Standard Operating Procedure for Archiving Essential Documentation relating to Clinical Trials of Investigational Medicinal Products (CTIMPs)

SOP ID Number: JRO/SPON/S21/06	**Effective Date:** 10/01/22
Version Number & Date of Authorisation: V06, 09/12/22	**Review Date:** 10/01/25
eDocument kept: S:\SLMS_RSC_ALL_STAFF\CLINICAL_TRIALS\SOPs\EFFECTIVE_SOPs_Guides\Sponsor SOPs\SPON_S21 SOP for archiving\SPON_S21_SOP_for_archiving V06.doc	

Revision Chronology:			
SOP ID Number:	**Effective Date:**	**Reason for Change:**	**Author:**
JBRU/SPON/S21/01	15/02/10		Dave Wilson
JRO/SPON/S21/02	01/04/12	Routine review Change in terminology, change of department name	Daniel Heather
JRO/SPON/S21/03	15/05/15	Change of the website link, update to archiving processes and reference numbers.	Stuart Braverman/ Kirsty Adams
JRO/SPON/S21/04	16/05/18	Update on Legislation and clarity on internal archiving process.	Nimrita Verma
JRO/SPON/S21/05	14/02/19	Further clarify Appendix 2	Nimrita Verma
JRO/SPON/S21/06	10/01/22	SOP updated to make clearer the processes for Sponsor File, TMF and ISF archiving.	Samim Patel

ACRONYMS:	
CI	Chief Investigator
GCP	Good Clinical Practice
ISF	Investigator Site File
JRO	Joint Research Office https://www.ucl.ac.uk/joint-research-office
MHRA	Medicines and Healthcare Products Regulatory Agency
PI	Principal Investigator
QA	Quality Assurance
REC	Research Ethics Committee
RM (ATMP)	Regulatory Manager (ATMP)
SOP	Standard Operating Procedure
SRA	Sponsor Regulatory Advisor
TMF	Trial Master File

Standard Operating Procedure for Archiving Essential Documentation relating to Clinical Trials of Investigational Medicinal Products (CTIMPs)

1. PURPOSE

This Standard Operating Procedure (SOP) has been written to describe the procedure for the archiving of essential documents relating to the management of clinical trials of investigational medicinal products (CTIMPs).

2. JOINT RESEARCH OFFICE (JRO) POLICY

All SOPs produced from the JRO must be used in conjunction with local NHS Trusts and UCL policies and procedures.

The JRO acts as the representative of the Sponsor and will be the official name used on all SOPs.

3. BACKGROUND

All SOPs are written in accordance with applicable GCP requirements as outlined in Directives 2001/20/EC and 2005/28/EC (in the UK, these Directives were transposed into UK law by SI 2004/1031, SI 2006/1928) and subsequent amendments. Where applicable it incorporates elements of ICH GCP tripartite guidelines (E6). In addition, for trials with EU and Northern Ireland sites the SOPs will have to be compliant with EU Clinical Trials Regulation No. 536/ 2014 if/when applicable.

4. SCOPE OF THIS SOP

This SOP covers the archiving of JRO Sponsor Files and the Trial Master Files and Investigator Site Files for CTIMPs sponsored by UCL and managed by the JRO.

5. RESPONSIBLE PERSONNEL

The JRO Data Team maintain oversight for the archiving of all documents relating to UCL Sponsored CTIMPs within the JRO. The physical listing and transfer of records will be delegated to the JRO Data Team where appropriate. The **named archivist for UCL is Mr Colin Penman (UCL Head of Records).**

6. PROCEDURE

6.1 Storage and archiving

To ensure that results from CTIMPs can be examined and subject to internal and regulatory audit, it is necessary that both the Sponsor and Chief Investigator keep records of the clinical trial throughout its life cycle (as per JRO/SPON/SOP11 and JRO/INV/SOP02).

Archived documents are stored in the UCL Library Services repository in Essex. A record of each box created and stored is available in the Reports section of the UCL Records Office System (under Departmental Box List).

6.2 Archiving of Sponsor File

The sponsor file is ready for archiving when the End of Trial Results have been reported and the 'Confirmation of Trial Close & Archiving' email has been issued to the Chief Investigator.

Section	Responsible Person	Activity
6.2.1	SRA/ RM (ATMP)	Perform a full review of the Sponsor File using the **Sponsor File Review Checklist** (JRO/SPON/SOP11). Any missing documents should be filed or file noted. When the checklist is completed, it must be reviewed & signed by the Clinical Trials Operations Manager. File the completed & signed checklist in the paper Sponsor File and on the S drive.
6.2.2	SRA/ RM (ATMP)	To order the archiving boxes, email UCL Records Office (records.office@ucl.ac.uk) stating the number of boxes required with your name and delivery address. The boxes will be sent to your address. Boxes not supplied by the UCL Records Office will NOT be accepted.
6.2.3	SRA/ RM (ATMP)	Place all the documents in the Archive boxes. You must follow the UCL Records Office Guidance: https://www.ucl.ac.uk/library/about-us/records-office/how-transfer-records-site-archiving This includes removing documents from lever arch folders and transferring them to paper folders/plastic wallets. The boxes should be filled but not overfull, not taped shut, and have nothing written on them. Place a Sponsor File Index in the front of each box.
6.2.4	SRA/ RM (ATMP)	Complete the **JRO Research Records Transfer Form** and email it to the JRO Data Team uclh.randd@nhs.net
6.2.5	JRO Data Team	JRO Data Team member will provide a Box List containing a Unique Reference Number for each box.

Section	Responsible Person	Activity
6.2.6	SRA/ RM (ATMP)	Save the PDF file of the Box List in the 'Trial Close Out & Archiving' folder on the S drive. Inside each box, print and place a copy of the Box List at the front of the archive box. Using a marker pen, write the Unique Box Number [JBRU/20xx/xxx] on the side of each archive box (just above the hole). NB: No other information is to appear on the outside of the box except for the Unique Box Number. If you are re-using an old box, ensure any old writing is covered up and do not attach anything else outside the box. Please ensure the correct printed Box List and Box Number matches. Failure to follow this exact procedure may result in the box not being accepted by the archive facility or may cause issues when trying to retrieve the archived files. When the boxes are ready email the JRO Data Team to arrange collection uclh.randd@nhs.net and enter details on the **Archiving Spreadsheet**. Ensure the boxes are kept in a secure, restricted access location until collection.
6.2.7	SRA/ RM (ATMP)	When the boxes have been collected: 1. Email the collection date to uclh.randd@nhs.net 2. Enter the collected date on the **Archiving Spreadsheet**. 3. Update EDGE (add archive date on the 'Workflows' tab and change status on the 'Details' tab).

6.3 Archiving of Trial Master File

The TMF is ready for archiving when the Sponsor has issued the 'Confirmation of Trial Close & Archiving' email to the Chief Investigator.

It is the responsibility of the Chief Investigator to archive the TMF using the UCL archiving facilities (records.office@ucl.ac.uk). Prior to archiving a full TMF review should be completed.

Section	Responsible Person	Activity
6.3.1	CI/Trial Manager	Perform a full review of the TMF using the **Trial Master File Review Checklist** (JRO/INV/S02). Any missing documents should be filed or file noted.

Section	Responsible Person	Activity
6.3.2	CI/Trial Manager	To order the archiving boxes, email UCL Records Office (records.office@ucl.ac.uk) stating the number of boxes required with your name and delivery address. The boxes will be sent to your address. Boxes not supplied by the UCL Records Office will NOT be accepted.
6.3.3	CI/Trial Manager	Place all the documents in the Archive boxes. You must follow the Records Office Guidance: https://www.ucl.ac.uk/library/about-us/records-office/how-transfer-records-site-archiving This includes removing documents from lever arch folders and transferring them to paper folders/plastic wallets. The boxes should be filled but not overfull, not taped shut, and have nothing written on them. Label each folder/plastic wallet with Short Trial Name/Sponsor ID/ Section of TMF (e.g., TOSCA/140249/Section 2 Agreements) Place a TMF index in the front of each box.
6.3.4	CI/Trial Manager	Complete the **JRO Research Records Transfer Form** and email it to uclh.randd@nhs.net
6.3.5	JRO Data Team	JRO Data Team Member will provide a Box List containing a Unique Reference Number for each box.
6.3.6	CI/Trial Manager	Inside each box, print and place a copy of the Box List at the front of the archive box. Using a marker pen, write the Unique Box Number [JBRU/20xx/xxx] on the side of each archive box (just above the hole). NB: No other information is to appear on the outside of the box except for the Unique Box Number. If you are re-using an old box, ensure any old writing is covered up and do not attach anything else outside the box. Please ensure the correct printed Box List and Box Number matches. Failure to follow this exact procedure may result in the box not being accepted by the archive facility or may cause issues when trying to retrieve the archived files. When the boxes are ready email uclh.randd@nhs.net to arrange collection. Ensure the boxes are kept in a secure, restricted access location until collection.

Section	Responsible Person	Activity
6.3.7	CI/Trial Manager	Email the PDF file of the Box List to the SRA/RM (ATMP). When the boxes have been collected email the collection date to uclh.randd@nhs.net copying in the SRA/RM (ATMP).
6.3.8	SRA/ RM (ATMP)	Save the PDF file of the Box List and collection date email in the 'Trial Close Out & Archiving' folder of the trial on the S drive in a sub-folder titled 'TMF Archive'.

6.4 Archiving of Investigator Site File

The ISF is ready for archiving when the Sponsor has issued the 'Confirmation of Site Close Out' email to the Principal Investigator. Sponsor oversight of the content of the site file is captured as part of the Site Close Out Procedures SOP (JRO/SPON/S10).

In a multi-centre clinical trial, it will be the responsibility of each investigator site to arrange its own archiving of CTIMP Essential Documents in paper and electronic form, in accordance with the Clinical Trial Site Agreement and their local trust policy.

For both Investigator Site File and Pharmacy File, the Principal Investigator will email the Sponsor/Chief Investigator the name of the archivist and the location of the archived documents.

Archiving of Investigator Site File at UCLH

For archiving of the ISF at UCLH, please refer to the UCLH SOP 10: Archiving of UCLH Investigator Site file, available on the JRO website.

Archiving of Pharmacy File

Pharmacies may be responsible for arranging their own pharmacy file archiving. If the Pharmacy File is not archived alongside the ISF, the Principal Investigator must have a **file note in the Investigator Site File outlining where the Pharmacy file is archived.**

6.5 Retrieving Archived Boxes

To retrieve records from the archiving facility, email the UCL Records Office (records.office@ucl.ac.uk) quoting the Unique Box Number(s).

6.6 Retention Policy

Research records are retained by UCL in accordance with its Records Retention Schedule. This follows relevant current legislation and regulation and will follow EU 536/2014 when it comes into force.

Until Regulation 536/2014 comes into force, the retention period as defined by SI 2006 1928 is for at least 5 years after the conclusion of a trial.

Retention period under Regulation 536/2014 is 25 years for Clinical Trials of Investigational Medicinal Products.

Retention period under Regulation 1394/2007 for Advanced Therapy Investigational Medicinal Product (ATIMP) traceability records, is at least 30 years after the expiry date of the product (unless a longer time period is required in the clinical trial authorisation) for Clinical Trials of ATIMPS. This applies to trial sponsors, the tissue establishments/procurement organisation, the manufacturer and the Investigator site where ATIMPs are developed, manufactured or administered.

7. REFERENCES

- Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
- ICH Harmonised Tripartite Guideline for Good Clinical Practice (E6)
- EU GCP Directive 2005/28/EC
- Advanced Therapy Medicinal Product Regulation (EC) No 1394/2007
- Guidelines on Good Clinical Practice specific to Advanced Therapy Medicinal Products 2019 European Regulations 536/2014

8. REFERENCED GUIDES / SOPs

1	JRO Sponsor SOP 11: Standard Operating Procedure for the Sponsor File
2	JRO Investigator SOP 02: Standard Operating Procedure for ISF/TMF
3	JRO Sponsor SOP 10: Standard Operating Procedure for Site & Trial Close Out
4	JRO UCLH SOP 10: for Archiving of UCLH Investigator Site File and Pharmacy Site File
5	JRO Website: http://www.ucl.ac.uk/jro
6	UCL Records Management Policy

9. TEMPLATES/LOGS ASSOCIATED TO THIS SOP

1	Sponsor File Review Checklist (JRO/SPON/S11)
2	Sponsor File Index (JRO/SPON/S11)
3	Trial Master File Review Checklist (JRO/INV/S02)
4	Trial Master File Index (JRO/INV/S02)
5	JRO Research Records Transfer Form
6	Archiving Spreadsheet

10. SOP DISSEMINATION AND TRAINING

New SOPs will be distributed to the concerned staff, by the named author on the front page of the SOP. Staff concerned by the SOP will sign the SOP training log (12. SOP TRAINING LOG) which is part of each SOP. In addition, each staff should have an "Individual Staff SOP and courses log" which will need to be updated once trained on the SOP.
The training will constitute the person reading the SOP and being provided with the opportunity to ask specific questions to the author of the SOP.

11. SIGNATURE PAGE

Author and Job Title:	Samim Patel, Sponsor Regulatory Advisor
Signature:	DocuSigned by: Samim Patel E218F1144A624FA...
Date:	09 December 2021 | 16:03 GMT

Authorised by: Name and Job Title	Helen Cadiou, Head of Quality Assurance
Signature:	DocuSigned by: Helen Cadiou 9FE319AE9B744D5...
Date:	09 December 2021 | 16:46 GMT

12. SOP TRAINING LOG

	Name of Staff	Job Title: Department:	Training Date	*I confirm that I understand & agree to work to this SOP* **SIGNATURE**	**Name of Trainer** (if training required)	Signature	Date
1							
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	Name of Staff	**Job Title:** **Department:**	**Training Date**	*I confirm that I understand & agree to work to this SOP* **SIGNATURE**	**Name of Trainer** (if training required)	**Signature**	**Date**
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	Name of Staff	**Job Title:** **Department:**	**Training Date**	*I confirm that I understand & agree to work to this SOP* **SIGNATURE**	**Name of Trainer** (if training required)	**Signature**	**Date**
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	Name of Staff	**Job Title:** **Department:**	**Training Date**	*I confirm that I understand & agree to work to this SOP* **SIGNATURE**	**Name of Trainer** (if training required)	**Signature**	**Date**
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