Royal Papworth Hospital
NHS Foundation Trust

Document Title: File Notes

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

Version Number	Modification:
Version 5.0	Updated to bring in line with updated eTMF process
Version 6.0	Minor admin changes

Key related documents:	Trust Research Policy SOP013 TMF Creation & Maintenance SOP050 Handling of Non-Compliance SOP077 Data Management Overview FRM021 Sponsor Green Light Index FRM038 Protocol Non-Compliance Form FRM039 Open Clinica Data Changes FRM068 Site File Index TPL007 File Note Template

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth staff who produce file notes related to research studies.

1 Purpose and Content

a. This document defines the Trust's research procedures for the production of study related file notes in research studies being undertaken at Royal Papworth Hospital NHS Foundation Trust and managed by PTUC.

2 Roles & Responsibilities

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

b. Staff involved with the production of Trial Master Files (TMF) for research studies at Royal Papworth Hospital must comply with the requirements set out in section 4.

c. During set-up of a study, the Principal Investigator will delegate the responsibility for creating file notes to a member of the study team.

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 Policy and Procedure

4.1 Policy

a. File notes are to be used to explain missing information or documentation. Any actions required to prevent reoccurrence should also be documented in the file note.

b. Errors or alterations made to data, which is not already clearly documented and explained on the Case Report Forms should be documented in accordance with SOP077 and documented using FRM039.

c. If there are discrepancies or deviations from the protocol, then SOP050 and FRM038 should be used.

4.2 Production of a file notes

a. An example file note template is given in TPL007.

b. For Royal Papworth Sponsored studies, site level files notes for the Royal Papworth site can be completed in OpenClinica eForms. This avoids the need for wet ink signed file notes.

c. File notes for externally-sponsored studies should be produced according to the study Protocol.

d. The number of the Sponsor or Site File section to which a file note pertains should be clearly indicated in the document name of each file note as well as in the header information if using TPL007.

e. The file note should be signed and dated by the author. The Principal Investigator should have oversight of the file notes and, if required, eForms should be printed and countersigned and filed in the TMF.

f. For studies with an electronic TMF (eTMF), the original paper (wet ink signed and dated) file note should be scanned using the eTMF scanner and this certified copy (i.e., scan) of the file note should be filed in the File Notes sub-folder, depending on whether it is a study-level (see FRM021) or site-level (see FRM068) file note.

g. For CTIMPs and any other studies with a paper TMF, the original paper file note should be filed in the relevant section of the paper Sponsor or Site File depending on whether it is a study-level or site-level file note.

4.3 File Note Log

a. A File Note Log should be maintained at both the study and site-level and filed as appropriate in the Sponsor or Site File respectively.

b. This is important to keep a track of all file notes for the study.

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 Trial 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 (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	N/A	N/A	N/A	N/A	N/A	N/A	N/A
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