Royal Papworth Hospital
NHS Foundation Trust

Document Title: Research and Development: Internal Good Clinical Practice (GCP) Audit

Document Number: PTUC SOP063

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
Document author/owner:	Senior R&D Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	September 2023

Summary of Amendments

Version Number	Modification:
4.0	**Minor Amendments Throughout**

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff who are involved in, or undertaking, research
- It describes the process for preparing and participating in an Internal Good Clinical Practice Audit and ensures compliance with the Trust's policies, Standard Operating Procedures (SOP's), GCP and Applicable Regulatory Requirements.

1 Purpose and Contents

a. The primary purpose of audit in the context of this SOP is to provide assurance as to the quality of all activities relating to research trials, and by extrapolation, the results of those trials. There is a requirement to provide assurance that all clinical trial activities carried out at Royal Papworth Hospital NHS Foundation Trust (RPH) and those under the auspices of the Royal Papworth Trials Unit Collaboration (PTUC) are done so in accordance with approved trial documentation and also to identify any deficiencies in supporting clinical trial processes and services. The Trust, therefore, undertakes a rolling program of systems audit's which serves to provide assurance that clinical trial activities are being performed in accordance with UK clinical trial legislation, guidelines, all applicable Standard Operating Procedures (SOPs) and Good Clinical Practice (GCP).

b. Triggered audits may also be carried out if concerns are raised with any aspect of a clinical trial necessitating immediate investigation. Such audits will be performed without notification; however, all other aspects of the audit process remain unaltered by this type of audit.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust.

b. The Quality Assurance team (QA) is responsible for maintaining an up-to-date rolling program of audit and the requirement for audit will be dictated by this. Details of the program of systems audits can be found S:\shared\R&D\QA meetings. All templates referred to within this SOP may be located at the following link: https://royalpapworth.nhs.uk/research-and-development/information-researchers/running-study/documents-and-templates-2

c. Auditors (staff completing audits) will be those staff within R&D identified, by the QA team, as being suitable in terms of both training and independence from the trial being audited, and must comply with the requirements set out in section 4. (We acknowledge staff must be independent of the trials being audited; however due to the limitations of qualified staff to undertake audits this is not always possible).

d. "Responsible person" as referred to in this SOP is defined as that person who has immediate responsibility for the study or process being audited and with whom liaison for all matters relating to the audit being undertaken must take place.

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

a. For the purpose of PHFT trial specific audit activities, audit must be performed by an individual(s) suitably qualified by education, training or experience and who are not associated with the day-to-day running of the trial in question. The individual would need to be fully conversant with the applicable clinical trial legislation and associated guidelines, local standard operating procedures and have received training in conducting audits. The Monitoring & Audit Co-ordinator will maintain a log of all staff who have received audit training which will also further define the SOP's or studies they have audited in order to define experience.

4.1 Audit Process

a. In the event that concerns are raised with any aspect of a study, a triggered audit may be performed that falls outside of the routine rolling program of audit. This type of audit will not provide the period of notice as detailed in section b below.

b. For audits undertaken in line with the rolling systems audit program, the auditor should liaise with all staff involved in order to confirm availability for proposed dates. The auditor must send notification of the audit to all personnel who are involved, or affected, two weeks in advance of the audit start date. For singular study audit the notification letter (FRM062) will be used. For audits investigating multiple studies; an email will be drafted to give notification to the Principle investigators. The letter or email must state the purpose of the audit, any documents required, anticipated number of days or duration of the visit. For audits performed under the rolling program of system's audits, notification should detail those SOPs against which the audit will be performed.

c. The responsible person for the processes/trial to be audited must ensure that all documentation, paperwork or provision for access to medical records required for the audit is available and accessible by the pre-arranged date. The duration of the audit will be dictated by the audit being carried out and its complexity. During this time, should it be necessary for any of the documentation or paperwork required for the audit to be removed for clinical reasons, it must be returned to the auditor by a date/time agreed with the auditor at the time they are taken. The agreed date for return of documentation must be noted on the audit report. Following completion of the audit, the responsible

person must ensure that all documentation and paperwork are returned to their correct locations.

d. Following completion of the audit, the auditor will prepare a written audit report within two weeks, using the template available (FRM025 Audit Report). Once this is complete the auditor must liaise with the responsible person to discuss findings, and agree necessary actions, which must be detailed in the finalised audit report.

e. The PI and or delegated research team will then address all findings, deviations and deficiencies presented by the auditor with a specified amount of time in which to complete these.

f. Evidence of completed actions must be entered onto the audit report and send back to the auditor to review. (Actions are sent out and received via email, emails are saved down as evidence of actions by the designated research team) Once satisfied the audit report is complete the auditor will file the report on the R&D shared drive/QA meetings/Audit where it will be presented at the next QA meeting for review

g. The QA team is responsible for maintaining a Corrective and Preventive Actions (CAPA) database. For all audits undertaken the following details must be added to the CAPA spreadsheet following the completion of the final audit report:

1. Details of the audit carried out including: audit reference number; person performing the audit, date the audit was undertaken.
2. Details of any audit findings
3. Details of all actions required to address audit findings
4. Details of who will be responsible for completion of each action
5. Date by which the action must be completed

h. In the event that actions remain unaddressed, or that issues arise during the process of addressing required actions that prevent the audit from being closed, the matter will be referred to the Clinical Director of R&D for further input or escalation.

i. The audit team have the right to re-audit at any time in line with the current audit SOP.

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 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 [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:	September 2023

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

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