Royal Papworth Hospital
NHS Foundation Trust

Document Title: Training Records for Research Active Staff

Document Number: R&D SOP002

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
Document owner:	Senior R&D Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
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Summary of Amendments

Section(s):	Modification:
Version 9	Amended to include IQM instead of OpenClinica for recording SOP compliance and GCP and CVs
Version 8	Minor administrative changes.
Version 7	Requirement for CV to be updated every 3 years Requirement for any self-directed learning to be logged

Key related documents:	Trust Research Policy TPL048 Research Passport SOP reading list

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Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff who are involved in research.
- It provides guidance on the steps involved in recording, maintenance and storage of the training records of research staff to ensure compliance with the Trust's policies.
- SOP compliance, GCP training and CVs will be recorded on IQM. The remainder of the training record will be stored on EDGE.

1 Purpose and Contents

a. This document defines the Trust's procedures for the recording of training for all personnel that are conducting research at the Trust. This includes the completion of Training Records and the training requirements for research staff.

b. The document clarifies the requirements for demonstrating appropriate training, knowledge and experience of research personnel as described in Good Clinical Practice.

c. The document aims to provide clear guidance on the creation, revision and storage of training records so as to comply with the Trust's policies on Information Governance.

2 Roles & Responsibilities

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

b. Staff involved in the conduct of research must comply with the requirements set out in section 4.

c. All personnel must comply with Trust mandatory training policy and provide evidence on request.

d. It is the responsibility of the department's personnel to ensure that they are familiar with and adhere to all current SOPs and have acknowledged this in IQM.

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

4.1 Training Records Structure and Content

a. Each set of electronic training records will contain:

1. Abbreviated curriculum vitae (CV) summarising current and previous relevant experience with dates and qualifications. The CV must be signed and dated. The CV should be updated at least every 3 years or earlier when significant changes occur.
2. Current job description/Role Profile. In the case of Consultant post holders, if a job description is not available then a copy of their current job plan is acceptable.
3. All research staff actively involved in CTIMP studies, Non CE marked device studies or other clinical studies, and who have signed a study delegation log, must include evidence of appropriate GCP training within the last three years.
4. Certificates of attendance of training and / or qualifications
5. Further examples of experience such as a publication list or full CV.
6. Competency skills record

b. Any other miscellaneous documents eg. Signed office etiquette policy. An R&D Administrator will create training records on EDGE.

c. Each individual member of staff is responsible for the maintenance of their e-training record by uploading all new documentation in a timely manner and ensuring it is fit for both internal and external audit.

d. Training records contain confidential information, the sharing of passwords for EDGE and IQM is strictly prohibited. Training records should be reviewed annually by the member of staff's Line Manager and a proportion will be audited annually as part of the internal audit plan. In addition, training logs may also be reviewed during external audit and inspections.

e. Medical staff involved in research will be required to provide evidence that they have maintained their training records at their annual appraisal.

4.2 SOP Training

a. SOP training will be documented on IQM. The QA administrator will provide a password and guidance for SOP training on IQM. By acknowledging the SOP on IQM the employee is confirming that they have read and understood the SOP, and that they agree to undertake the procedure within the scope of their role.

b. SOP training requirements are defined as per the SOP Training Matrix, which is updated by the SOP Administrator. This matrix defines the minimum SOPs that need to be followed by each role group and this is used to set the individuals access to the SOP list on IQM.

c. For those completing research under a Research Passport, Letter of Access (LoA) or RPH Bank staff, a core list of SOPs will be provided to read (TPL048 Research Passport SOP reading list). Those persons completing this list of SOPs (including any additional ones) will be decided at the RGPAS meeting when their study is reviewed and whether they need to be registered on IQM or a paper record is sufficient. If TPL048 is to be completed on paper the wet ink / DocuSigned document should be filed in the study site file. PI's or those completing CTIMPS will be added to IQM for completion of their SOPs as described in this SOP.

d. All R&D staff will be notified that new SOPs have been ratified and released via email.

4.3 Archiving of Training Records

a. Upon leaving Royal Papworth R&D, the member of staff's training records contained on EDGE and IQM will be deactivated. If the member of staff subsequently returns to the Trust the records will be re-activated on EDGE and IQM. Any paper training records belonging to Royal Papworth R&D staff who have left the Trust and do not have an allocated EDGE account will be archived.

b. The departing member of staff may take the original copies of any certificates or attendance sheets providing that a copy is left in the training record for archiving.

c. Training records are stored in accordance with Trust Procedures – Information Governance Policy DN108

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.

The Research and Development Directorate is responsible for the ratification of this procedure.

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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 (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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