Document Title: Subcontracting of Research Activities (Vendor Selection)

Document Number: PTUC SOP066

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
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Department:	Research and Development
For use by:	NHS Staff Trust-Wide
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Summary of Amendments

Version Number:	Modification:
5.0	SOP amended to incorporate electronic signatures
6.0	SOP amended to reference new Vendor Oversight Plan at 4.1g

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff who are involved in the preparation and / or review of research study contracts or Clinical Trial Agreements (CTAs).
- It provides guidance on the processes of to ensure compliance with the Trust's policies.

1 Purpose and Contents

a. This document defines the Trust's research procedures for subcontracting activities pertaining to Research Studies and Clinical Trials at Royal Papworth Hospital to external providers.

b. The document describes the requirements for the establishment of a contract between these parties so as to comply with the Good Clinical Practice guidelines (GCP: 'a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected').

c. The document provides guidance on who should contribute to, review and approve contracts so as to comply with the Trust's policies on Information Governance and Financial Agreements.

d. The management of Research Finances is outside the scope of this SOP and is described in SOP023: Financial Procedures for Research Studies, and the management of contracts and their review is described in SOP024: Contract Negotiation and Review

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust including: staff that are full or part-time employees of the Trust, those working at the Trust with employment contracts funded partially or wholly by third parties including those within CUHP AHSC and those seconded to and providing consultancy to the Trust, and to students undertaking training at the Trust.

3 Policy

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

4 Procedure

4.1 Selection, Assessment and Contracting Process for Clinical Trial Sub-Contractors

a. Prior to approaching any potential sub-contractors the study project team must meet to agree the requirements, expectations, deliverables and timelines required for the study.

b. A suitably qualified team member will then be delegated to work with the study Clinical Project Manager to identify possible sub-contractors who meet the study requirements

c. Suitable sub-contractors will be identified, on the basis of where necessary:

1. Pre-Qualification questionnaires
2. Assessment of CVs and previous experience
3. Review of references
4. Assessment of quality systems/procedures

d. It is good practice to obtain quotes for work to be undertaken from a number of suitable contractors. The final decision to use a specific contractor should be based upon some or all of the following criteria:

1. Appropriate licenses and qualified personnel in place
2. The contractor shows a full understanding of the services required
3. Royal Papworth has experience of working with the contractor previously or the contractor demonstrates experience of working on similar trials
4. Visits made to the potential subcontractors and outcomes (if necessary)
5. The estimated price that is quoted
6. Recommendation by another trust/trial unit working on similar trials

e. Once a shortlist of potential sub-contractors has been identified arrangements will be made to meet with them. This meeting will be carried out at the site where the study work will be performed. The meeting will include, but not be limited to:

1. A tour of the facilities, where appropriate
2. Introduction to relevant team members
3. Review of training records and staff qualifications
4. Quality assurance records, Standard Operating Procedures and previous audit records
5. Plans for the work to be performed including timelines, deliverables, standards or work, format of end product
6. Communication requirements
7. Costs

All meetings with potential sub-contractors must be fully documented and copies of the meeting notes retained in the trial master file and also in Research and Development. A list will be maintained of potential preferred suppliers and those who did not meet expected standards.

f. Once a suitable sub-contractor has been agreed, no work will be entered into until a finalised agreement/contract is in place. This will include, but not be limited to, expected standards of work including responsibilities, record keeping and retention of records, expected deliverables, timelines for deliverables, location of work to be performed, monitoring and audit requirements, communication requirements and payments. Sub-contractors will not be allowed to further sub-contract any work being undertaken on behalf of the Royal Papworth Hospital Research and Development department without, written permission.

g. An oversight plan must be put into place at the start of the study to ensure that the sponsor can maintain appropriate oversight of the sub-contractor as per SOP 063: please use FRM085: Vendor Oversight Plan

4.2 Research Contracts

a. Copies of the sub-contract must be sent to the R&D Operational Manager for review. A copy of the protocol must also be provided to be reviewed alongside the Clinical Trial Agreement.

b. Royal Papworth Hospital NHS Foundation Trust is the legal body with whom all contracts / agreements must be made. Principal Investigators must not enter into agreements with third parties.

c. All agreements/contracts are subject to English Law – no agreements will be entered into that fall outside this requirement without prior consultation with the Trust Secretary. If a contract is to be used that falls outside English Law there will be additional fees, and this expense will be covered by the research group.

4.3 Signatures

a. Finalised contracts will be signed by the Clinical Director of Research and Development. In their absence contracts will be signed by their Deputy or the Medical Director. If the Clinical Director of R&D is the Investigator for the study or involved in the study conduct then the contract will be signed by the Deputy Director of R&D or the Medical Director.

b. The contract can be signed by either a wet ink signature or using an electronic signature system, see SOP 086

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.

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 (2018)
Key related documents:	Trust Research Policy

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:	July 2025

I certify the contents of this SOP has been reviewed and ratified

DocuSigned by:
Dr Patrick Calvert
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13-Jul-2022

Signed by Dr Patrick Calvert, Clinical Director of R&D

Date