

Document Title: File Notes

Document Number: 024

Version:	2
Ratified by:	R&D Committee
Date ratified:	30/11/20107
Name of originator/author:	Lucy Parker
Directorate:	Corporate Services
Department:	Research and Development
Name of responsible individual:	Rachel Fay, R&D Manager
Date issued:	04/12/2017
Review date:	04/12/2020
Target audience:	All research staff
Intranet:	NA
Key related documents:	SOP006 Roles and Responsibilities for the Conduct of Research Studies SOP019 Investigator Site File SOP021 Delegation Log SOP054 Preparation and Maintenance of the TMF RFLRDDOC0002 File Note Template RFLRDDOC004 Staff Delegation of Duties Log
This document supports: <i>Standards and legislation</i>	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care (2017)
Date equality analysis completed.	30/11/2017
<u>This is a controlled document</u>	
Whilst this document may be printed, the electronic version maintained on the RF website is the controlled copy. Any printed copies of this document are not controlled.	

SOP 24: File Notes:

V2 04 OCT 2017

Uncontrolled document when printed or downloaded. Current SOP versions available <https://www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/>

Version Control

Version	Date	Author	Status	Comment
1.1	24_FEB-2017	Rachel Fay	Final	Non-substantial amendment to correct to date issued, date of review, named responsible person, update to SOP template V2.0
1.2	03 OCT 2017	Lucy Parker	Final	SOP Review Date Time Extension
2.0	04 OCT 2017	Lucy Parker	Final	New template. Removal of file note template as now referenced as a standard doc. Additional of staff delegation log into key related documentation. Addition of conducting a root cause analysis where possible. Removal of SOP030 from key related documents. Update from Research Governance Framework for Health and Social care (2005) to UK Policy Framework for Health and Social Care (2017)

SOP 24: File Notes:

V2 04 OCT 2017

Uncontrolled document when printed or downloaded. Current SOP versions available <https://www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/>

Contents

Section		Page
1	Introduction	4
2	Objective	4
3	Definitions	4
4	Scope	5
5	Equality statement	5
6	Duties	5
7	Details of procedure	6
8	Policy	7
9	Risk management/liability/monitoring & audit	7
10	Forms/templates to be used	7
11	Flowcharts	7
Appendices		
Appendix (1)	SOP reading log	8
Appendix (2)	Equality analysis guide and tool	9

SOP 24: File Notes:

V2 04 OCT 2017

Uncontrolled document when printed or downloaded. Current SOP versions available
<https://www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/>

1. INTRODUCTION

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

It aims to provide clear guidance on how research staff should produce, authorise and track study related Site Files in clinical trials to ensure compliance with the Trust's research governance standards.

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 themselves. Where any aspect of the study requires further explanation a file note may be produced.

2. OBJECTIVE

This document defines the Trust's research procedures for the production of study related file notes at the Royal Free London NHS Foundation Trust.

3. DEFINITIONS

RF - Royal Free London Hospital NHS Foundation Trust

RM&G - Research Management & Governance

R&D - Research & Development

Clinical Trial of Investigational Medicinal Product (CTIMP) - Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal products(s) and/or Study absorption, distribution, metabolism and excretion of one or more investigational product(s) with the object of ascertaining its (their) safety and/or efficacy.

Sponsor - Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities in this research governance framework that are relevant to the study.

CI - Chief Investigator (CI) is the authorised health care professional who takes primary responsibility for the conduct of the trial. There is only one Chief Investigator per Member State.

PI - Principal Investigator (PI) is the person who takes responsibility for the initiation and conduct of the study at site. There is one Principal Investigator at each site participating in a research study. For a single site study the Chief investigator may also take on the role of Principal investigator

SOP 24: File Notes:

V2 04 OCT 2017

Uncontrolled document when printed or downloaded. Current SOP versions available <https://www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/>

GCP - Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

TMF - The Trial Master File (TMF) contains all essential documents held by the sponsor/Chief Investigator which individually and collectively permits the evaluation of the conduct of a trial and the quality of the data produced.

4. SCOPE

This SOP 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, those working at the trust under honorary contract or under the remit of a valid research passport, those seconded to and providing consultancy to the Trust, and to students undertaking training at the Trust.

5. EQUALITY STATEMENT

The Royal Free London NHS Foundation Trust is committed to creating a positive culture of respect for all individuals, including job applicants, employees, patients, their families and carers as well as community partners. The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability (including HIV status), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. It is also intended to use the Human Rights Act 1998 to treat fairly and value equality of opportunity regardless of socio-economic status, domestic circumstances, employment status, political affiliation or trade union membership, and to promote positive practice and value the diversity of all individuals and communities.

This document forms part of the trust's commitment. You are responsible for ensuring that the trust's policies, procedures and obligation in respect of promoting equality and diversity are adhered to in relation to both staff and service delivery.

The equality analysis for this SOP is attached at Appendix (2).

6. DUTIES

The Trust is committed to the delivery of world class care and expertise to both staff and patients, and our values of positively welcoming, actively respectful, visibly reassuring and clearly communicating are fundamental to the delivery of this. This policy has been developed with our values in mind, and is intended to be implemented within the spirit of these values.

Staff involved with the production of site files for research studies at RF must comply with the requirements set out in section 7.

During set-up of a study, the Principal Investigator may delegate the responsibility for drafting file notes to a member of the study team. This should be documented in the staff delegation log (For RF Sponsored studies – read SOP021 Delegation Log and use template RFLRDDOC004 Staff Delegation of Duties Log). The Principal

Investigator must sign and date those file notes concerning medical care of trial subjects and those that affect the integrity of the study data and conduct.

7. DETAILS OF THE PROCEDURE

Person Responsible	Task
CI	<p>7.1. Production of a file note for RFL sponsored studies</p> <p>This procedure documents how file notes should be produced for RFL sponsored research studies. An example file note template (RFLRDDOC0002) can be downloaded from the RF R&D's SOP webpage. www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops</p> <p>Reference should be made to any relevant document version numbers and dates, study groups and subject study numbers.</p> <p>Where possible, a root cause analysis should be undertaken.</p> <p>A description of the actions taken should be provided in a logical order, stating who took the action and when (if possible).</p> <p>Any outcome or impact of the deviation on the study should be investigated and detailed.</p> <p>Remedial, corrective or follow-up actions should be detailed where appropriate.</p> <p>The original file note should be signed and dated by the author and filed in the relevant section of the Site File and Sponsor File. (See also SOP006 Roles and Responsibilities for the Conduct of Research Studies, SOP019 Investigator Site File and SOP054 Preparation and Maintenance of the TMF)</p> <p>It must also be signed and dated by the Principal Investigator for those file notes concerning medical care of trial subjects and those that affect the integrity of the study data and conduct.</p>
PI	<p>7.2. Production of a file note for non-RFL sponsored studies</p> <p>File notes for externally-sponsored studies should be produced according to the study Protocol and using the Sponsor's template.</p> <p>The original file note should be signed by the author and filed in the relevant section of the Site File.</p>

SOP 24: File Notes:

V2 04 OCT 2017

Uncontrolled document when printed or downloaded. Current SOP versions available <https://www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/>

8. POLICY

This SOP is mandatory and non-compliance with it may result in disciplinary procedures.

9. RISK MANAGEMENT/ LIABILITY/MONITORING & AUDIT

- The SOP Working Group will ensure that this SOP and any future changes to this document are adequately disseminated.
- The R&D Office 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).
- In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the RM&G Manager/Deputy R&D Director 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 R&D Office is responsible for the ratification of this procedure.

10. FORMS/TEMPLATES TO BE USED

RFLRDOC0002 File Note Template

11. FLOWCHART

None applicable

Equality Analysis Checklist

Go through each protected characteristic below and consider whether the policy, practice, function, business case, project or service change could have any impact on groups from the identified protected characteristic, involve service users where possible and get their opinion, use demographic / census data (available from public health and other sources), surveys (past or maybe carry one out), talk to staff in PALS and Complaints and Patient Experience.

Please ensure any remedial actions are Specific, Measureable, Achievable, Realistic, and Timely (SMART).

Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
Age	None identified	R&D administrative document	N/A	N/A	This SOP on the preparation and maintenance of the TMF introduces a requirement to include the Trust Equality Statement in all SOPs that describe the standard activities used in Research Studies and Clinical Trials at the Royal Free London Hospital NHS
Disability	None identified	R&D administrative document	N/A	N/A	
Gender Reassignment	None identified	R&D administrative document	N/A	N/A	
Marriage and Civil Partnership	None identified	R&D administrative document	N/A	N/A	
Pregnancy and maternity	None identified	R&D administrative document	N/A	N/A	
		R&D	N/A	N/A	

SOP 24: File Notes:

V2 04 OCT 2017

Uncontrolled document when printed or downloaded. Current SOP versions available <https://www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/>

Equality Group	Identify negative impacts	What evidence, engagement or audit has been used?	How will you address the issues identified?	Identifies who will lead the work for the changes required and when?	Please list positive impacts and existing support structures
Race	None identified	administrative document			Foundation Trust. It also introduces a new Equality Analysis Template for the SOPs, that requires the presence of the Equality statement. These actions are designed to embed the equality agenda and promote equality compliance within the Trust.
Religion or Belief	None identified	R&D administrative document	N/A	N/A	
Sex	None identified	R&D administrative document	N/A	N/A	
Sexual Orientation	None identified	R&D administrative document	N/A	N/A	
Carers	None identified	R&D administrative document	N/A	N/A	

SOP 24: File Notes:

V2 04 OCT 2017

Uncontrolled document when printed or downloaded. Current SOP versions available <https://www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/>

SOP 24: File Notes

It is important to record the names of everyone who has contributed to the policy, practice, function, business case, project or service change.

Equality Analysis completed by: (please include every person who has read or commented and approval committee(s). Add more lines if necessary)	Organisation	Date
SOP Working Group	Royal Free London NHS Foundation Trust	20/10/2017
R&D Committee	Royal Free London NHS Foundation Trust	30/11/2017

SOP 24: File Notes:

V2 04 OCT 2017

Uncontrolled document when printed or downloaded. Current SOP versions available <https://www.royalfree.nhs.uk/research/for-investigators/standard-operating-procedures-sops/>