Royal Papworth Hospital
NHS Foundation Trust

Document Title: Assessment and Registration of Trust Risk Rating for Research Studies

Document Number: R&D SOP025

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
Document owner:	Senior R&D Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	November 2028

Summary of Amendments

Version:	Modification:
9.0	Amendments to section 4 and whole document updated in line with FRM013. Reviewed for changes in regards to the new clinical trial R3 regs.
8.0	Amendment to section 4. f.
7.0	Minor administrative changes. Changes in accordance with the Trust Risk Management Strategy

Key related documents:	Trust Policy DN001 Document Control Procedures DN139 Risk Management Strategy DN290 Risk Assessment Procedure Research and Development Standard Operating Procedures entitled: SOP016 Monitoring Research Studies

	SOP034 Trust Confirmation of Capacity and Capability to Conduct Research Studies SOP065 Risk-adapted Approach to the Management of Clinical Trials of Investigational Medicinal Products SOP083 Specific considerations for the risk adapted monitoring of CTIMPS SOP085 Monitoring Research Studies - External Monitors and Remote Monitoring FRM013 Risk Assessment Tool

Key Points of this Document

- This document sets out the risk assessment procedure for the calculation of risk that a clinical trial or research study poses and registration of the risk in line with Risk Management Strategy.

- It provides guidance on the procedures to be undertaken to safeguard patients, personnel and the Trust's reputation in light of any risks and hazards identified prior to the commencement of a study.

1 Purpose and Content

a. This document defines the procedure in terms of identifying the risks posed by Research Studies and Clinical Trials that will be performed at Royal Papworth Hospital NHS Foundation Trust, and how these risks are registered in accordance with the Trust Risk Management Strategy (DN139).

b. The document describes the requirement for performing risk assessments in line with the Trust Risk Strategy.

c. The document aims to provide clear guidance on performing the risk assessment of studies as part of the Trust Confirmation of Capacity and Capability (TCCC) process and subsequent actions.

d. The monitoring of a study or trial to ensure it is being conducted in accordance with the approved study protocol is outside the scope of this SOP and is described in SOP016: Monitoring Research Studies NOT requiring MHRA approval, SOP085 Monitoring Research Studies - External Monitors and Remote Monitoring and SOP083 Specific Considerations for the Risk Adapted Monitoring of CTIMPS.

e. The TCCC process is outside the scope of this SOP and is described in SOP034: Trust Confirmation of Capacity and Capability to Conduct Research Studies.

f. In addition to the risk assessment outlined below, all Royal Papworth sponsored clinical trials of investigational medicinal products (CTIMPs) must undergo an additional risk review as detailed in SOP065 Risk-adapted Approach to the Management of Clinical Trials of Investigational Medicinal Products.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust.

b. Staff involved in the design and set-up of research studies and clinical trials must comply with the requirements set out in Section 4.

c. Investigators, researchers and other relevant personnel must take account of the risks a study poses when designing research to be sponsored by Royal Papworth and take steps to minimise or avoid such risks.

d. The Clinical Project Manager assigned to the study or the Operational Research Team and Research Governance Team (in the case of non-Royal Papworth Sponsored studies) is responsible for performing a risk assessment for that study, and the members of the Research Governance Project Approval System Committee (RGPAS) are responsible for highlighting key risks and their mitigations. A draft / initial risk assessments should be included within the RGPAS document pack when studies are presented to RGPAS for review.

e. The Clinical Project Manager (or member of the Operational Research Team and / Research Governance Team as appropriate) and Investigator are mutually responsible for identifying risks and the generation and review of any associated action plans. It should be noted that the Investigator retains ultimate responsibility for the risks and mitigations documented within.

f. Senior Managers within R&D are responsible for escalation of risks greater than 12 to the Trust Risk Register. All new risks are reviewed by the Trust Quality & Risk Management Group (QRMG) and approved where appropriate. Once discussed at QRMG a risk of 15 and above may be escalated to the Board Assurance Framework (BAF).

g. Under The Medicines for Human Use (Clinical Trials) Regulations 2025, a Sponsor is able to request a copy of the research location's risk assessment.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance may result in disciplinary procedures.

4 Procedure

a. All research taking place within the Trust must undergo formal risk assessment prior to TCCC and commencement of the research. The outcome of the risk assessment is Risk Rating Number (RRN), which determines how the risk is recorded and managed.

b. For all Royal Papworth sponsored research, the management and mitigation of risk commences during the process of protocol writing and is a continual review process in partnership with all stakeholders involved in the protocol development. Risks identified and actions to mitigate risks are recorded onto FRM013: Risk Assessment Tool and are taken into consideration at RGPAS when sponsorship of the study is being assessed. The Chief Investigator (CI) will be notified of any additional risks identified at this meeting along with any actions that are required to be taken in order to mitigate risks identified.

   For CTIMPs a pragmatic risk assessment must also be completed see SOP065 Risk-adapted Approach to the Management of Clinical Trials of Investigational Medicinal Products.

c. For all externally sponsored research, a draft / initial risk assessment of the study is drafted by the study team in conjunction with a member of the Research Governance Team using FRM013: Risk Assessment Tool prior to RGPAS as part of the feasibility review. This draft should be included in the RGPAS document pack.

d. In the case of both Royal Papworth Sponsored/managed and externally sponsored studies, a further review of the draft / initial risk assessment of the study will be undertaken prior to TCCC. The final draft will be sent to the Chief / Principal Investigator for their review and sign-off.

e. Severity of risk should be graded by consideration of the potential for:

- Risk to the Participant
- Risk to Staff (exceptional risks only)
- Risk to the Study
- Risk to the Trust

f. Severity of risk in each area should be graded by assigning a predicted Severity Score (1-Very Low to 5-Very High). Likelihood of risk in each area should be graded by assigning a predicted frequency of occurrence of the adverse outcome (1-Extremely Unlikely I to 5-Very High). All risk assessments will be approved by the PI prior to the issuing of TCCC.

g. The form: FRM013 Risk Assessment Tool describes in detail the issues for consideration in each of the areas. FRM013 is a guidance tool and Appendix 2 within the Form provides examples / some areas of consideration for risks. Risks not listed on the FRM013 can be added as relevant to the study under review. Risks listed can be moved to higher or low categories if relevant to the study under review. An outline of the risks, their mitigations and scoring both before and after mitigation, should be outlined within the narrative box at the start of the risk assessment. An overall risk scoring should be provided for before and after mitigation.

h. The risk for each category is assessed against likelihood. The RRN is calculated from the formula; RRN = severity x likelihood and is based on risk when all the identified controls are in place and operating.

i. The highest risk rating from any of the risk areas determines the overall RRN. If the risk for a certain area can be reduced or controlled via measures, the risk can be re-assessed.

j. If actions and/or measures to mitigate risk are required, these are recorded on the Risk Assessment Tool and shared with the CI or PI, with a copy retained by the Research Governance Team and in the TMF or site file as appropriate, with actions being reviewed and recorded.

k. An overall risk assignment is given to the trial once unanimous agreement is reached by key stakeholders involved in the research. Risks that cannot be agreed upon will be escalated to the RGPAS panel for review and further escalation if required.

l. The level of risk assigned to the study is reported and monitored in accordance with the Risk Assessment Procedure DN290 and Risk Management Strategy DN139 and consequent monitoring arrangements will be notified to the investigator.

m. Where the Trust's capacity and/or capability to deliver the study is significantly impacted (modification or otherwise), the risk assessment should be reviewed by the study team and, if required, presented at RGPAS.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current active version approved date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter.

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	No

Positive/Negative							
Review date:			November 2028				