Papworth Hospital NHS
NHS Foundation Trust

Document Title: Financial Procedures for Research Studies

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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
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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 of contracts, grants and funding bids for research studies.
- It provides guidance on how financial data are collected, documented and stored to ensure compliance with the Trust's policies.

1 Purpose and Content

a. This document defines the Trust's procedures for the management of finances for research studies either managed by Papworth Trials Unit Collaboration, or sponsored by Papworth Hospital NHS Foundation Trust.

b. The document describes the requirements for ensuring accurate and thorough financial management to ensure a research study is appropriately resourced as described in Good Clinical Practice (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. This document provides guidance on how financial data should be collected and stored so as to comply with the Trust's policies on Information Governance and Fraud.

d. The preparation and negotiation of contracts is outside the scope of this SOP and is described in SOP024: Contract Negotiation and Review, and the subcontracting of research activities is described in SOP 066: 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.

b. Staff involved in preparing grant applications, contracts or reviewing Clinical Trial Agreements (CTAs) must comply with the requirements set out in section 4.

c. The financial management of all sponsored studies is the responsibility of the Investigator, the R&D Finance, Contracts and Admin Manager and the Finance Department. The R&D Finance, Contracts and Admin Manager is responsible for oversight of the research accounts and the account signatories are responsible for managing the individual research accounts.

d. The Investigator, or their designated trial team member, is responsible for the timely and accurate submission of expenses and costs incurred on behalf of research to the appropriate research account.

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.

b. All studies must be adequately costed as per SOP 024

4 Procedure

4.1 Research Account Management

a. All financial contracts related to Research, including clinical trial agreements (CTAs), grant applications or educational grants must have the finance details checked by the R&D Department in liaison with the lead investigator and with the assistance, when required, of the Research and Development Directorate (RDD) Finance representative and the Trust Secretary.

b. Financial contracts will be signed on behalf of the Trust by the Clinical Director of R&D. In the absence of the Clinical Director of R&D contracts maybe signed by the Deputy Director of R&D or the Medical Director. If the Clinical Director of R&D is an Investigator on the study or involved in the study then the contract will be signed by the Deputy Clinical Director of R&D or the Medical Director.

c. All research monies connected with the Trust are held within research accounts and will be managed by the R&D Department and the Principal Investigator. The set up and closure of these accounts will be managed by R&D in conjunction with the Principal Investigator and Finance, and will be managed in accordance with the Trust's Research Account Terms and Conditions

d. A new research account number may be requested from the Research and Trust Fund Finance Officer if required. Research projects have an individual research account for the duration of the project, which is managed by the Investigator, R&D and the Finance Department. The fund holder will then be requested to complete an Authorised Signatory Form in order to activate setting up this account.

e. All commercial (Sponsor) and non-commercial research income, which is not a documented charitable donation, will be managed in designated research accounts. Up to three signatories can be nominated for the account, one of which must be R&D.

f. R&D will monitor research account income and expenditure (I&E) in accordance with the Trust's agreed financial procedures and will highlight any variance from expenditure in time for adjustments to be made before the end of the project.

g. In order for invoices to be raised in a timely and accurate manner, it is important that Principal Investigators or their research staff notify R&D when the payment 'triggers' detailed in the CTA are reached. When the study is complete, any surplus funds may be transferred into a generic Trust account by the Trust's Finance department, following discussion with the R&D department and the study Investigator.

4.2 Invoicing

a. Invoices will be raised as per the CTA.

b. The Sponsor's CTA will state when the Trust can raise an invoice and the preferred payment plan. A completed request for raising a debtor invoice is sent to Finance. This process is completed by the R&D Finance, Contracts and Admin Manager or other authorised personnel. The details of the requisition are added to the Invoice Log. Once the official invoice has been raised this is indicated on the log. A copy of the request of an invoice to be raised, along with the official invoice raised is placed in each study's finance file. VAT is to be added by the Finance Department

c. The Trust's preferred method of payment is by raising an invoice and receiving payment by cheque or via BACs, although some International companies automatically generate a payment once the data is verified.

4.3 Processing Cheques

a. When a cheque arrives in R&D it is the R&D Finance, Contracts and Admin Manager's responsibility to ensure the payment is correct, in accordance with the CTA. Cheques are sent to the Trust's cashier with a covering memo clearly identifying the name and number of the research account and a short statement of what the payment represents. Copies of these documents are also sent to the Research and Trust Fund Finance Officer in order for the payment to be tracked and a copy is placed in the study's finance file.

4.4 Payment to Departments

a. Research Studies regularly use services of other departments in the Trust. These include Pharmacy, Radiology, Respiratory Physiology and Pathology. These departments are required to send R&D an internal invoice on a regular basis. The activity on these invoices is checked with the Principal Investigator or their delegate and when agreed, an email request is sent to the Research and Trust Fund Finance Officer to transfer the agreed sum from the research account to the designated account.

b. All income/outgoing payments for each individual trial are recorded in the appropriate finance file.

c. The amount of, and method of payment for patient travel expenses payments and mechanism for payments will be agreed with the sponsor on an individual basis. A separate Patient Travel Form is generated clearly stating the research account number. The Patient's Travel Form is signed by the R&D Finance, Contracts and Admin Manager or designated signatory and taken to the cashier for payment in cash, or cheque if the amount is greater than £25.00.

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							
Positive/Negative							

Review date:	June 2019

Version Control

Version	Date effective	Valid to	Approved by	Date of approval
1.0	September 2009	August 2011	RDD	4 Sept 2009
2.0	June 2013	April 2016	RDD	19 April 2013
3.0				
4.0				

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

..... 18 Aug 2016

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

SOP release date: 6/9/16