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

SOP ID Number: JRO/SPON/S21/05	**Effective Date:** 14/02/19
Version Number & Date of Authorisation: V05, 04/02/19	**Review Date:** 14/02/22
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 V05.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	01/04/2012	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

ACRONYMS:	
CI	Chief Investigator
GCP	Good Clinical Practice
ISF	Investigator Site File
JRO	Joint Research Office www.ucl.ac.uk/jro/
MHRA	Medicines and Healthcare Products Regulatory Agency
PI	Principal Investigator
QA	Quality Assurance
REC	Research Ethics Committee
SOP	Standard Operating Procedure
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 and when applicable Regulation 536/2014 and subsequent relevant SIs. Where applicable it incorporates elements of ICH GCP tripartite guidelines (E6).

4. SCOPE OF THIS SOP

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

Further details as to the procedure for the UCL Archiving System is shown in Appendix 1.

5. RESPONSIBLE PERSONNEL

The JRO R&D 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 Sponsor and Chief Investigator keep records of the clinical trial throughout its life cycle (as per JRO/SPON/SOP11 and JRO/INV/SOP02)

Sponsor File

A sponsor file is ready for archiving when the Chief Investigator of a CTIMP informs the JRO that the **End of Trial Study Report has been submitted via EudraCT to the MHRA**. The time frame for submitting the report is within six months of the end of trial

for paediatric clinical trials or within one year of the end of trial for non-paediatric clinical trials to the Research Ethics Committee and MHRA.

	Responsibility	Activity
1	SRA	Contact UCL Records Office (records.office@ucl.ac.uk) to request the amount of boxes required with your name and delivery address. The boxes will be sent to your address.
2	SRA	Place all the documents in the Archive boxes as per section 8.1 of this SOP. Complete the JRO Research Records Transfer form and email to uclh.randd@nhs.net
3	Data Team-JRO	Member of JRO Data Team provides a receipt containing a Unique Reference Number (URN).
4	SRA	Place a copy of the receipt inside the archive box and write the URN outside on each box. When boxes are ready to be archived email uclh.randd@nhs.net to arrange collection.
5	SRA	Update status of study on the archiving spreadsheet

Records 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 Records Office System (under Departmental Box List).

Chief investigator TMF

It is the responsibility of the Chief Investigator to archive the TMF using the UCL archiving facilities (records.office@ucl.ac.uk), except where the TMF is also the Investigator Site File (ISF), in which case it will need to be archived in the Trust. Prior to archiving a TMF review will be completed as per the Investigator SOP for End of Trial (JRO/INV/SOP07) and the study specific monitoring plan.

Investigator Site File

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. Sponsor oversight of the content of the site file is captured as part of the end of trial SOP (JRO/INV/SOP07).

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 will have **a file note in the Investigator Site File outlining where the Pharmacy file is archived.**

Multicentre Trials

For both investigator site file and Pharmacy site file, the Principal Investigator will email the Chief Investigator to let him know where his files have been archived.

6.2 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.

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

Retention period under Regulation 1394/2007 is at least 30 years after the expiry date of the product years for Clinical Trials of Advanced Therapy Investigational Medicinal Products (ATIMPS)

7. REFERENCES

- Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
- Section 8 of ICH Harmonised Tripartite Guideline for Good Clinical Practice (1996)
- Medical Research Council "Ethics Series on Good Clinical Practice"
- EU GCP Directive 2005/28/EC
- EU General Data Protection Regulation
- Advanced Therapy Medicinal Product Regulation (EC) No 1394/2007
- Human Medicines Regulations 2012/1916 Detailed guidelines on good clinical practice specific to advanced therapy medicinal products [ENTR/F/2/SF/dn D(2009) 35810
- European Regulations 536/2014

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 Investigator SOP 07: Standard Operating Procedure for End of Trial
4	UCL Records Management Policy
5	http://www.ucl.ac.uk/jro

8. APPENDICES

Appendix 1: Research Records Transfer Form

Appendix 2: UCL Records Office Archiving System (8.1 to 8.9 below)

Appendix 2 (8.1 to 8.9 below)

8.1 Registering with UCL records

Prior to archiving registration with the UCL records office will need to be completed.

- Go to:
  http://www.ucl.ac.uk/library/about/records-office/transfer-records

  Then click on "completing a registration form".
- This will open a Word document; this form must be filled in and signed. Complete Sections 1 and 2. Section 3 will be completed by the Records Office.

Scan and email the completed signed form to records.office@ucl.ac.uk

8.2 Ordering archiving boxes

To request archive boxes email records.office@ucl.ac.uk with the number of boxes required with your name and delivery address. The boxes will be sent to your address.

8.3 Prepare your files for archiving

- Order boxes – see section 8.2
- You must follow Records Office guidance: http://www.ucl.ac.uk/library/about/records-office/transfer-records. This includes removing documents from lever arch folder and transferring them to paper folders. Place the paper files in the archiving box, supplied by UCL Records Office. Boxes should be filled, but not overfull, not taped shut, and nothing written on them except the system-generated number.
- Label each folder with Short Trial Name/REDA #/ Section of SPF (e.g Section 2 Agreements)
- Place a SPF index in the front of each box

8.4 Recording the archiving on the UCL records database

- To logon to Archive Database enter the following URL in web browser https://www.ucl.ac.uk/services/
- Scroll down to R
- Click on 'Records Office Systems'
- Click on 'Launch Records Office Systems'
- Login using normal IS username and IS p/w.
- Click on 'Records Office'
- Select 'Department Users' then 'Clients Data Entry' which will take you on to the 'Data Entry' screen

-

- Click "New Box" [*Cursor will be at "reference" and be yellow in colour*].
- Put in reference (format for all sponsor files: JROCTIMPS/REDA #/YEAR (REDA # in format xx-xxx)
- Enter "File type" by clicking grey square and selecting "2" (Research) from the drop down list [*this will apply only for the first record of each new box only*]
- Click into "File title" and enter the description and contents of that folder e.g. short trial name, REDA number- sponsor file- section of the folder such a Section 2 agreements file 1/3.

  N.B Add the file title to the archiving spreadsheet saved: S:\ SLMS\RSC ALL STAFF\CLINICAL TRIALS\SOPs\EFFECTIVE SOPs Guides\Sponsor SOPs\SPON S21 SOP for archiving
- Click ok
- Enter the dates in the From and Last Date boxes. The From Date is the date of the earliest document in the file. The Last Date is the date of the latest document in the file. Enter date in the format xx-xxxx.
- Press F10 and OK to save record.

Note that:

Item number will now be saved.

Box No reference will be automatically generated by the system (e.g. JJRO/2015/2). It is **THIS** reference that is written on the front of the archive box under **"Box No."** before shipping to UCL Records Office. Nothing else must be written on the outside of the box.

The above Box No Reference must also be recorded on the Spreadsheet S:\ SLMS\RSC ALL STAFF\CLINICAL TRIALS\SOPs\EFFECTIVE SOPs Guides\Sponsor SOPs\SPON S21 SOP for archiving

Each separate paper folder within the archiving box must also be logged on the system, individually.

8.5 Recording second Item in the same box

- Press green + sign to add a record [*note that "Item no." automatically changes to next consecutive number*].
- Change the 'file title' contents to reflect the information contained in that folder e.g. Section 2 Agreements file 2/3.
- Repeat process until all folders within the archiving box have been logged on the system.

The above information must also be recorded on the Spreadsheet. Record each folder on the spreadsheet with the reference number. This makes it easier to locate the correct boxes, if archived retrieval is required.

8.6 Entering a NEW Record (i.e. a new box)

Click "New Box" and repeat stages as above (section 8.3)

8.7 Adding records or modify a 'New' Box

This action will be needed if adding documents or modifying a record in a box that has been allocated a box code, but has not yet been marked for collection:

- On the menu bar choose 'Query' and then 'Enter'.
- In the box number field put the details in of the box you require e.g. JRO/2015/2.
- On the menu bar choose 'Query' and then 'Execute'. This will bring up the box details.
- Scroll to the last record and then press F6 or the arrow key at the top of the page to add a new record. (To modify a record scroll to the relevant record and make relevant change).
- To save new/modified records press F10 or choose 'Save' from the 'Action' menu.

8.8 Boxes ready for collection

Once the boxes have been created, and they are ready to be transferred to UCL.

- Click on the 'Boxes Ready for Collection' tab. This will show a table of the boxes that have been created. To mark all boxes ready for collection click the 'Boxes Ready for Collection' button on the top right. Or, if only some of the boxes are ready to be collected, tick the tick box next to the individual box(es) that need to be transferred.

- Go to Records Office click Reports, click box list, click departmental box list. Select your boxes from the list and press print box list. Save a copy of this list in the JRO Sponsor file.

- This will generate a report in Acrobat Reader showing individual box lists. Print off a copy of the list and place in the appropriate box. (**N.B** In order to be able to print, the 'pop-up' function must be enabled to allow Adobe reader to open).

- Once boxes are ready for collection, email the Records Office, with your location, contact names and numbers, and the number of boxes to be collected.

- When finished close the box list window and then on the menu bar choose 'Action' and then 'Exit'.

8.9 Retrieving archived boxes

To retrieve records, email the Records Office.You can request whole boxes or individual files.

The requested records will be returned to the UCL Records Office on the afternoon of the following working day.

Contacts: records.office@ucl.ac.uk

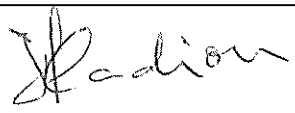
9. TEMPLATES/LOGS ASSOCIATED TO THIS SOP

1	Appendix 1 Research Records Transfer Form
2	Appendix 2: **8.1 to 8.9 of this document:** Operation of the UCL Archiving System (Citrix Program Neighbourhood)

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:	Nimrita Verma, Sponsor Regulatory Advisor/Device Lead
Signature:	
Date:	04-FEB-2019
Authorised by: Name and Job Title	Helen Cadiou, Head of Quality Assurance
Signature:	
Date:	04/02/19

12. SOP TRAINING LOG

	Name of Staff (Capital letters)	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	MICHELLE QUAYE	Regulatory Manager ATMPs	04 Feb 19		—	—	—
2	ALISON EVANS	Regulatory Manager ATMPs	4 Feb 19		—	—	—
3							
4							
5							
6							
7							

	Name of Staff (Capital letters)	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
8							
9							
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14							

15	Name of Staff (Capital letters)	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
16							
17							
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