Royal Papworth Hospital
NHS Foundation Trust

Document Title: Royal Papworth Sponsorship of Research Studies

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Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
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Directorate:	Research and Development
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Summary of Amendments

Version Number	Modification:
V5.0	Administrative changes throughout
V6.0	Section 4.1.j updated to include reference to new email template (TPL051) that provides record of official sponsorship approval in study files

Key related documents:	Trust Research Policy Trust Policy DN1 Document Control Procedures SOP034: Trust Approval and Research Governance TPL051 Confirmation of sponsorship and permission to activate sites FRM028 MoU for Clinical Trial Delegation of Sponsorship Responsibilities FRM098 RPH Sponsor Green Light Check List

Key Points of this Document

- This document sets out the procedures to be followed by all Staff who would like Royal Papworth Hospital NHS Foundation Trust (Papworth) to act as Sponsor for their research.
- Papworth may sponsor studies where the Chief Investigator (CI) is based at Royal Papworth, or because the study involves the Papworth Trials Unit Collaboration (PTUC) and requires an NHS sponsor.
- Sponsorship must be agreed before any regulatory submissions can be made.

1 Purpose and Contents

a. This document describes the requirements for agreeing and maintaining Sponsorship so that Royal Papworth may fulfil its duties as Sponsor 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').

b. The sponsor of a clinical trial is the organisation who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial.

c. The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting.

d. Co-Sponsorship can be agreed whereby the duties of the sponsor are shared between more than one sponsor.

2 Roles & Responsibilities

a. This Policy applies to all researchers applying for Trust sponsorship and all Chief Investigators of Royal Papworth Sponsored studies.

b. The CI of a research study is responsible for ensuring that the study is sponsored and that all the relevant regulatory approvals have been obtained. The actual procedure for obtaining sponsorship may be delegated to a responsible member of the core research team.

c. Staff involved in sponsorship applications, both submission and review, must comply with the requirements set out in section 4.

3 Policy

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

4 Procedure

4.1 Applying for sponsorship

a. Initial enquiries about applying for Royal Papworth sponsorship should be sent to the R&D Enquiries address box papworth.randdenquiries@nhs.net.

b. A Project Manager (PM) will be designated to work with the CI.

c. The CI (or his delegate) and the PM should liaise as soon as possible prior to applying for Trust sponsorship to ensure suitability and feasibility.

d. The CI/delegate should submit the following documents to the PM in draft format:

i. A full protocol
ii. A Patient Information Sheet (PIS) where appropriate
iii. An informed consent Form (ICF) where appropriate
iv. A submission ready IRAS Ethics or R&D application form

e. The PM will review these documents and advise if any changes are needed prior to submission for review at the Research Governance Meeting (RGPAS) (see SOP034: Trust Approval and Research Governance). The CI is responsible for ensuring that these changes are made prior to submission.

f. The PM will request that the study is listed on the agenda for the next available RGPAS meeting. The PM and the CI should ensure that all the paperwork is made available one week before the meeting.

g. The CI/delegate is invited to attend and present the study at the RGPAS meeting.

h. The RGPAS review will include review of the feasibility and funding of the study as well as the financial, safety and legal implications for the Sponsor.

i. RGPAS may approve the sponsorship application subject to certain changes or conditions. These will need to be made / agreed before the sponsorship application is authorised.

j. For Royal Papworth CTIMPs, confirmation of Trust sponsorship will be communicated via email to the CI and PM by an R&D Manager or Clinical Director. This confirmation email (TPL051 Confirmation of sponsorship and permission to activate sites) must be filed in the trial master file. For other studies, specific confirmation of sponsorship can be issued on request. Otherwise, it will simply be recorded in the minutes of the RGPAS meeting.

k. Once sponsorship has been agreed in principle at the RGPAS meeting, the CI/PM may proceed with regulatory approval submissions. This process will require the Clinical Director of R&D to sign off the IRAS application form in their capacity as sponsor representative.

l. In the event that the Clinical Director is the CI of the study, Sponsorship can be approved by the deputy Clinical Director of R&D or the Trust's Medical Director.

m. For CTIMP/device trials where sponsorship has been agreed in principle, gaining sponsor green light will be dependent on the CI and all delegated personnel involved in the trial, being fully up to date with SOP training. Please see FRM098 (RPH Sponsor Green Light Check List).

n. A sponsorship responsibilities agreement (FRM028 MoU for Clinical Trial Delegation of Sponsorship Responsibilities) should be completed to indicate the division of responsibilities between the Sponsor and the CI.

o. In the event that sponsorship is refused, the CI will receive feed-back from the RGPAS committee and advised if a second application for the study is appropriate.

p. The R&D Unit will retain a complete copy of all final submissions and correspondence with the regulatory bodies for research studies sponsored by the Trust. It is the responsibility of the CI to ensure that R&D receives the necessary copies. These should be filed in the trial master file.

4.1.2 Peer review of sponsored studies

a. If grant funded:

1. The level of peer review required is proportionate with the type of research.

2. Royal Papworth sponsored research funded by an external grant award will not be required to provide additional evidence of peer or scientific review other than notice of the award.

b. Or,

a. For high risk non-CTIMPs, CTIMPs and non-CE marked device studies (i.e. those that require MHRA approval) peer review must be completed by two external reviewers (unless grant funded).

b. For student research projects, review by the academic supervisor, and/or clinical management group is considered appropriate. A signed IRAS form is considered acceptable evidence.

c. For all other studies, peer review may be requested if concerns are raised at RGPAS.

4.2 Application for Co-Sponsorship

a. Applications for Co-Sponsorship will be considered using the same process detailed in 4.1. If available, evidence of sponsorship from the other Co-Sponsor should be submitted along with the required paperwork.

b. One of the Co-Sponsors will be named as the lead sponsor for the purposes of the research ethics committee (REC) application and a sponsor letter should be included with the REC application describing the responsibilities of each sponsor.

4.3 Authorised Sponsor Signatories for Regulatory Applications

a. Agreement for sponsorship will be needed before any further regulatory applications can be made as the Sponsor's signature is required on the submissions.

b. Signatures on behalf of the Sponsor on submissions to other regulatory bodies (i.e. IRAS forms) must be signed by the Clinical Director of R&D or an approved delegate.

4.4 Maintaining Sponsorship

a. On-going Sponsorship & Trust Management approval are subject to the compliance with the conditions of R&D approval.

4.5 Withdrawal of Sponsorship

a. The Trust reserves the right to withdraw sponsorship if there is justifiable reason for doing so e.g. breach of the conditions of R&D approval or other serious concerns e.g. persistent breach of the research protocol.

b. Serious concerns about the conduct of the study should be reported to the Senior R&D Manager or his/her delegate.

c. The Senior R&D Manager, or delegate, will discuss the concerns with the Clinical Director of R&D. If the Clinical Director of R&D is unavailable or if he is the CI for the study, then the discussion will be with either the Deputy Clinical Director of R&D or the Trust's Medical Director.

d. A proposed decision to remove sponsorship should be discussed with the CI, the PM and other key stakeholders as appropriate e.g. Trial Steering Committee (TSC), the Data Monitoring Committee (DMC) Funder(s).

e. The final decision to withdraw Trust Sponsorship will be confirmed in writing. The CI and stakeholders should be notified e.g. TSC, DMC, Funder(s), research teams.

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: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	Executive Directors' Committee
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 (2023)

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							

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