Papworth Hospital NHS
NHS Foundation Trust

Document Title: Contract Negotiation and Review

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Staff involved in development: *Job titles only*	RM&G Manager, R&D Administration Manager, Research Officers
Document author/owner:	R&D Administration Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	June 2019

Summary of Significant Change(s) (for this version only)

Section(s):	Modification:
	Minor administrative changes only

Key Points of this Document

- This document sets out the procedures to be followed by all 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 process of contract review and preparation to ensure compliance with the Trust's policies.

1 Purpose and Content

a. This document defines the Trust's procedures for preparing and reviewing contracts pertaining to a clinical trial that is either managed by Papworth Trials Unit Collaboration, or sponsored by Papworth Hospital NHS Foundation Trust.

b. The document details the requirements for the establishment of a contract between the 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 details who should have 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 Finance is outside the scope of this SOP and is described in SOP023: Financial Procedures for Research Studies, and the management of the subcontracting of research activities is described in SOP066: Subcontracting of Research Activities.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust including: 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 Research Contracts

a. Copies of the contract, clinical trials agreement/statement of agreement (including financial agreement) between the Trust and the study sponsor must be sent to the R&D

Finance, Contracts and Admin Manager for review. A copy of the protocol must also be provided to be reviewed alongside the CTA.

b. 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.

d. Amendments to the contract will be reviewed in accordance with SOP 037

4.2 Reviewing Contracts

a. The Trust prefers that the NIHR Clinical Trial Agreement is used for all contracts.

b. Where the NIHR Clinical Trial Agreement is not used the review will include input from the Trust Secretary and if necessary also the Trust Solicitors.

4.3 Costing

a. The R&D Department with input from the clinical project team, is responsible for ensuring that the study is adequately costed. The costs should include additional staff time, additional procedure time, and all additional research test procedures, clinical and administrative activity required by the trial. In addition, the cost of other core departments which may be involved in the trial (eg Radiology, Pathology) should be detailed. The costs covered in the contract should be clear and understandable, and should also identify what is not covered.

b. All externally funded commercial research activities are subject to a one-off non-refundable set-up fee, which shall be paid by the sponsor to R&D on sign off of the CTA for the proposed study. Other fees may apply, but these will be advised by the R&D department.

4.4 Signatures

a. Finalised contracts will be signed by the Clinical Director of Research and Development. In their absence contracts will be signed by the Deputy Clinical Director of Research and Development 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 – see SOP034

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: *Managment/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. Research Governance Framework for Health and Social Care (2005)
Key related documents:	Trust Research Policy [Insert list of linked or relevant documents to this SOP]

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:	June 2019

Version Control

Version	Date effective	Valid to	Approved by	Date of approval
1.0				
2.0	June 2013	April 2016	RDD	19th April 2013
3.0				
4.0				

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

..... 18th August 2016

Signed by Dr Ian Smith, Clinical Director of R&D — Date

SOP release date: 6/9/16