

## Sponsorship of Research Projects SOP

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<b>APPROVAL</b>			
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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.		
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Equality and Diversity Impact Assessment: (Policies only)	The author has carried out an E&DIA and there are <b>no negative or unknown</b> impacts. The E&DIA Form is attached to this document.		
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## 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?	Y/N	Go to question 2.	Arrange document removal with the Executive Lead/Approval Group and inform the Corporate Governance Team ( <a href="mailto:corporateoffice@cpft.nhs.uk">corporateoffice@cpft.nhs.uk</a> )
2.	Has there been any change in guidance or national policy since the previous version?	Y/N	Go to question 4.	Go to question 3.
3.	Can Executive authorisation (only) be granted if <b>minor</b> changes have been made to the document?	Select Y/N	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 ( <a href="mailto:corporateoffice@cpft.nhs.uk">corporateoffice@cpft.nhs.uk</a> )	Go to question 3.
4.	Can formal ratification be granted if <b>major</b> changes have been made to the document?	Select Y/N	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: <a href="mailto:corporateoffice@cpft.nhs.uk">corporateoffice@cpft.nhs.uk</a> )	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	Dec 2025	R&D Manager	N/A	CPFT R&D Operations Meeting	N/A	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 The purpose of this Standard Operating Procedure (SOP) is to outline the process required for obtaining research Sponsorship from Cambridgeshire and Peterborough NHS Foundation Trust
- 1.2 Under the UK Policy Framework for Health and Social Care Research all health and social care research projects require a Sponsor. The Sponsor is the organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to setup, run and report a research project. All health and social care research should have a Sponsor. This includes all research that involves NHS patients, their tissue or information.
- 1.3 Health and social care research covers a wide spectrum of research from non-interventional questionnaire studies to complex interventional trials. Some of the more interventional and high-risk research falls under the jurisdiction of the Medicines and Healthcare Products Regulatory Agency (MHRA) and is required to comply with specific legal requirements for such trials (Regulated trials). These are Clinical Trials of Investigational Medicinal Products (CTIMPs); Device trials (Clinical Investigations), Trials of Advanced Therapies (medical products involving cell or gene therapy or tissue engineering) (ATIMPs) and combinations of these.

## 2.0 WHO IS IT FOR?

- 2.1 This SOP is for all staff who would like CPFT R&D to act as Sponsor for their research project, and all staff working within the R&D Department who are involved in the review and confirmation of CPFT Research Sponsorship
- 2.2 **Chief Investigator (CI)** – is responsible for ensuring that correct and complete information is provided to the R&D Department to determine whether the study can be supported. Deliberate submission of false information will be classed as fraud and can lead to a misconduct hearing.
- 2.3 **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.
- 2.4 **Research and Development Manager** – will authorise Sponsorship through signature of Sponsorship Letter

## 3.0 GUIDELINES / SOP DETAILS

- 3.1 Initial enquires about applying for Cambridgeshire and Peterborough NHS Foundation Trust (CPFT) Sponsorship should be send to R&D Enquiries address box [randd@cpft.nhs.uk](mailto:randd@cpft.nhs.uk)
- 3.2 A member of the project development / governance team will be assigned to work with the Chief Investigator (CI).

- 3.2 The CI (or their delegate) and the member of the project development / governance team should liaise as soon as possible prior to applying for Trust sponsorship to ensure suitability and feasibility.
- 3.3 The CI/delegate should submit the following documents in draft form for review:
- A full protocol
  - A Patient Information Sheet (PIS) where appropriate
  - An Information Consent Form (ICF) where appropriate
- 3.4 Confirmation of Sponsorship requires clear evidence of
- Contractual relationship of CI (protocol author) to the Trust
  - Funding
  - Insurance
    - All research studies must have insurance against potential harm to participants arising from:
      - The management of the research. This is provided by the substantive employer of the CI.
      - The design of the research. (Insurance for this is provided by the substantive employer of the CI).
      - The conduct of the research. Where NHS patients are participants, NHS Indemnity applies.
      - For all other participants, the sponsor of employing organisation will provide insurance.
  - PPIE Consultation in the development of protocol / regulatory approval submission pack
    - It is expected that all studies that are applying for CPFT Sponsorship are registered with the CPFT PPIE service and that appropriate review and development support is secured.
    - Evidence of this needs to be supplied prior to confirmation of Sponsorship
  - Independent Scientific Peer Review
    - It is the responsibility of the Sponsor to ensure that proposals have a suitable review of scientific quality before submission for regulatory approvals
    - If funding is secured via a competitive process such as NIHR and the specific protocol in questions has been reviewed, additional independent scientific peer review is not required.
    - For student research projects, review by the academic supervisor, and/or clinical supervisor is considered appropriate.
    - For all other studies that do not fall within these two categories it is expected that two to three Independent Scientific Peer reviews are obtained.
    - The member of the Project Development / Research Governance team that is assigned to the project will oversee and administer this process.
- 3.5 **Sponsor Risk Assessment** – once initial information documents have been gathered the Sponsor Risk Assessment will be carried out in line with the process outlined within the Sponsor Risk Assessment SOP.
- 3.6 Sponsorship must be agreed before any regulatory submissions can be made.
- 3.7 Submission to regulatory and/or funding bodies may require a pre-Sponsorship letter which accompanies the submissions. The Project / Research Governance team member assigned to the project can arrange this.

3.8 Two or more organisations may agree to act as co-sponsors or joint sponsors. Co-Sponsors allocate specific sponsor responsibilities between them whilst joint sponsors each accept liability for all of the sponsor’s responsibilities. A sponsor can delegate specific tasks to any other individual or organisation that is willing and able to accept them. Any co-sponsorship, joint sponsorship or delegation of tasks to another party should be formally agreed and documented by the sponsor(s).

**3.9 Clinical Trials of an Investigational Medicinal Product (CTIMP)**

- For the Sponsorship of CTIMPS the Trust will delegate Sponsor oversight to a UK Clinical Research Collaboration UKCRC Registered Clinical Trials Unit
- A study specific Delegation of Responsibility will be put in place specific to each project and CTU. (see Appendix 1 for an example of a Delegation List that could be used between Sponsor, CI and CTU)

**3.10 Application for Co-Sponsorship and Joint Sponsorship**

- Applications for both types of Sponsorship will be considered using the same process detailed in the previous sections. If available, evidence of sponsorship from the other Co-Sponsor should be submitted along with the required paperwork.
- One of the Co-Sponsors will be named as the lead sponsor for the purposes of the submission for regulatory approval. A sponsor letter should be included with the submission describing the responsibilities of each sponsor.

**3.11 Authorised Sponsor Signatories for Regulatory Applications**

- Agreement for sponsorship will be needed before any regulatory applications can be made as the Sponsor’s signature is required on the submissions.
- Signatures on behalf of the Sponsor on submissions for regulatory approval must be signed by the R&D Manager or an approved delegate.

**3.12 Sponsorship of a study may be terminated during a study if**

- the safety of participants is at risk
- the CI is no longer employed by the Trust
- a breach of any existing research standard operating procedures (SOPs), policies, procedures or conditions of regulatory approvals is identified

**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 (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP and its amendments has been read and understood.

**5.0 DEFINITIONS**

5.1

CTIMP	Clinical trial of an investigational medicinal product (Any other type of research is known as a non-CTIMP)
Chief Investigator (CI)	The investigator with overall responsibility for the research. In a multi-site study, the

	CI has co-ordinating responsibility for research at all sites. All applications for ethical review should be submitted by the CI.
Sponsor	The person or body who takes on ultimate responsibility for the initiation, management and financing (or arranging the financing) of a clinical trial. Note: The Clinical Trials Regulations allow for two or more persons to take responsibility for the functions
Patient and Public Involvement and Engagement (PPIE)	By public involvement we mean a range of activities that enable patients and the public to have a say in decisions about the way health research is planned, designed, delivered, developed, evaluated, managed and regulated.  It also means where patients and the public are actively involved in the conduct of research studies.
Clinical Trials Unit (CTU)	CTUs are specialist units that are experts in the design, execution, analysis, and publication of clinical trials and other studies that assess the efficacy and effectiveness of clinical therapies and treatments. Their role is pivotal in improving patient outcomes and advancing medical research through the collaboration of specialist expertise and provision of guidance necessary for high-quality, regulatory compliant studies.
UK Clinical Research Collaboration (UKCRC)	The UK Clinical Research Collaboration brings together the NHS, research funders, industry, regulatory bodies, Royal Colleges, patient groups and academia in a UK-wide environment that facilitates and promotes high quality clinical research for the benefit of patients.
UKCRC Registration of CTU	CTUs must demonstrate their expertise and ongoing capability to an international panel of experts. This involves providing evidence of their ability to centrally coordinate multi-centre clinical trials, including taking full responsibility of the trial lifecycle from development to the analysis and dissemination of results. Additionally, CTUs must have well-established and rigorous systems in place to ensure that all clinical trials are conducted and delivered to the highest quality standards.

## 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 Sponsorship Risk Assessment SOP
- 9.2 Research Misconduct Policy
- 9.3 Monitoring and Oversight of CPFT Sponsored and Hosted non-CTIMP research studies

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.	6.0	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 is confirmed 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: Delegation of Responsibilities between Sponsor, CI, CTU

## Delegation of Duties

Cambridgeshire and Peterborough NHS Foundation Trust acting as Sponsor, delegates the responsibilities below to the CI and XXXXX

DUTIES	Chief Investigator	CTU	CPFT as Sponsor
<b>1. Funding</b>			
1.1. Holder and management of research budget			
1.2. Monitoring of participating centres delivery budget and coordinating with Sponsor for the confirmation of site payments			
1.3. Reports to the research funder			
<b>2. Trial Design and Protocol Development</b>			
2.1. Writing of the Clinical Trial Protocol including the determination of the scientific rationale, clinical feasibility, schedule of events and recruitment strategy.			
2.2. Registration of Protocol with ISRCTN			
2.3. Statistical input into trial design			
2.4. Final Protocol Approval			
<b>3. PPIE</b>			
3.1 Development of a PPIE plan for the duration of the trial			
3.2 Coordinating PPIE input into trial design and patient documents			
<b>4. Risk Assessment</b>			
4.1. Develop, review and maintain a trial risk assessment throughout the duration of the trial			
<b>5. Approvals</b>			
5.1. Preparation and submission of IRAS application to REC and HRA			
5.2. Review submissions			
5.3. Authorisation of Submissions			

5.4. Preparation and submission of study amendments to REC and HRA			
5.5. Review of Amendment Tools			
5.6. Authorisation of Amendment Tools			
<b>6. Sponsorship and Insurance/Indemnity</b>			
6.1. Confirming Sponsorship and maintain Sponsorship Agreement and Delegation of Duties			
6.2. Ensuring indemnity is in place for clinical trial participants at NHS sites			
6.3. Ensuring clinical trial insurance is in place at third party organisations involved in the study			
<b>7. Site selection and coordination</b>			
7.1. Carrying out site feasibility assessments			
7.2. Conducting site initiation			
7.3. Obtain appropriate site approvals for confirmation of Capacity and Capability			
7.4. Signing of site level agreements			
7.5. Provide information to sites including an Investigator Site File (ISF)			
7.6. Provide sites with 'Green Light' to open to recruitment			
7.7. Point of contact for site and coordination of site related study activities			
7.8. Resolving trial related clinical queries from participating sites			
7.9. Assessment of site performance			
<b>8. Trial Management</b>			
8.1. Coordinate investigator meetings			
8.2. Coordinate and write reports for Trial Management Group, Trial Steering Committee and Data Monitoring Committee meetings			
8.3. Generating and updating trial documentation for the duration of the study (i.e. study protocol, patient documents etc.).			

8.4. Ensuring document control procedures are in place and maintained for the duration of the study, including version control logs of all regulatory approved documents.			
8.5. Creating, distributing and implementing study-specific SOPs			
8.6. Prepare and maintain a Trial Master File			
<b>9. Data Management</b>			
9.1. Develop and maintenance of a data management plan for the duration of the study			
9.2. Development, validation and maintenance of trial specific database			
9.3. Management of data queries			
9.4. Coordinate database lock prior to undertaking any data analysis			
9.5. Ensuring that all generated data is recorded, handled, stored and reported accurately, securely and in accordance with the protocol, the Data Protection Act 2018 and GCP.			
<b>10. Site Monitoring</b>			
10.1. Develop and review a Trial Monitoring Plan			
10.2. Approve monitoring plan			
10.3. Conduct on site and remote monitoring			
10.4. Coordination of resolution of issues arising from monitoring visits			
<b>11. Audit and Inspection</b>			
11.1. Plan and conduct audits of study and third parties that are appropriate to trial			
11.2. Coordinate any regulatory inspections relating to the trial			
<b>12. Pharmacovigilance and Safety Reporting</b>			
12.1. Providing Pharmacovigilance oversight for the project where required			
12.2. Define reportable events in the protocol			

12.3. Ensure there is a validated system for the reporting of adverse events by sites			
12.4. Data management of Adverse Events reported by sites			
12.5. Undertaking medical review of all serious adverse events, including their severity, causality, relatedness and expectedness.			
<b>13. Management of Serious Breaches and Urgent Safety Measures</b>			
13.1. Reporting of Serious Breaches of GCP to the Sponsor, the competent authority and REC			
13.2. Reporting and follow up of all suspected potential serious breaches of GCP and / or the protocol to Sponsor within 24 hours of becoming aware of the breach. This should include management of issues in liaison with sponsor ensuring Corrective and Preventative Action (CAPA) is conducted in full.			
<b>14. Close out</b>			
14.1. Coordinating the close out of study sites			
14.2. Providing the authorisation for the closing sites and archiving of trial related documentation at sites			
<b>15. Statistical Analysis</b>			
15.1. Develop a statistical analysis plan and conduct statistical analysis			
15.2. Prepare and review trial report			
<b>16. Publication and reporting of trial updates and results</b>			
16.1. Informing the Sponsor and Funder of planned publications/ presentations etc. as early as possible and prior to publication.			
16.2. Creating and submitting the Clinical study report within one year of end of trial notification, following review by Sponsor.			
16.3. Publication of the trial results of the trial on a suitable public clinical trials database i.e. ISRCTN			
<b>17. Archiving</b>			
17.1. Ensuring all trial management documents relating to the trial are archived in an appropriate archiving facility for a minimum			

of 10 years.			
17.2. Ensuring all site documents are archived at all sites for a minimum of 10 years.			

## 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.