Document Title: SOPs: Production, Approval and Review

Document Number: R&D SOP001

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:	February 2023

Summary of Amendments

Version Number	Modification:
Version 10.0	**Minor procedural changes throughout**
Version 9.0	**Changes to reflect that OpenClinica is being used instead of paper training records.**
Version 8.0	**To amend the process for review of currently approved SOPs – limiting review and implementation of amendments to a lead Clinical Project Manager (CPM) along with two further CPMs acting as reviewers.**

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff who are involved in the preparation, review, dissemination and implementation of Standard Operating Procedures (SOPs) for the core activities of clinical research.
- It provides guidance on the steps involved in the preparation of SOPs to ensure compliance with the Trust's policies.

1 Purpose and Contents

a. This document defines the Trust's procedures for preparing, managing and reviewing Standard Operating Procedures (SOPs) that describe the standard activities used in research at Royal Papworth Hospital NHS Foundation Trust and Papworth Trials Unit Collaboration (PTUC).

b. The document details the requirements for written SOPs to provide quality assurance as described in Good Clinical Practice.

c. All core clinical trial activities need to be supported by appropriate SOPs. This document provides guidance on the preparation and review of these departmental and trials unit SOPs so as to comply with the Trust's policies on document preparation and control.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust. Staff involved in the preparation, review and dissemination of SOPs must comply with the requirements set out in section 4.

b. It is the responsibility of all personnel involved in research at the Trust to ensure that they are familiar with and adhere to all current SOPs, and have signed on OpenClinica to confirm that the relevant SOP's have been read.

2.1 SOP Committee

a. The R&D Department SOP committee consists of the R&D Managers, Clinical Project Managers, SOP Administrator, Team Leaders, Research Nurse/Clinical Trial Coordinator.

Clinical representation from a Consultant Clinician will be sought as and when required depending upon the SOPs being reviewed.

b. The R&D SOP Committee is responsible for identifying the need for a new SOP and arranging its production, review, ratification and implementation. The need for a new SOP may also be identified by other staff within the department and communicated to the SOP committee for action.

c. The SOP Committee, SOP review programme and meeting dates are available from the SOP Administrator. The meeting activities may be completed by remote means (e.g. email, teleconference) when necessary.

d. The committee is responsible for identifying and organising further representation from the specialists/staff groups for the inception/review of an SOP where they may be particularly affected by the implementation of that SOP.

e. The task of preparing the SOP may be delegated to R&D personnel who are deemed to have the appropriate knowledge and experience.

f. The SOP committee is responsible for identifying and arranging provision of any training that the introduction of a new SOP will require for staff to be able to perform their role in compliance with the SOP.

3 Policy

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

4 Procedure

4.1 Writing SOPs

a. A review of the background context, including statutory or regulatory requirements, should be undertaken as part of the development of a new SOP. Stakeholders should be consulted as required including those who will carry out the SOP in practice.

b. Before an SOP is produced, the activity will be mapped to describe the process in a stepwise fashion. This will be used to draft the SOP using the department's standard SOP template to ensure compliance with the Trust's policy DN1. Updates to the SOP template will be managed by the SOP Administrator and all versions will be stored and can be made available upon request.

c. All SOPs must include a version control history that must be updated with each change to the SOP. All SOPs will have a review date and version number in the footer, and numbered pages in the page x of y format. The preferred numbering system is: version 1.0 (initial approved document); versions 2.0, 3.0 etc (subsequent updated documents which have been approved).

d. Unapproved draft versions for review will be marked with version 1.1, 1.2 etc. The "DRAFT" watermark should be displayed diagonally on the page.

e. New SOPs should be generated in MS Word from the current SOP template. This will be managed by the SOP Administrator.

f. New SOPs will be given the next sequential number (SOPXXX) according to the Complete Current Listing controlled by the SOP Administrator. Changes to the title of an SOP, when preparing a new version, will not require a new number.

g. SOPs which are only relevant for studies either sponsored by Royal Papworth Hospital or managed by Papworth Trials Unit Collaboration are named PTUC SOPXXX. SOPs which are relevant to all personnel that are conducting research at the Trust including staff that are full or part-time employees of the Trust are named R&D SOPXXX.

h. On completion, the draft SOP will be reviewed internally by the SOP Committee to look at compliance with the regulations, readability and accuracy of information.

i. Any forms, templates or guidance documents that are quoted, enclosed or embedded within the SOP will also be reviewed by the SOP Committee.

j. For each new/revised SOP, the SOP Committee will assess what level of training is required, and in what format it will be delivered. The type and level of training should be appropriate to the roles and responsibilities of specific members of staff and the procedure concerned. Class-room based training may be required when competency sign-off is necessary, where complex processes or concepts are involved, or for staff new to the role or task. Realistic timeframes for the completion of training should be set.

k. The training requirement for each SOP (i.e. read only or class-room training) will be minuted and indicated on the SOP email circulated by the SOP Administrator. The arrangements for any training will be delegated by the SOP Committee to the most appropriate member of staff and logged according to Training Records SOP002.

l. The Summary of Amendments table at the front of the document will be completed to document any changes since the previously ratified SOP.

4.2 Authorising SOPs

a. When the SOP committee agrees that the SOP is ready for ratification the SOP administrator must ensure:

   1. the SOP is on the correct template;
   2. the watermark is removed;
   3. the version number updated to the next whole number and planned review date added to the footer and front page of the SOP.

b. The SOP is then submitted by the SOP Administrator to the Clinical Director of Research and Development for approval.

c. The Clinical Director will decide whether the SOP needs any amendments prior to ratification and whether the SOP is to be ratified by Chair's Action or the Research & Development Directorate (RDD) committee.

d. If RDD approval is required, the SOP will be presented at a quorate RDD Committee where a senior manager or Clinical Director of R&D is in attendance to present the SOP and answer any questions. This will be minuted to provide written evidence of approval.

e. SOPs approved by chair's action are to be listed on the RDD agenda for the RDD committee's information.

f. Changes to existing SOPs which are deemed to be minor by the SOP Committee e.g. typo corrections, updates on links, may be approved by the Committee and ratified by the Chair of the SOP Committee.

g. Once approved the Clinical Director must sign and date the SOP. The date of SOP approval will be added to the relevant section of the SOP spreadsheet.

h. All SOPs will have an effective date of four weeks after the SOP is circulated via email, to allow any required training to be performed prior to its implementation.

4.3 Authorising template documents and templates

a. The SOP administrator will submit forms, templates and guidance documents to the Chair of the SOP Committee for approval.

b. Once approved, guidance documents will be signed and dated and uploaded as a PDF. Forms and templates will be uploaded, unsigned.

4.4 Distribution and Implementation

a. Upon authorisation, the SOP Administrator will submit

1. the scanned version of the ratified signed SOP for inclusion on the R&D and PTUC SOP web pages.
2. the scanned version of the ratified signed guidance documents for inclusion on the R&D and PTUC web pages.
3. The word / excel version of the form or guidance document for inclusion on the R&D and PTUC web pages.

b. New SOPs will be highlighted at the top of the page.

c. All R&D staff including local Chief and Principal Investigators will be notified of new and amended SOPs via e-mail. Significant amendments to the SOP will be highlighted in the email by adding the Summary of Amendments table. The SOP Committee will minute if this is required.

d. All R&D personnel and study support staff will be made aware of new versions of SOPs via email, the monthly departmental staff ('Buzz') meetings, and Royal Papworth Medical Advisory Committee (PMAC).

e. Any existing clinical trial documentation, or departmental written and electronic material that refers in any way to a superseded version of an SOP, should be updated to reflect the new SOP.

f. Staff should record that they have read and completed any required training relating to the SOP in OpenClinica

g. SOPs should be read within four weeks of release, and required training completed before the member of staff performs the particular clinical trial activity. Compliance will be monitored by auditing of the OpenClinica records (Training Records SOP002).

h. The impact of new or revised SOPs on ongoing trials will be reviewed by the SOP Committee. Actions to ensure stakeholders are alerted to any potential impact, the actions which may be needed to address these, and training requirements will be identified and minuted.

i. Whilst SOPs may be printed, the electronic version maintained on the Trust's Intranet is the controlled copy. Any printed copies are not controlled.

4.5 Deviations from SOPs

a. The R&D Department has an open policy to encourage declaration of deviations from SOPs. It is the responsibility of staff to report SOP deviations to the Senior Managers and record these deviations as file notes or non-compliance (SOP050) in the trial master file making clear which version of the SOP is being implemented.

b. All reported deviations will be reviewed by the QA committee and any necessary actions agreed.

4.6 Review of currently approved SOPs

a. SOPs should be reviewed at least every three years to ensure compliance with the Trust's Policy DN1 or if the SOP Committee is alerted to SOPs that need amending before their review date eg in response to changes in practice, regulations or legislative requirements.

b. The designated review date of a particular SOP will be detailed on the SOP itself.

c. The SOP Administrator will keep a log of the effective dates of all the departmental SOPs. SOPs should be flagged for review within the department three months prior to the specified review date to enable a new version to be prepared and ratified if necessary.

d. The SOP Administrator will inform the Committee of any SOP requiring review, identifying two members of the SOP committee who will review the currently approved SOP and propose any necessary amendments.

e. It will be the responsibility of these identified members, to also ensure any hyperlinks; references; associated forms or templates are also current.

f. Where an SOP requires updating, identified members will make all necessary changes, and submit the SOP to the next SOP committee meeting. Approval will then take place in the same way as detailed in section 4.2.

g. If the SOP does not need updating, or the changes are purely administrative, the amended SOPs will be submitted to the Chair of the SOP committee for final review prior to being submitted to the Clinical Director of R&D for signature.

h. The review date of an amended SOP will be shifted to reflect the date of the latest review.

i. Superseded (approved and implemented) versions of SOPs will be archived and retained on the R&D system by the SOP Administrator. All previous versions will remain saved on the directory as a PDF version only, and Word versions will not be kept.

4.7 Review of currently approved forms, templates and guidance documents

a. Forms, templates and guidance documents should be reviewed alongside the relevant SOP.

b. Where a form, template or guidance document requires updating, identified members will make all necessary changes, and submit to the next SOP committee meeting *for information only.* Approval will then take place in the same way as detailed in section 4.3.

c. The amended documents will be submitted to the Chair of the SOP committee for final review and approval. If the amendments are relating to a regulatory or process change the SOPs will be returned to the SOP committee for full review.

d. The Chair of the SOP Committee will sign the Guidance document and the SOP Administrator will submit the scanned version of the ratified signed guidance document for inclusion on the R&D and PTUC SOP web pages.

e. Forms and templates will uploaded unsigned.

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:	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 Trust Policy DN1 Document Control Procedures

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:	February 2023

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

.....

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

6th February 2020.

Date

SOP Release Date: 24th February 2020