool will be authorised and returned to the study team.

4.2.3 The study team will upload the Amendment Tool to IRAS for submission to regulatory bodies and study sites following the specific guidance as detailed on the Amendment Tool EXCEL spreadsheet.

4.2.4 All versions of the Risk Assessment evidencing Sponsor review shall be held 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
RGM	Research Governance Manager

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).

8. APPROVALS

Approved by:	Date:
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	14 Feb 2024