NHS
Royal Papworth Hospital
NHS Foundation Trust

Document Title: GCP Training for Research Staff

Document Number: PTUC SOP049

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:	March 2024

Summary of Amendments

Version Number	Modification:
Version 4.0	**Minor procedural changes throughout**

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) tutor-led 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 involved in research related activity in interventional studies (i.e. clinical trials that require MHRA approval and surgical/ interventional trials) have appropriate GCP training prior to performing any study related activity. This training must be through a recognised course and the NIHR GCP course (either classroom or on-line) is recommended.

c. All staff undertaking research-related activities for non-interventional studies should undertake appropriate GCP training prior to their involvement in a research study (irrespective of the study type). This includes any staff not in the direct research team undertaking research related activities that follow the normal care pathway but require collection of additional data.

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. NIHR Tutor-led GCP Training

- The dates for the Eastern CRN NIHR GCP training can be found on-line at:

  https://learn.nihr.ac.uk/mod/facetoface/view.php?f=348

- Book your place via the on-line NIHR Learning Management System:

  https://learn.nihr.ac.uk/course/view.php?id=296#section-2

b. 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

c. Royal Papworth Hospital NHS Foundation Trust Introductory GCP Training course. These are organised in a bespoke manner. Contact papworth.randdenquiries@nhs.net to arrange training.

4.3 Evidence of Training

a. A copy of the certificate should be forwarded to Royal Papworth R&D Governance team either by e-mail to papworth.randdenquiries@nhs.net or through the Internal Post addressed to: R&D Enquiries, R&D, Royal Papworth Hospital.

b. A copy of the certificate should be retained in the individual's personal training file and uploaded to the Research Database, EDGE, as per SOP035: Using the Research Governance Database. The EDGE system will issue reminders to the R&D Governance team when R&D staff member's GCP expiry dates are approaching. The R&D Governance team forward this 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 (2018)
Key related documents:	Trust Research Policy Research and Development Standard Operating Procedures entitled: SOP034: Trust Approval and Research Governance

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:	March 2024

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

..... 24th March 2021

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

SOP release date: 7th April 2021