Royal Papworth Hospital
NHS Foundation Trust

Document Title: Email Correspondence: Study Related

Document Number: PTUC SOP064

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:	January 2023

Summary of Amendments

Version Number	Modification:
Version 3.0	Administrative changes throughout.
Version 3.1	Administrative changes throughout

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff who are involved in research studies at Royal Papworth Hospital NHS Foundation Trust.
- It provides guidance on the steps involved in managing study related email correspondence to ensure compliance with the Trust's policies.

1 Purpose and Contents

a. This document defines the Trust's procedures for ensuring that all required study related email correspondence is correctly stored.

2 Roles & Responsibilities

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

b. Staff involved in managing study related email correspondence must comply with the requirements set out in section 4.

c. It is the responsibility of all personnel to ensure that they are familiar with and adhere to all current SOPs, and have signed the relevant log in their training record.

3 Policy

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

4 Procedure

a. Pertinent email correspondence that is necessary for the reconstruction of key activities and decisions in relation to a research study, or that contains other significant information must be retained. For example, safety protocol violations, incidences, protocol changes, minutes of meetings.

b. Emails must be titled in line with the naming convention. Guidance on filing in the TMF structure can be found in GD019 eTMF Process Overview.

c. Email correspondence must be filed in the Sponsor and/or Site File as per Sponsor File index (FRM021) and Site File Index (FRM068) guidance.

d. Emails should be saved from Outlook and filed in PDF format. For studies with a paper Sponsor/Site File, emails should be printed and filed.

e. Emails that have attachments will be grouped into sub-folders within the appropriate

correspondence folder. Attachments will be saved with the same name as the parent email chain plus 'attachment 1 of X' at the end

f. Email correspondence must be filed in a timely manner and filed in chronological order avoiding duplicate emails and repetitive email chains.

g. Emails generated from pertinent study correspondence should be stored in a specified study named folders in Outlook.

h. In the event of study staff leaving the study they must ensure that any emails stored in their personal folders are filed in the Sponsor/Site File and/or the electronic study folder on the R&D shared drive.

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

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:	January 2023

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

02-May-2023 DocuSigned by: Patrick Calvert 81A52758BFFF421...

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