Royal Papworth Hospital
NHS Foundation Trust

Document Title: GCP Training for Research Staff

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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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Summary of Amendments

Version Number	Modification:
Version 6.0	**Amendments made to detailing Governance taking on GCP compliance in IQM and not EDGE**
Version 5.0	**Amendments made to details of ICH GCP courses available.** **The use of IQM for storage of GCP certificates – never ratified as waiting for completion of move to IQM for GCP**
Version 4.0	**Minor procedural changes throughout**

Key related documents:	Trust Research Policy SOP034: Trust Approval and Research Governance

Key Points of this Document

- This document details the Trust's requirements regarding 'Good Clinical Practice' (GCP) training.
- All personnel involved in a research study with human subjects and responsible for actions which are not parts of routine clinical care must have training in GCP.
- It is the responsibility of the principal investigator (PI) to ensure that the research team have up to date (that is within 3 years) training in GCP.

1 Purpose and Content

a. This document defines the Trust's requirements with regards to training 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 document details which staff require training, the responsibilities for ensuring that training has occurred, the frequency of updates required and identifies appropriate training routes.

2 Roles & Responsibilities

a. This Policy applies to all personnel conducting research at the Trust whether 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), those seconded to and providing consultancy to the Trust, and to students undertaking training at the Trust.

b. Staff involved in research with human subjects must comply with the requirements set out in section 4.

c. The PI is responsible for ensuring that they themselves and their research staff are trained in, and compliant with, GCP.

3 Policy

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

4 Procedure

4.1 Trust Requirements

a. Chief or Principal Investigators of Royal Papworth Sponsored research studies are required to undertake a National Institute for Health Research (NIHR) on-line GCP training, refresher course or equivalent, prior to, their involvement in the clinical trial. This training must be renewed every three years throughout the individual's involvement in the trial.

b. The PI is responsible for ensuring that all members of staff on the delegation log have appropriate and in-date GCP training prior to performing any study related activity. This training must be through a recognised course or the NIHR GCP course.

c. Any staff not in the direct research team undertaking research related activities that follow the normal care pathway but require collection of additional data should undertake appropriate GCP training prior to their involvement in a research study (irrespective of the study type). The NIHR provide a course for support staff called Research Practice in Clinical settings, the link to this can be found here: https://www.nihr.ac.uk/career-development/clinical-research-courses-and-support/good-clinical-practice

d. After 3 years, staff still engaged in research must take a refresher course.

e. Some commercial sponsors require PIs to undertake their own in-house training, this would be accepted. Some sponsors may require more recent training which research staff will be required to comply with.

4.2 Training Courses

a. On-line NIHR GCP Training: Details of the on-line course can be found at:

https://learn.nihr.ac.uk/course/index.php?categoryid=5

4.3 Evidence of Training

a. A copy of the certificate should be emailed to Royal Papworth Governance team at: papworth.randdenquiries@nhs.net to be uploaded to IQM.

b. The IQM system will automatically issue reminders when R&D staff member's GCP expiry dates are approaching. The governance team may also send a reminder to the individual.

c. Copies of the certificate should be included in the site files of the studies that the staff member is involved in.

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)	Date of current active version
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 (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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