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SOP 044: Standard Operating Procedure for Archiving

Version v2.3 13 NOV 2019

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Version Control

Version	Date	Author	Status	Comment
JBRU/RF H/INV/SO P-2 Version 1	25/08/2011	Daniel Heather	Superseded	Reasons for amendments: <ul style="list-style-type: none"> • Significant change in archiving strategy for RFL • Change in SOP layout/harmonization with RMGRSS SOP series
JRO RMG RSS SOP-13- Royal Free Version 2.0	31/08/2012	Daniel Heather	Superseded	Reasons for amendments: <ul style="list-style-type: none"> • Separation of study closeout and archiving in to two separate SOPs • Change in SOP layout
SOP 044 v1	02/03/2015	Heidi Saunders	Superseded	<ul style="list-style-type: none"> • Localised RFL policy.
SOP 044 v1.1	01/08/2015	Liba Stones	Ratified	<ul style="list-style-type: none"> • Minor administrative changes as a result of audit.
1.2	03/10/2017	Lucy Parker	Final	SOP Review Date Time Extension
2	04/10/2017	Lucy Parker	Final	<p>New Template Named Research Archivist added.</p> <p>Appendix 1 removed and created as a standard document.</p> <p>Addition of information on how to request retrieval.</p> <p>Change from reference to Research Governance Framework for Health and Social care (2005). to UK Policy Framework for Health and Social Care (2017)</p>
2.1	18/10/2018	Lucia Possas	Draft	<ul style="list-style-type: none"> • Change form Data Protection Act (1998) to Data Protection Act (2018). • Introduction of the new R&D policy stating that all new studies are to be archived internally and related issues. • Archiving of Roche and

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				<p>Novartis studies.</p> <ul style="list-style-type: none"> • Electronic media. • For RFL sponsored studies, a copy of the final research report sent to REC to become mandatory in the TMF. • Study teams to ensure that all applicable support department documents supporting the study at RFL to be included in the archiving (i.e. pharmacy, laboratory, RFL-UCL biobank, etc). • Information on PIC archiving.
2.2	06/04/2019	Lucia Possas	Draft	<ul style="list-style-type: none"> • Clarification re. e-archiving and third party archiving
2.3	13/11/2019	Lucia Possas	Final	<ul style="list-style-type: none"> • New guidance re. e-archiving and third party archiving

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1. INTRODUCTION

The European Clinical Trials Directive (EUCTD) 2001/20/EC was transposed into UK Regulations by the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) on the 1st of May 2004. UK regulations will be the term used to cover the UK legislation and the EUCTD in this document. The UK regulations set out the standard for archiving clinical trials essential documentation from Clinical Trials of Investigation Products (CTIMPS). Archiving requires systematic storing of a large volume of trial related documentation at a safe and protected repository that meets professional archiving standards and adheres to the Data Protection Act (2018). 'Iron Mountain' is the current Royal Free London Hospital NHS Foundation Trust approved repository.

2. OBJECTIVE

This SOP describes the procedures to be followed by all RFL staff in preparation of research study records being sent for archiving at the Royal Free London NHS Foundation Trust.

It aims to provide clear guidance on the archiving and recalling of all essential documents related to research studies carried out at RFL.

3. SCOPE

This SOP describes the procedure for archiving research study documentation produced as a result of clinical research undertaken at the Royal Free London NHS Foundation Trust. It is applicable to both CTIMPs (Clinical Trials of Investigative Medicinal products) and non-CTIMPs (e.g. research administering questionnaires, research limited to working with tissue samples, imaging studies etc.).

This SOP does not apply to the archiving of the main patient health record and other records designated as source documents. These should be managed via The Royal Free London's centralised Health Records System. More details are available via the Trust's intranet site (see the section on Medical Records)

This SOP does not cover specifics with regards to requests and contact made with Iron Mountain. A working practice document (RFLRDWPD0003 Archiving) is used in the R&D Office by the Named Research Archivist or authorised R&D delegate

4. DEFINITIONS

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.

Clinical Trial of Investigational Medicinal Product (CTIMP) - Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic 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.

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Essential documents - are those documents, which enable both the conduct of the clinical trial and the quality of the data produced to be evaluated; and show whether the trial is, or has been, conducted in accordance with the applicable regulatory requirements.

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.

Named Research Archivist – Rachel Fay, the Research and Development Manager is the named Research Archivist for Royal Free London Hospital NHS Trust

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.

RFL - Royal Free London Hospital NHS Foundation Trust

R&D - Research & Development

RM&G - Research Management & Governance

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.

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.

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 the archiving of research must comply with the requirements set out in section 7.

The Sponsor of a research study is responsible for arranging the archiving of the study related material. The actual procedure may be delegated to a responsible member of the site's research team.

Studies that opened since 2017: The R&D policy is that all new studies should be archived via the trust's vendor: Iron Mountain. Details should be included in the site contracts.

Studies the opened prior to this policy may have contracted for the sponsor to archive i.e. Novartis and Roche. The trust's archivist will review on a study-by-study and will liaise with the sponsor to ensure PI oversight of the archived records and a process to retrieve the records.

Studies that opened prior to this policy may have a contract for the archiving being done by the sponsor. In these circumstances R&D will review on a study-by-study basis and liaise with the sponsor to ensure PI oversight of the archived records (i.e. tracker of the archived records on the R&D database so that they can be retrieved).

7. DETAILS OF THE PROCEDURE

Person Responsible	Task
PI if hosted study, CI if sponsored study	<p>7.1 Archiving Considerations</p> <p>Arrangements for archiving should be agreed during the contract negotiations prior to the commencement of the study. These will include costs, responsibilities, duration and where study documents will be archived.</p> <p>All essential documents must be archived.</p> <p>Archiving arrangements should enable the prompt retrieval of records if required for any audit or inspections that may subsequently take place.</p> <p>In cases where it is agreed that the sponsor be responsible for the archiving R&D will ensure that the sponsor's archive</p>

	<p>meets the following requirements:</p> <ul style="list-style-type: none"> • Named archiving vendor and their location must be known to the R&D archivist • R&D archivist must be informed if vendor move our files /boxes to a different location. • R&D archivist must have the right to audit the archive (and would be added to our audit program) • Sponsor should not have access to the boxes • Any eCRFs or other electronic files must be stored in a “memory stick”. Any CDs must be transferred into a trust encrypted memory stick for the purposes of archiving • Only site’s named archivist will have permission to withdraw boxes (not PI or nurse) to ensure RFL oversight systems and integrity is maintained. • There is guarantee of direct withdrawal between site and archive vendor (should there be payment /contractual issues between sponsor and vendor) • Site’s nominated archivist must have transfer process records (not PI or nurse). This process would need to be supplied to site in writing. • Sponsor should provide evidence they have tested their archive retrieval process – that only named site personnel can authorise boxes release (never the sponsor) • If the sponsor changes vendor, the RFL must see and agree the vendor selection process. Same conditions above must apply. <p>PIs and research delivery staff should not release any documents to the sponsor for archiving until the R&D Manager or delegate has confirmed the archiving meets the standards above.</p>
<p>CI of RFL sponsored studies</p>	<p>Final Research Report of RFL sponsored studies</p> <p>The study will not be archived until RFL R&D receives a copy of the final research report. The CI should send a summary of the final research report to the REC within 12 months of the end of the study. The report needs to be in the trial master file that is archived.</p> <p>https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/</p>
<p>PI if hosted study, CI if sponsored study</p>	<p>7.2 Archiving Procedure</p> <p>The PI or their nominated delegate should contact</p>

	<p>rf.randd@nhs.net to request appropriate archiving boxes.</p> <p>Records packed in boxes not supplied by R&D will not be transferred offsite.</p> <p>The PI or delegated member of their study team should follow the instructions given on the Research Records Transfer Form (RFLRDDOC0023).</p> <ul style="list-style-type: none"> • There should be only one study per box. Do not mix different research studies in the same archive box. • The boxes will be numbered and indicate the total quantity of boxes for that study (e.g. 1 of 7) clearly on the outer label of each box. • Any lever arch files and any plastic wallets should be removed. It is preferred if lever arch files are dismantled wherever possible to save space. • Ensure that all documents are secure and not loose. If required, use document ties to ensure documentation is kept together. • Remove any metal fastenings wherever possible e.g. staples, paperclips • The boxes must not be overfilled past the fill line. They must be able to withstand manual handling and moving. • Each box must be entered on the research records archive transfer form (RFLRDDOC0023), so that the content of each box can be retrieved for the entire study. <p>Ensure that all support departments documents that relate to the study at RFL are included in the archiving. R&D will coordinate with pharmacy the collection and tracking of their pharmacy records. The CI/PI is responsible for ensuring all other support department or service records e.g. Laboratory records) are archived along with the site file.</p> <p>It is advisable to use a site file checklist (RFLRDDOC0003 ISF non CTIMP Index V1 19 OCT 2017/ RFLRDDOC0013 TMF Index V1 25 OCT 2017), or study close down document provided by the sponsor to ensure all documents are included.</p>
<p>PI and R&D archivist or delegate</p>	<p>Studies that opened prior to 2017 whose contract states the sponsor will archive with a third-party vendor.</p> <p>R&D will check with each sponsor to make sure that their</p>

	<p>archive vendor meets the minimum requirement to be GCP compliant (See WPD00028 Archiving). The CRA or sponsor may visit the PI/study team and perform close out visit (COV) and ask for the archive form to be signed. This needs to be signed by R&D manager or delegate (R&D Coordinator). R&D will check there is a process and contract agreed with the sponsor for them to archive. Currently R&D have a process with Roche and Novartis to archive with their vendor: RESTORE.</p> <p><u>The R&D coordinator must have copies of the transmittal forms and track the archive process on the EDGE database so that boxes can be retrieved</u></p>
<p>CI of RFL sponsored or PI if hosted</p>	<p>Studies that stored samples or used the UCL-RFL biobank</p> <p>Contact janet.north@ucl.ac.uk and arrange collection of biobank paperwork for archive. Follow the same procedure but include the UCL-RFL biobank documents, including evidence of sample chain of custody forms in the PI's site file. If there is not enough room the biobank files should have their own archive box and be labelled as such on the transmittal sheet. Where necessary, R&D will coordinate the uplift of the boxes directly from UCL biobank</p> <p>Once the boxes have been prepared, the completed transfer form (RFLRDDOC0023) and transmittal sheets must be sent as an attachment to rf.randd@nhs.net</p>
<p>CI of RFL sponsored studies</p>	<p>If the CI has used any third-party vendors e.g. clinical trial units (CTUs), external university labs, their records need to be included in the archive. Boxes should be prepared as above.</p> <p>Once the boxes have been prepared, the completed transfer form (RFLRDDOC0023) and transmittal sheets must be sent as an attachment to rf.randd@nhs.net who arrange collection and uplift.</p>
<p>Pharmacy and the PI if hosted</p>	<p>In instances where a pharmacy file has been generated (e.g. a CTIMP), the PI or a delegate should also inform Pharmacy when a trial is to be archived so that Pharmacy can collate all relevant trial associated documents (dispensing logs, destruction logs etc.).</p> <p>R&D will then coordinate to arrange collection and uplift from pharmacy.</p> <p>RL Studies involving the Centre for Cell, Gene and Tissue Therapeutics (CCGTT)</p> <p>Trials running through the CCGTT have their own archiving</p>

	<p>process that is separate from R&D via the Gene Therapy manufacturing process. Please contact: Owen.bain@nhs.net. A file note should be put in the PI's site files before archiving as an audit trail of where the CCGTC documents are retained.</p>
<p>R&D Office Named Research Archivist or Nominated Delegated Staff Member</p>	<p>Once the boxes are ready to be despatched.</p> <p>Once the boxes are prepared – the investigator should contact the R&D Office to arrange a check of the boxes: rf.randd@nhs.net</p> <p>Prior to collection of the boxes, the Named Research Archivist: lucy.parker2@nhs.net from R&D or their nominated staff member will visit the department to quality check a sample of the boxes and affix barcode references to both the boxes and the transmittal sheets (so the boxes can be tracked).</p> <p>The pharmacy site file for CTIMP trials may be archived separately.</p> <p>The Named Research Archivist, Lucy Parker or their nominated staff member will liaise with the study team member to arrange a collection date for the boxes. The archiving company will collect the boxes directly from the department. There is no need to bring the boxes to R&D</p> <p>Copies of all completed transmittal sheets and Research Records Transfer Form must be emailed to The Named Research Archivist or their nominated delegate, so that they can be stored on the R&D central database. The original archive transmittal sheets should be given with the boxes to the Iron Mountain/archive company representative at collection.</p> <p>Boxes will then be collected and stored with Iron Mountain.</p> <p>The status of the study will be updated to 'Archived' on the R&D database: EDGE once both Investigator Site File and the R&D file have been sent off to Iron Mountain.</p>
<p>Principal Investigator</p>	<p>Archiving of PIC</p> <p>Where the PIC agreement includes an archiving requirement the PIC documents must be archived.</p> <p>Otherwise the PIC files do not need to be archived if they meet the following criteria:</p> <ul style="list-style-type: none"> • R&D archivist or delegates has confirmed there is no

	<p>contract requirement to archive</p> <ul style="list-style-type: none"> • R&D archivist or delegate has confirmed they have retained the following documents on the R&D database <ul style="list-style-type: none"> ○ Contract ○ R&D approvals/confirmation of capacity ○ HRA/REC approval ○ TFC approval (if applicable) ○ The sponsor has confirmed that the documents can be destroyed by site. Email retained on the R&D database
<p>Sponsor Representative</p>	<p>7.3 Retention of Records</p> <p>It is the responsibility of the Sponsor to determine how long the investigator site should retain their records (with reference to the minimum retention periods promulgated in the statutory instrument and Directive 2003/63/EC). Currently, R&D archive ATMPs for 30-years minimum, 25-years for CTIMPs.</p> <p>The minimum applicable retention period should be stipulated in the site agreement or study protocol. If there are any queries about destruction of archived studies they should be referred in the first instance to the Named Research Archivist.</p> <p>Unless otherwise specified, RFL Sponsored studies' documentation <u>that involve adult participants</u> should be retained for a minimum of 5 years from the date of archive of the study.</p> <p>RFL Sponsored studies' documentation <u>that involve paediatric participants</u> should be retained until the participants reach the age of 21 years as a minimum, in line with the duration of the retention of their medical records. The age of the youngest eligible participant in the protocol should be used to calculate and duration of archiving. Where there is doubt the paediatric study should be archived for 21 years.</p>
<p>Named Archivist with study team.</p>	<p>7.4 Retrieval of Archived Records</p> <p>Requests for retrieval must come from the research team, R&D and or support departments and requests directly from the Sponsor will not be accepted. Requests must be made to the Named Research Archivist.</p> <p>Details of what is required to be pulled back from archive is</p>

	<p>required to allow the Named Archivist/delegate to determine exactly what box(es) are required for retrieval.</p> <p>Once the research team no longer needs the retrieved boxes, they should contact the Named Archivist to arrange for the box(es) to go back into archive and for the transmittal sheets and archive records to be updated as appropriate.</p> <p>Should it be the case that the contents of the retrieved box(es) are to be destroyed, communication with the Named Research Archivist needs to take place beforehand.</p>
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For more details on the execution of the various archiving tasks, please refer to the Archiving working practice document (RFLRDWPD0003 Archiving).

8. POLICY

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

9. RISK MANAGEMENT/ LIABILITY/MONITORING & AUDIT

- The QMS Group will ensure that this SOP and any future changes to this document are adequately disseminated.
- 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).
- 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 Research and Development Directorate is responsible for the ratification of this procedure.

10. FORMS/TEMPLATES TO BE USED

RFLRDDOC0023 Research Records Archive Transfer Form

11. FLOWCHART

None applicable for this SOP.

APPENDIX 1

SOP Reading Log

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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	SOP for Archiving
Briefly describe its aims and objectives:	This SOP describes the procedures to be followed by all RFL staff for preparation of research study records for archiving at The Royal Free London NHS Foundation Trust. It aims to provide clear guidance on the archiving and recalling of all essential documents related to research studies carried out at RFL.
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) The Freedom of Information Act (2000). Data Protection Act (2018).
Is the Trust Equality Statement present?	Yes No if no do not proceed with Equality Analysis (EA)

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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
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	

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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
					and promote equality compliance within the Trust
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 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, and project or service change.

Equality Analysis completed by: (please include every person who has read or commented and approval	Organisation	Date
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committee(s). Add more lines if necessary)		

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