Royal Papworth Hospital
NHS Foundation Trust

Document Title: File Notes

Document Number: PTUC SOP041

Staff involved in development: *Job titles only*	RM&G Manager, R&D Administration Manager, Research Officers
Document author/owner:	R&D Administration Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
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Key Points of this Document

- This document sets out the procedures to be followed by all 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 Clinical Trials at the Papworth R&D and Clinical Trials Unit (the 'Unit').

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust including: staff that are 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 and those seconded to and providing consultancy to the Trust, and to students undertaking training at the Trust.

b. Staff involved with the production of site files for research studies at 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 when there are discrepancies or deviations from the protocol, if further clarification is required, or to explain missing information or documentation. File notes are also used to explain errors or alterations made to data, which is not already clearly documented and explained on the Case Report Forms or protocol deviation log.

4.2 Production of a file notes

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

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

c. 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. The file note should be signed and dated by the author.

d. For studies with an electronic TMF (eTMF), the electronic copy (scan) of the file note should be filed to the File Notes sub-folder, depending on whether it is a study-level or site-level file note. For the electronic Sponsor File (see FRM021), this is Section 1.1 and for the electronic Site File (see FRM068), this is Section 1.2.

e. 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. The electronic copy (scan) of the file note should be filed to the File Notes sub-folder of the electronic TMF (eTMF). For the electronic Sponsor File (see FRM021), this is Section 1.1 and for the electronic Site File (see FRM068), this is Section 1.2.

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)*	November 2017
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. Research Governance Framework for Health and Social Care (2005)
Key related documents:	Trust Research Policy Sponsor File SOP013 Investigator File SOP010 TPL007 File Note Template

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

Review date:	November 2020

Version Control

Version	Date effective	Valid to	Approved by	Date of approval
1.0		July 2011	RDD	04.09.2009
2.0	28th Dec 2012	Dec 2015	RDD	14.12.2012
3.0	17th Mar 2015	Feb 2018	RDD	13.03.2015
3.1	19th May 2015	Feb 2018	Minor Amendment Appendix 1 removed and saved as TPL007	
4.0				

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

....10th January 2018

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

SOP release date: 15th January 2018