

Sponsorship Risk Assessment SOP

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Directorate:	Corporate		
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Standards, legislation and key related documents:	UK Policy for Health and Social Care Research		
APPROVAL			
<u>Level 1</u> Approval Group:	Does not need to go through Level 1 as SOP/Protocol.		
	Date Approved:	N/A	Review Date: N/A
<u>Level 2</u> Ratification Group:	CPFT Research and Development Operations Meeting		
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<u>Level 3</u> Formal Sign-Off:	Quality, Safety and Patient Experience Board Sub-Committee		
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Financial Implications:	Where a document has any financial implication on the Trust, the Local Counter Fraud Specialist (LCFS) has the authority to investigate and challenge this document with regards to current fraud and bribery legislation and to ensure appropriate counter fraud measures are in place.		
Counter Fraud Approval:	Yes or No:	No	Date: 18/12/2025
Equality and Diversity Impact Assessment: (Policies only)	The author has carried out an E&DIA and there are no negative or unknown impacts. The E&DIA Form is attached to this document.		
Staff Side Approval:	Yes or No:	Yes	Date: 18/12/2025

AUTHOR'S CHECKLIST

Document Title: Not applicable as new SOP.

Secretariat Index Number:

To be completed when reviewing existing published documents

Consideration for all documents		Y/N	Action to be taken	
			'Yes'	'No'
1.	Is the document still required?	Select	Go to question 2.	Arrange document removal with the Executive Lead/Approval Group and inform the Corporate Governance Team (corporateoffice@cpft.nhs.uk)
2.	Has there been any change in guidance or national policy since the previous version?	Select	Go to question 4.	Go to question 3.
3.	Can Executive authorisation (only) be granted if minor changes have been made to the document?	Select	Executive lead to approve new review date by email. Update dates on the document and send the updated document and Exec email to the Corporate Governance Team (corporateoffice@cpft.nhs.uk)	Go to question 3.
4.	Can formal ratification be granted if major changes have been made to the document?	Select	Agree content at Level 1 Specialty Oversight Group. Seek Approval at Level 2 Exec Led Approval Group. Seek Ratification at NED led Board Sub-Committee (via: corporateoffice@cpft.nhs.uk)	Go to question 3.

VERSION CONTROL SUMMARY

FORMAL RATIFICATION RECORD

Version	Date	Author	Details of Previous Version:	Oversight Group	Approval Group	Ratifying Committee	Date:
1.0	December 2025	Research and Development Manager	N/A	N/A	Research and Development Operations Meeting	QS&PEC	

MINOR CHANGE RECORD

Version	Date	Author	Description of Change/s Made:	Authorising Executive	Date:

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The latest version of this document is on the Document Library.

Any printed copies must be checked against the Document Library version to ensure that the latest version is being used.

1.0 WHY DO WE NEED THESE GUIDELINES/SOP

- 1.1 This procedure describes the process by which all studies which are applying for Cambridgeshire and Peterborough NHS Foundation Trust (CPFT) Sponsorship will be assessed for risk.
- 1.2 The UK Policy Framework for Health and Social Care Research states that the sponsor takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project.
- 1.3 It is important that a research sponsor identifies all risks associated with research studies and has a plan to mitigate these risks.

2.0 WHO IS IT FOR?

- 2.1 All staff members involved in the application for, review of and confirmation of research sponsorship within CPFT.

3.0 GUIDELINES / SOP DETAILS

- 3.1 All studies applying for Sponsorship by CPFT will have a risk assessment completed and the process will start with receipt of a request for sponsorship.
- 3.2 Upon receipt of a sponsorship request the R&D Project Lead / Research Governance member of staff will create a sponsor risk assessment using the template shown in appendix 1.

Ad hoc meetings will be scheduled to review the Risk Assessment attached to each study. Within this meeting one of three options will be available

- Research and Development Manager signature
- Risk Assessment score mandates escalation to Research and Development Director for signature
- Additional information required from CI to facilitate further discussion which will result in further follow-up meeting.
- Within follow-up meeting one of the three outcome options previously listed will be selected.

4.0 TRAINING REQUIREMENTS ASSOCIATED WITH THIS GUIDANCE / SOP

- 4.1 All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual should be completed to document that the content of this SOP and its amendments has been read and understood.

5.0 DEFINITIONS

- 5.1 **Chief Investigator (CI)** – is responsible for ensuring that correct and complete information is provided to the R&D Department in order to determine whether the study can be supported. Deliberate submission of false information will be classes as fraud and can lead to a misconduct hearing.
- 5.2 **Research Governance Co-ordinator** – will be responsible for reviewing research documents, determining if all information is present, correct and adheres to relevant research legislation, including sponsorship decisions.
- 5.3 **Research and Development Manager** – will authorise Sponsorship through signature of Sponsorship Letter
- 5.4 **Research and Development Director** – will review and sign risk assessment form

6.0 KEY DUTIES AND RESPONSIBILITIES

- 6.1 The Research and Development Department are responsible for the implementation of this SOP.

7.0 HOW WILL THIS GUIDANCE / SOP BE MONITORED FOR EFFECTIVENESS?

- 7.1 Compliance with this procedure will be monitored as part of the normal working processes of the R&D department.

8.0 LINKS TO RELATED DOCUMENTS

- 8.1 [Clinical Trials of Investigational Medicinal Products \(CTIMPs\) - Health Research Authority](#)
- 8.2 [UK Policy Framework for Health and Social Care Research - Health Research Authority](#)

9.0 REFERENCES AND ACKNOWLEDGMENTS

- 9.1 Research Misconduct Policy
- 9.2 Policy and Procedure CPFT/POL005 Research studies – Review and set up process for confirming capacity and capability
- 9.3 Sponsorship of Research Projects

Document Section		Control	Check to be carried out	How often will the check be carried out	Responsible for carrying out the check	Results of check reported to	Frequency of reporting
Page	Section	WHAT?	HOW?	WHEN?	WHO?	WHERE?	WHEN?
5.	3.0	Compliance with this SOP will be monitored through our built in Quality Assessment prior to regulatory approval submission held within EDGE.	These checks will ensure Sponsorship Risk Assessment is completed because of comprehensive review and risk assessment.	Per Sponsorship request.	Project Development and Research Governance Teams	Any discrepancies or omissions will be directed to the member of the Research Governance Team tasked with the implementation of this SOP.	Oversight meetings when required.

APPENDIX 1: Sponsor Risk Assessment Form

SPONSOR RISK ASSESSMENT FORM	
Short Title & EDGE ID:	
Chief Investigator:	
Research Category:	Choose an item.
Other – please describe:	

Summary of research

Risk can be defined as the likelihood of a potential hazard occurring and resulting in harm to the participant and/or an organisation, or to the reliability of the results. The risk-assessment should focus on identifying and mitigating **study-specific** risks.

A. Investigational Medicinal Product.

Cambridgeshire and Peterborough NHS Foundation Trust will only sponsor CTIMPS if Sponsor oversight is delegated to a UKCRC Registered Clinical Trials Unit

Risk Factor Potential source of risk to the trial	Concerns Provide details of study-specific considerations/risks/concerns or indicate N/A	Likelihood 1 – 5 (L)	Impact 1-5 (I)	Rating (LxI)	Controls Address all concerns identified	FOR R&E USE ONLY Central/On-site monitoring methods
Device type - Invasive vs non-invasive - CE marked and/or used within intended purpose(s) - not CE marked and/or use outside intended purpose(s)						

Risk Factor Potential source of risk to the trial	Concerns Provide details of study-specific considerations/risks/concerns or indicate N/A	Likelihood 1 – 5 (L)	Impact 1-5 (I)	Rating (LxI)	Controls Address all concerns identified	FOR R&E USE ONLY Central/On-site monitoring methods
Clinical experience with device - of research team - of clinical teams - is the device new to market or not been used for this indication before?						
Management of device - added to Trust medical device register - How is the device serviced - does the device require consumables; are these known or new?						

Additional rows may be added as required

B. Participants' Rights and Safety

Risk Factor Potential source of risk to the trial	Concerns Provide details of study-specific considerations/risks/concerns or indicate N/A	Likelihood 1 – 5 (L)	Impact 1-5 (I)	Rating (LxI)	Controls Address all concerns identified	FOR R&E USE ONLY Central/On-site monitoring methods
Participant population - safety monitoring - impact of cancelled follow up appointments - impact of any revised schedule/method of follow up appointments - access to trial interventions						
Enrolment - recruitment halt at sites - impact on screening						
Consent						
Participant privacy (data protection) - data access remote working - accessing personal identifiable data remotely - collect sensitive information remotely - data sharing/transfer outside UK/EU						
Study assessment methods - Visit schedules/windows? - Clinical follow up - Alternative methods of data collection required?						
Other						

Additional rows may be added as required

C. Facilities, Equipment and Resources

Risk Factor Potential source of risk to trial	Concerns Provide details of study-specific considerations/risks/concerns or indicate N/A	Likelihood 1 – 5 (L)	Impact 1-5 (I)	Rating (LxI)	Controls To reduce likelihood of risk happening	FOR R&E USE ONLY Central/On-site monitoring methods
Study site staff resource						
Partner organisations - additional sites, external service provider/third party - geography - language - international regulations						
Resource availability - departments/clinics/wards - (special) equipment - equipment servicing/maintenance						
Financial						
Other – specify						

Additional rows may be added as required

D. Study Design and Reliability of Results

Risk Factor Potential source of risk to trial	Concerns Provide details of study-specific considerations/risks/concerns or indicate N/A	Likelihood 1 – 5 (L)	Impact 1-5 (I)	Rating (LxI)	Mitigation Address all concerns identified	FOR R&E USE ONLY Central/On-site monitoring methods
Data collection/management - impact of missing data						
Study recruitment - Impact of recruitment halt on milestones						
Blinding and/or randomisation - unblinding procedures						
Primary and secondary outcomes - objective vs. subjective - (un)blinded assessors - external verification						
Other Statistical Considerations						
Other – Specify (e.g. substudies)						

Additional rows may be added as required

E. Documentation, Governance and Compliance

Risk Factor Potential source of risk to trial	Concerns Provide details of study-specific considerations/risks/concerns or indicate N/A	Likelihood 1 – 5 (L)	Impact 1-5 (I)	Rating (LxI)	Mitigation Address all concerns identified	FOR R&E USE ONLY Central/On-site monitoring methods
Trial Master File maintenance						
Insurance/indemnity arrangements						
Protocol, regulatory and SOP compliance						
Oversight - monitoring/auditing - management groups - steering committee - meetings						
Trial milestones						

Additional rows may be added as required

Reference Material:
<i>List any documentation (including versions/dates) used as a reference to complete this risk assessment, e.g. Protocol, SmPC, Investigator Brochure.</i>

This section is to be signed once all risk management strategies have been agreed and before a study is given sponsor green light to start.

Approval:

Chief Investigator
Name (Printed):
Signature
Date

Research and Development Director
Name (Printed):
Signature
Date

Risks will be assessed according to the following matrix

Likelihood	Impact/Severity				
	1 Minor	2 Moderate	3 Serious	4 Major	5 Catastrophic
1 Rare	1	2	3	4	5
2 Possible	2	4	6	8	10
3 Likely	3	6	9	12	15
4 Very Likely	4	8	12	16	20
5 Almost certain	5	10	15	20	25
Overall Risk Rating	Very Low Green 1, 2, 3	Low Yellow 4, 5, 6	Moderate Amber 5,8, 9, 10	High Red 12, 15, 16	Extreme Purple 20, 25

APPENDIX 2: QUALITY ASSURANCE CHECKLIST

TO BE COMPLETED BY THE CORPORATE GOVERNANCE TEAM

		Y/N	Comments
1.	Title of document		
	Is the title clear and unambiguous	Y	
2.	Type of document (e.g. policy, guideline etc)		
	Is it clear whether the document is a policy, guideline or procedure?	Y	
3.	Introduction		
	Is the introduction clear?	Y	
	Are reasons for the development of the document clearly stated?	Y	
4.	Content		
	Is the correct corporate template used?	Y	
	Is the document in the correct format?	Y	
	- Paragraphs numbered consecutively?	Y	
	- Headers: logo on front page only?	Y	
	- Footers: on every page except front page?	Y	
	Are the version control numbers correct on the front page and in footer?	Y	
	Are objectives/aims clearly stated?	Y	
	Are duties, roles and responsibilities clearly explained? (Policies only)	N/A	
	Are definitions of terms clearly explained?	Y	
	Does this document concern the handling, moving or storage of personal identifiable or commercially sensitive information? If yes, has there been engagement with the Information Governance Team?	N/A	
	5.	Evidence Base	
Is the type of evidence to support the document explicitly identified?		Y	
Are associated documents referenced?		Y	
6.	Approval		
	Does the document identify which Oversight Working Group is responsible for reviewing the content?	N/A	
	Does the document identify which Exec Led Approval Group is responsible for approval?	Y	
	Does the document identify which NED led Ratification Group is responsible for ratifying?	Y	
7.	Review Date		
	Is the review date identified and 3 years (max) following initial development (sign off by Oversight Working Group)?	Y	
8.	Equality and Diversity		
	Is a completed Equality Impact Assessment attached?	N/A	
9.	Monitoring Compliance		
	Has section 'Monitoring Compliance' been completed?	Y	

If answers to any of the above questions is 'no', then this document is not ready for approval and needs further review.