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Version Control

Version	Date	Author	Status	Comment
1	01/07/2014	Heidi Saunders	Final	Original document
1.1	03/10/2017	Lucy Parker	Final	SOP Review Date Time Extension
2	04/10/2017	Lucy Parker	Final	New SOP Template used. Removal of formal letter to be sent to other sites (emails are sufficient). Addition of references to R&D Office standard templates. Change from reference to Research Governance Framework for Health and Social care (2005). to UK Policy Framework for Health and Social Care (2017)
2.1	19 Oct 2018	Neil Hubbard	Final	Update from ReDA to EDGE Database. Removal or references to SOP Working group and replacing with QMS Working Group. Deletion of Reading log.
2.2	27 JAN 2020	Lucy Parker	Final	Update to new SOP template 3.1 (Updated table of contents and revision to section 9 to incorporate reference to the agreed R&D Audit programme.) Addition of HTA as a reference regulation. Addition of sample management for multi-site studies if a study terminates early. Updates post review by Gloria Okojie, Head of Quality & Licensing – Human Tissue & Organ for RFL. Correction of Typos and formatting.

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1. INTRODUCTION

This document sets out the procedures to be followed by all Royal Free London Hospital NHS Foundation Trust staff who are involved in the close-down, termination, suspension or final reporting of RFL Sponsored or hosted research studies.

2. OBJECTIVE

This SOP aims to provide clear guidance on how trial related documentation is managed during close-out so as to ensure compliance with the Data Protection Act (1998) and the UK Policy Framework for Health and Social Care (2017).

3. DEFINITIONS

GCP – Good Clinical Practice 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.

REC – Research Ethics Committee

EDGE - Research management system

RFL - Royal Free London Hospital NHS Foundation Trust

R&D - Research & Development

RM&G - Research Management & Governance

RPM- Research Portfolio Manager

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.

SAE – Serious Adverse Event (SAE) is any adverse event that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.

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.

ISF - The Investigator Site File (ISF) contains all essential documents held by Principal Investigator(s) conducting a trial which individually and collectively permit 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.

Staff involved in running or managing clinical trials must comply with the requirements set out in section 7.

This document defines the Trust's procedures that occur when a research trial is concluded or terminated at an individual site or study wide. This includes the roles and responsibilities of research staff, the actions to be taken and who to inform.

This SOP clarifies the responsibilities and actions of the Investigator and Sponsor in the event of premature termination or suspension of a trial as described in Good Clinical Practice (GCP). Investigators must be aware of their roles and responsibilities as they pertain to the study. These are described in SOP006 Roles and Responsibilities.

The archiving of study data is outside the scope of this SOP and is described in SOP044: Archiving SOP.

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.

7. PROCEDURE

Person Responsible	Task
CI or delegated team member	<p>7.1 Planned trial closure of RFL Sponsored studies</p> <p>The CI or their designee is responsible for informing RFL R&D office as Sponsor Representative within 90 days of the end of the study, that the trial is closed, by using the appropriate Declaration of the End of a Study Form (RFLRDDOC0009).</p> <p>The definition of the end of the study is stated in the protocol.</p> <p>The CI or their designee should inform the Research Ethics Committee, which approved the research that the study has closed by using the Declaration of the End of a Study Form (RFLRDDOC0009) within 90 days of the end of the study.</p> <p>The CI or their designee should submit the End of Study report (there is no defined format for this report, but the R&D Office template RFLRDDOC0005 can be used) to the REC within 12 months of the end of the study.</p> <p>The CI or their designee should then follow the SOP on Archiving (SOP44).</p>
CI or delegated team member	<p>7.2 Closure of RFL Sponsored multi-centre studies</p> <p>The CI, or their designee, is responsible for informing RFL R&D office as Sponsor Representative within 90 days of the end of the study, that the trial is closed, by using the appropriate Declaration of the End of a Study Form (RFLRDDOC0009).</p> <p>The CI, or their designee, is responsible for informing the PIs at other sites, in writing (email is sufficient), that the trial has closed.</p> <p>A study visit may be necessary to verify or complete the closure process at a participating site and will be conducted by either the CI, or their designee. A site can be deemed to be closed once the following are reconciled or complete:</p> <ul style="list-style-type: none"> • Investigator/institution and Sponsor files are reviewed and all essential documentation for a particular site are present in the relevant files to ensure a clear audit trail of study conduct at the site. • All site data are collected, entered, validated and all data queries resolved where feasible.

	<ul style="list-style-type: none"> • All issues from previous study monitoring procedures are resolved or documented. • All financial matters are resolved and all site payments are complete as agreed and documented in study contracts/agreements/approvals. Finance to be notified that all financial matters are resolved and that the study site has closed. • All unused trial supplies are returned or destroyed according to study and/or Sponsor requirements. • Investigator(s) are aware of and have implemented relevant ongoing requirements such as site archiving, subsequent audit/inspection procedures and any ongoing reporting requirements. <p>Details of site closure visits must be documented, normally in the form of a written report. The report should be saved in the Trial Master File (TMF).</p> <p>If a site closure visit is deemed not necessary, a confirmation letter can be sent to document that all activities related to study close out are complete, copies of essential documents are held appropriately and a site visit was not required. This must be saved in the TMF.</p>
PI or delegated team member	<p>7.3 Planned closure of RFL hosted studies</p> <p>Upon closure of the trial, all study documentation is retained by the PI until such time as all data queries are resolved and the trial Sponsor's database is closed. At this time all trial documentation is archived according to the study protocol.</p> <p>The PI is responsibility for informing the RFL R&D office of the study closure to ensure that the central R&D records can be up-dated and, where appropriate, any study-related payments are reconciled.</p>
CI or delegated team member	<p>7.4 Early termination or temporary suspension of a RFL Sponsored trial</p> <p>The CI should notify the main REC within 15 days of the closure by using the Declaration of the End of a Study Form (RFLRDDOC0009).</p> <p>The following information is required:</p> <ul style="list-style-type: none"> • Justification of the premature ending of the trial • Number of participants still receiving treatment • Proposed management of participants still receiving treatment

	<p>All investigators must be informed of the trial termination/suspension using expedited means of communication and receipt of notification acknowledged. The reasons for early termination (or temporary suspension) must be made clear.</p> <p>Participants should be contacted to tell them of the termination or suspension of the study and to inform them of the actions they need to take. A follow-up appointment should be made for patients so that their condition can be reviewed and any concerns addressed.</p> <p>For multi-site studies that have been terminated early, the CI must ensure appropriate sample management if the study involved the use of samples. This would ensure seeking written confirmation from all sites (including RFL if a site) that the samples have either been disposed of, or are covered by an appropriate HRA Licence.</p> <p>Documentation and all records should be archived according to SOP044: Archiving SOP</p>
CI or delegated team member	<p>7.5 End of Trial Reporting</p> <p>It is the responsibility of the CI to ensure the results of the study are analysed and reported within a reasonable timeframe.</p> <p>A summary of the final report on the research should be sent to the main REC and R&D Office within 12 months of the end of the project. There is no defined format for this report, but the R&D Office template RFLRDDOC0005 can be used.</p> <p>The CI should make all necessary efforts to get the results reported in a peer reviewed journal</p>
R&D office assigned RPM	<p>Receipt of End of Study Form</p> <p>Save the form within the study file on EDGE and update the study status as “completed”.</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 and as part of the agreed R&D Audit programme. 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

End of Study Report Template RFLRDDOC0005

Declaration of the End of a Study Form RFLRDDOC0009

11. FLOWCHART

Not 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 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	

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	R&D administrative document	N/A	N/A	
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	

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	27/09/2017
R&D Committee	Royal Free London NHS Foundation Trust	26/10/2017