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Name of originator/author:	Lucy Parker
Directorate:	Corporate Services
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Name of responsible individual:	Rachel Fay, R&D Manager
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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)
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<u>This is a controlled document</u>	
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Version Control

Version	Date	Author	Status	Comment
1	01/10/2014	Heidi Saunders	Final	New Document
1.1	03 OCT 2017	Lucy Parker	Final	SOP Review Date Time Extension
2	04 OCT 2017	Lucy Parker	Final	<p>New SOP Template Addition of references to standard documents. Update from Research Governance Framework for Health and Social care (2005) to UK Policy Framework for Health and Social Care (2017)</p> <p>Included the requirement for PI and site personnel to version control documents that have been produced to assist them in the conduct of the trial i.e. source data worksheets.</p>

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1. INTRODUCTION

This document sets out the procedures to be followed by all Royal Free London staff who are involved in the preparation of study documents for RF sponsored research studies.

It aims to provide clear guidance on the correct use of version numbers in the production and finalisation of study documentation, so as to ensure compliance with the Trust's Information Governance Policies, the Data Protection Act (2000), and the Research Governance Framework (2005).

2. OBJECTIVE

This document defines the Trust's procedures for the writing and preparation of study documents for use in Research Studies at Royal Free London NHS Foundation Trust.

The document aims to provide clear guidance on how to produce correctly version controlled documentation and how these should be reviewed and updated.

Version control is the process by which different drafts and versions of a document are dated and managed. It provides an audit trail for the drafting and updating of a finalised version of a document. Version control must be used when more than one version of a document exists, or when this is likely to be the case in the future.

3. DEFINITIONS

RF - Royal Free London Hospital NHS Foundation Trust

RM&G - Research Management & Governance

R&D - Research & Development

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

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 clarifies the requirements for accurate version control of study documents produced for RF sponsored research studies as to comply with the requirements stated in section 6 of the Good Clinical Practice guidelines (GCP).

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 preparing RF Sponsored study documents must comply with the requirements set out in section 7. Staff preparing study documents for externally Sponsored studies should follow the Sponsors SOP on version control.

7. DETAILS OF THE PROCEDURE

Person Responsible	Task
CI	<p>During initial drafting each successive draft of a document must be numbered sequentially from 0.1, 0.2, 0.3... Once a finalised version is complete this should be titled Version 1.0.</p> <p>The version number and date should be added to the end of the file name and within the document, i.e. on the title page and also in the header or footer of each page.</p>

	<p>Procedures should be in place to ensure that in addition to the completed version, each draft version of the document is saved and clearly identified by its file name.</p> <p>If version 1.0 is revised, drafts should be numbered as 1.1, 1.2... until version is completed. The finalised version should then be numbered 2 etc.</p> <p>A copy of each finalised version of a document should be included in the Trial Master File and the Investigator Site Files. (SOP054 and SOP019 respectively)</p> <p>The CI must ensure that only up-to-date versions of documents are used – for example where documents are pre-printed, processes must be in place to update the documents as per the current version.</p>
CI	<p>The Chief Investigator (CI) is responsible for the version control of the documents. (SOP006 Roles and Responsibilities for the Conduct of Research Studies)</p> <p>They must notify the research team of any changes to version controlled documentation and ensure appropriate training is given, if required, following the new version.</p> <p>The CI must ensure that if they delegate the role of version control to another member of the research team, that they have sufficient knowledge and expertise. (SOP021 Delegation Log and RFLRDLOG0004 Staff Delegation of Duties Log)</p>
CI	<p>All previous versions should be marked clearly as superseded.</p>
PI and research delivery teams.	<p>Any documents that are created by the RFL site personnel i.e. research delivery teams, to assist them in the conduct of the trial, for the example a source document worksheet must also be version controlled, including the reference of the protocol to ensure the correct document is used and reduce the risk of protocol non-compliance</p>
R&D Office	<p>The R&D team should also read and follow RFLRDWPD0005 Document control for important R&D Office Documentation</p>

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 R&D 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

NA

11.0 FLOWCHART

None applicable

**APPENDIX 1
SOP Reading Log**

READ BY			
NAME	TITLE	SIGNATURE	DATE

APPENDIX 2

Royal Free London NHS Foundation Trust Equality Analysis guide and Tool

An equality analysis is a review of a policy, practice, function, business case, project or service change which establishes whether there is a negative effect or impact on particular social groups. This In turn enables the organisation to demonstrate it does not discriminate and, where possible, it promotes equality to meet the needs of the diverse patients and communities we serve.

This check list is a way to help you think carefully about the likely impact on equality groups and take action to improve services. This is also an opportunity to evidence positive practices in our services and demonstrate strategic integrity to ensure that our services and employment practices are fair, accessible and appropriate for all patients, visitors and carers, as well as our talented and diverse workforce.

Name of the policy / function / service development being assessed	Version Control of Study Documents
Briefly describe its aims and objectives:	This document defines the Trust’s procedures for the writing and preparation of study documents for use in Research Studies at Royal Free London NHS Foundation Trust.
Directorate and Lead:	Medical Directorate
Evidence sources: DH, legislation. JSNA, audits, patient and staff feedback	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care (2017)
Is the Trust Equality Statement present?	Yes X if no do not proceed with Equality Analysis (EA)

If you are conducting an EA on a procedural document please identify evidence sources and references, who has been involved in the development of the document, process or strategy, and identify positive or negative impacts. It is the discussion regarding the equality impact of the document that is important.

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 includes the Trust Equality Statement, as well as the results from the Equality Assessment for this SOP. These actions are designed to embed the equality agenda and promote equality compliance within the Trust.
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	
Race	None identified	R&D administrative document	N/A	N/A	
Religion or Belief	None identified	R&D administrative	N/A	N/A	

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
		document			
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	

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