Title: Non-Commercial Study Archiving of Investigator Site file and Pharmacy Site File (if applicable)

SOP Number and Version: UCLH SOP 10, Version 2.1	**Effective Date:** 06/09/2017 **Review Date**: 06/09/2020
For Trust-wide SOPs, please check this is the **latest version of the SOP** on the Joint Research Office website: www.ucl.ac.uk/jro. For Departmental SOPs, please check this is the **latest version of the SOP** with the Research Unit QA Manager.	

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Revision Chronology:			
Version Number:	**Effective date:**	**Reason for change:**	**Author:**
UCLH SOP 10, V1	14/02/2014	Initial standardised SOP for use within UCLH	Daniel Heather
UCLH SOP 10, V2	03/04/2017	SOP updated to include new archiving retention periods for ATIMPs and CTIMPs; separate archiving process for commercial studies; further details regarding JRO process for archiving and clarification on archiving patient identifiable research-related records.	Stuart Braverman
UCLH SOP 10, V2.1	06/09/2017	SOP updated to remove reference to UCL Records Office address and archiving warehouse, as any archiving requests are solely coordinated by the JRO and UCL Records team via email. Reference to UCL Records Office costs have also been removed, as the service is offered free of charge for applicable research studies. Minor changes made throughout document. A template Investigator Site File Contents Checklist has been included as an appendix (Appendix 2) to aid researchers in maintaining essential documents.	Stuart Braverman

ACRONYMS

SOPs	Standard Operating Procedures
CCTU	Cancer Clinical Trial Unit
CRF	Clinical Research Facility
RN	Research Nurse
LRN	Lead Research Nurse
R&D	Research and Development Department
QA	Quality Assurance
DM/S	Data Manager/Staff
GCP	Good Clinical Practice
SF	Site File
MHRA	Medicines and Healthcare Products Regulatory Agency
PI	Principal Investigator
TMF	Trial Master File
ISF	Investigator Site File
CTIMP	Clinical Trial of an Investigational Medicinal Product
ATIMP	Advanced Therapy Trial of an Investigational Medicinal Product
Non-CTIMP	Any research study that is not a clinical trial of an investigational medicinal product
UCL ROS Database	University College London Records Office System Database
ECG	Echocardiogram
ICF	Informed Consent form

1. BACKGROUND

This Standard Operating Procedure (SOP) describes the process of archiving essential documents (ISF/TMF/Pharmacy file) of non-commercial studies such as CTIMPs, ATIMPs and non-CTIMP studies carried out in UCLH. ISF and Pharmacy files (if applicable) should be archived through the **University College London (UCL) Records Office.**

The purpose of this SOP is to lay out the correct **archiving storage and retrieval procedures** for ISF and Pharmacy files for non-commercial studies.

In instances where the below conditions do **not** apply (i.e. commercially sponsored studies), the records will be archived via an accredited commercial third party. To discuss in more detail, please contact the UCLH Archivist and Records Manager **annie.lindsay@uclh.nhs.uk.**

2. PURPOSE

The sponsors should have an index of the documents to be filed in the ISF. If the sponsor does not have an index, the **UCLH SOP 8 on Essential Documents and ISF/TMF** outlines a list of documents which need to be filed in the ISF (Appendix 2).

In cases where the PI is also the CI and the sponsor has delegated to the CI the archiving of the TMF, then this should follow the same process as of the ISF and Pharmacy Site File.

3. PROCEDURE

	Actions (When? How?)	Responsible persons (Who?)
1	The Principal Investigator (PI) or delegated person (typically Data Manager (DM)/Staff or Research Nurse (RN)) is responsible for ensuring that all essential documentation (ISF and Pharmacy file) for the study is archived as per current regulations[1] (EU Clinical Trials Directive (2001/20/EC), International Conference for Harmonisation – Good Clinical Practice (ICH-GCP) Guidelines and GCP Directive). Records pertaining to CTIMPs must be archived for 25 years. Records pertaining to ATIMPs must be archived for 30 years. Paperwork for other studies must be archived **for the duration stated in the protocol by the sponsor**. UCL Records Office retains the documents. **Archiving Pharmacy Files** The PI or delegated RN/DM needs to inform Pharmacy and collect the Pharmacy file from Pharmacy and archive it with the ISF.	**P.I/Delegated Person (e.g. Data Staff/Research Nurse)**
2	Studies should be archived when the **Sponsor has instructed or agreed for the site** to archive the ISF and Pharmacy files. The actions outlined in the **UCLH SOP 9: Study Close Down** should be carried out prior to starting the archiving process.	**Sponsor**

[1] **Please note the archiving regulatory requirements are dependent on the type of study.**

3	Providing that one of the following conditions are met, the records should be archived via UCL Records Office: • The legal sponsor for the study is UCL • The local investigator holds a contract (honorary or substantive) with UCL • The study is hosted at a UCL managed or joint UCL/UCLH managed facility (e.g. UCL/UCLH Clinical Research Facility; UCL Institute of Neurology etc.) **In instances where the conditions above do **not** apply, the records will be archived via an accredited commercial third party. To discuss in more detail please contact the UCLH Archivist and Records Manager **annie.lindsay@uclh.nhs.uk**.	**UCL Records Office/accredited commercial third party**
4	Where these conditions do apply, the member of the research team undertaking archiving should review the instructions contained in the **Research Records Transfer Form** (Appendix 1), which are reproduced below for convenience: 1) Please **contact the UCL Records Office via email (records.office@ucl.ac.uk) to request boxes**. Boxes not supplied by the UCL Records Office will NOT be accepted. Box dimensions are as follows 360mm (L) x 140mm (H) x 255mm (W). Please stipulate: • Number of boxes required • Location where boxes should be delivered to 2) Once you have the boxes, **write a temporary running order** (in pencil only) on the front of each box (1, 2, 3). Do NOT write or stick anything else on the boxes. 3) Put the ISF and Pharmacy site file (if applicable) in the boxes. **Remove papers from bulky ring-binders and lever arch files** as these take up space. Do not place additional boxes (e.g. magazine files) inside the boxes. 4) **List the box number and contents of that box on the Research Records Transfer Form (**Appendix A). Complete the form in Microsoft Word format and email as an attachment to randd@uclh.nhs.uk The form will not be accepted in hardcopy or as a PDF.	**Delegated research team member undertaking archiving**
5	JRO staff will enter the relevant information onto the UCL ROS (Records Office System) Database on receipt of the Research Records Transfer Form (Appendix A). JRO staff will then e-mail the research team representative the ROS output form, containing the unique box reference number generated by the UCL ROS system. There will be one output form per box.	**JRO**
6	The research team representative will insert the information generated by UCL ROS into the boxes and will e-mail randd@uclh.nhs.uk to confirm this	**Delegated research**

	has been done.	**team member undertaking archiving**
7	On receipt of the above mentioned e-mail, JRO representatives will arrange for the UCL Porters to collect the boxes from their current location and transferred to the UCL Records Office. The overall archiving process time takes on average 4 weeks to complete.	**JRO**
8	The JRO will keep a record of the box reference numbers and will request the return of 1 box every 3 months, for monitoring purposes.	**JRO**

Patient Hospital/Medical Notes
Please refer to the UCLH Records Management Policy. Under **NO** circumstances should patient/medical notes be archived by the UCL Records Office. Other research related paperwork containing patient identifiable data (for example ICFs, lab reports and ECG data) may be archived in accordance with this SOP.

Retrieval of boxes
In the event that boxes need to be retrieved from Archiving, study teams should e-mail randd@uclh.nhs.uk with study title and R&D reference number, as well as details of where the boxes should be delivered to. The JRO Data and Information Management team will liaise with the UCL Records Office to organise the retrieval of these boxes.

Destruction of Archived Boxes
The UCL Records Office will be in contact when the **stated archiving time** for a box has expired to see if documents can be destroyed. The relevant RN/PI should contact the Department where the PI was conducting the study to confirm destruction. If further archiving time is required, the research nurse of PI should inform the Records Office via **records.office@ucl.ac.uk.**

4. IMPLEMENTATION & TRAINING

Staff following this SOP must confirm they have read and understood the procedures outlined above by completing their relevant training log as a record of acknowledgement. It may be necessary to ensure staff are trained in the implementation of specific SOPs.

5. PUBLICATION & COMMUNICATION

This SOP is authorised and published on the JRO website: http://www.ucl.ac.uk/jro. The latest version of the SOP will be made available on the JRO website.

The original fully signed master copy is stored in a designated binder within the JRO and maintained by the JRO Research Quality & Safety Manager (or Research Unit QA Manager if a Departmental SOP).

6. TEMPLATES ASSOCIATED WITH THIS DOCUMENT

	Document	Stored
1.	Research Records Transfer Form	*ReDA SOP Store and JRO Website*

7. REFERENCES

UCLH SOP 2	Definition of Responsibilities
UCLH SOP 8	Essential Documents and ISF/TMF
UCLH SOP 9	Study Close Down
UCLH Policy	Records Management Policy

8. APPENDICES

Appendix 1: Research Records Transfer Form
Appendix 2: Site File Contents Checklist

Appendix 1: Research Records Transfer Form

Joint Research Office

RESEARCH RECORDS TRANSFER FORM

INSTRUCTIONS

- Please contact the UCL Records Office (records.office@ucl.ac.uk) to request boxes first. Boxes not supplied by the UCL Records Office **will not** be accepted. Box dimensions are as follows 360mm (L) x 140mm (H) x 255mm (W). Please stipulate:
  a) Number of boxes required
  b) Location boxes should be delivered to
- Once you have the boxes write a temporary running order (in pencil only) on the front of each box (1,2,3). Do not write or stick anything else on the boxes
- Put the records in the boxes. Remove papers from bulky ring-binders and lever arch files as these take up space. Do not place additional boxes (e.g. magazine files) inside the boxes.
- List the box number, and contents of that box on this form as shown below. Ensure you complete the form in Microsoft Word format and email as an attachment to randd@uclh.nhs.uk.

Details of records		
Box number	*Contents list: Please include type of documents (e.g. CRFs, Protocol, Informed Consent Forms etc)* *(To insert a new column please right click on the last column and select inset>column down and complete as appropriate)*	Covering dates
1/3	Patient log, Monitoring, Correspondence, Site initiation and training, CVs	06/04/2009 – 19/03/2012
2/3	Administrative binder: patient log, monitoring, correspondence, site initiation and training, CVs, financial disclosures, investigator agreement	22/04/2010 – 07/06/2012
3/3	Patient 2, 3 and 4 binder: enrolment and informed consent forms, discharge summary	22/04/2010 – 07/06/2012

- The boxes will be registered in Records Office System (ROS) by the Joint Research Office and you will be provided with a receipt to put in the box and a unique reference number which will have to be written on the box. One UCL ROS output form per box needs to be included.
- JRO will then arrange collection of the box for storage.

PLEASE NOTE

- Only the Investigator Site File (ISF) and Case Report Forms (CRFs) should be transferred offsite. Under no circumstances should patient notes/medical records or other source documents leave UCLH.
- Please ensure the ISF contains all records stipulated by the study sponsor as per their SOP. In the absence of a sponsor SOP for the Site File please use the UCLH SOP 8 for Essential Documents and the Study File (TMF/ISF).

YOUR DETAILS

Details of depositor	
Name of person transferring records	
Job Title (e.g. Research Nurse, Data Manager)	
Email and telephone number	

Details of transfer	
Number of boxes	

Date form completed	
Location to be collected from (please be as specific as possible)	

Study details	
R&D number	
Short title	
Full title of study	
P.I. name	
Sponsor name	

Details of records in each box		
Box number	*Contents list: Please include type of documents (e.g. CRFs, Protocol, Informed Consent Forms etc.)* *(To insert a new column please right click on the last column and select inset>column down and complete as appropriate)*	Covering dates

(For JRO use ONLY)

Short Ref	**Box number**	**R&D No**	**JRO Ref Number**	**Archive End Date**	**ROS Archive Ref Number** **(This reference will have to be written on the box)**

Appendix 2 – Site File Contents Checklist

Title:	
Protocol number:	**ISRCTN/Clintrial.Gov number:**
EudraCT number:	**Chief Investigator:**
REC number:	**Principal Investigator:**
R&D number:	

TABLE OF CONTENTS	Study Type	Y N N/A	Comments
Contacts List		☐ ☐ ☐	
1.0 CORRESPONDENCE			
1.1 Emails/Letters/Telephone Conversation/Meetings Minutes		☐ ☐ ☐	
2.0 SPONSORSHIP / R&D MANAGEMENT			
2.1 Scientific Peer review		☐ ☐ ☐	
2.2 Risk Assessment		☐ ☐ ☐	
2.3 Feasibility		☐ ☐ ☐	
2.4 Insurance certificate / statement		☐ ☐ ☐	
2.5 Clinicaltrials.gov or ISRCTN registration		☐ ☐ ☐	
2.6 NIHR adoption letter		☐ ☐ ☐	
2.7 NHS IRAS forms		☐ ☐ ☐	
2.8 NHS permission/Site Capacity & Capability		☐ ☐ ☐	
2.9 Sponsor open to recruitment letter/Sponsors approval letter if academic or other industry, i.e. funded by industry but sponsored by University.		☐ ☐ ☐	
3.0 AGREEMENTS AND FINANCE			
3.1 Finance and costings budget template		☐ ☐ ☐	
3.2 HRA Statement of Activities/Schedule of Events (studies approved from May 2016)			
3.3 Grant application and award letter		☐ ☐ ☐	
3.4 Signed agreements (e.g. CI, CTA/CTSA, lab, supply, MTA)		☐ ☐ ☐	
3.5 LCRN funding letters		☐ ☐ ☐	
3.6 Invoices and payments		☐ ☐ ☐	
3.7 Reports to funder		☐ ☐ ☐	
4.0 REGULATORY APPROVALS (where applicable to study type)			
4.1 IRAS applications		☐ ☐ ☐	
4.2 REC Letters (provisional and favourable opinion)		☐ ☐ ☐	
4.3 HRA Approval and correspondence (studies approved from May 2016)			
4.4 MHRA Notice of Acceptance Letter OR **Email confirmation that study does not fall under the Clinical Trial Regulations.**	CTIMP	☐ ☐ ☐	
4.5 MHRA No objection for a clinical investigation	Medical devices	☐ ☐ ☐	
4.6 HTA certificate	Tissue	☐ ☐ ☐	
4.7 ARSAC research certificate / IRMER approval	Radiation	☐ ☐ ☐	
4.8 GTAC favourable opinion	Gene therapy	☐ ☐ ☐	
4.9 Amendment notifications		☐ ☐ ☐	
4.10 Amendment acknowledgement / approval letters		☐ ☐ ☐	

4.11 REC Annual Progress Reports		☐ ☐ ☐	
5.0 PROTOCOL			
5.1 Current approved signed protocol		☐ ☐ ☐	
5.2 All previously approved versions of protocol		☐ ☐ ☐	*Or file note to where located*
5.3 Version History Log		☐ ☐ ☐	
5.4 Protocol amendments		☐ ☐ ☐	
5.5 Log of (Protocol or GCP) Deviations / Violations / Potential Serious Breaches / Serious Breaches / Urgent Safety Measures		☐ ☐ ☐	
5.6 Sample protocol violation and deviation form		☐ ☐ ☐	
6.0 PARTICIPANT INFORMATION			
6.1 Patient Information Sheet(s)		☐ ☐ ☐	
6.2 Consent Form(s)		☐ ☐ ☐	
6.3 GP letter(s)		☐ ☐ ☐	
6.4 Patient Contact Card(s)		☐ ☐ ☐	
6.5 Patient Diary Card(s)		☐ ☐ ☐	
6.6 Signed consent forms		☐ ☐ ☐	
6.7 Version History Log		☐ ☐ ☐	
6.8 All previously approved versions of PIS, ICF and GP letters		☐ ☐ ☐	*Or file note to where located*
6.9 Patient Screening and Enrolment Log		☐ ☐ ☐	
6.10 Identification Code List		☐ ☐ ☐	
6.11 Randomisation code (if applicable)		☐ ☐ ☐	
6.12 Registration/Randomisation faxes (if applicable)		☐ ☐ ☐	
6.13 Sent GP letters		☐ ☐ ☐	
7.0 RESEARCH TEAM			
7.1 Delegation Log (signed and dated)		☐ ☐ ☐	
7.2 CV / GCP certificates (signed and dated)		☐ ☐ ☐	*Or file note to where located*
7.3 Staff Training Records		☐ ☐ ☐	*Or file note to where located*
7.4 Research Passport(s) and issued Honorary Research Contract(s) and/or Letter(s) of Access		☐ ☐ ☐	*Or file note to where located*
8.0 PHARMACOVIGILANCE / SERIOUS ADVERSE EVENT (if applicable to study type)			
8.1 SAE reporting guidelines			
8.2 SUSAR/SAE Log		☐ ☐ ☐	
8.3 Sample SAE form		☐ ☐ ☐	
8.4 Completed SAE forms		☐ ☐ ☐	
8.5 24 hour contact card (if applicable)		☐ ☐ ☐	
8.6 Sponsor SOPs		☐ ☐ ☐	
8.7 Emergency Un-blinding details (if applicable)		☐ ☐ ☐	
8.8 Correspondence to Sponsor reporting SAEs		☐ ☐ ☐	
8.9 Development Safety Update Reports (annual safety reports)		☐ ☐ ☐	
8.10 Drug company safety reports		☐ ☐ ☐	
8.11 DSMC terms of reference		☐ ☐ ☐	
8.12 DSMC meeting minutes / emails		☐ ☐ ☐	
8.13 Safety meeting minutes / emails		☐ ☐ ☐	
9.0 MONITORING AND AUDIT			
9.1 Monitoring plan		☐ ☐ ☐	
9.2 Site Initiation Visit	CTIMP	☐ ☐ ☐	

9.3 Log of Monitoring Visits		☐ ☐ ☐	
9.3 Monitoring reports	CTIMP	☐ ☐ ☐	
9.4 Study close-out visit report		☐ ☐ ☐	
9.5 Audit reports / certificate		☐ ☐ ☐	
9.6 Inspection Findings		☐ ☐ ☐	
10.0 STANDARD OPERATING PROCEDURES			
10.1 Relevant SOP and applicable policies		☐ ☐ ☐	
11.0 TREATMENT RELATED DOCUMENTS (applicable to study type)			
11.1 Investigator Brochure (IB)	CTIMP Medical devices	☐ ☐ ☐	
11.2 Summary of Product Characteristics (SPC)	CTIMP	☐ ☐ ☐	
11.3 Version History Log		☐ ☐ ☐	
11.4 Previous versions		☐ ☐ ☐	*Or file note to where located*
11.5 IMP Dossier	CTIMP	☐ ☐ ☐	
11.6 Sample labels		☐ ☐ ☐	
11.7 Ordering and shipping records	CTIMP	☐ ☐ ☐	
11.8 QP release	CTIMP	☐ ☐ ☐	
11.9 Accountability Log		☐ ☐ ☐	
11.10 Destruction Log		☐ ☐ ☐	
11.11 Pharmacy Site File	CTIMP	☐ ☐ ☐	*Or file note to where located*
11.12 Essential requirements checklist	Medical devices	☐ ☐ ☐	
11.13 CE-mark certificate(s) and confirmation from manufacturer the device will be used within specification	Medical devices	☐ ☐ ☐	
11.14 Declaration of Conformity	Medical devices	☐ ☐ ☐	
11.15 Technical Dossier	Medical devices	☐ ☐ ☐	
12.0 DATA MANAGEMENT (COLLECTION, HANDLING & STORAGE)			
12.1 Data management plan		☐ ☐ ☐	
12.2 Statistics plan		☐ ☐ ☐	
12.3 Current template CRF/data collection tool		☐ ☐ ☐	
12.4 Previous versions of CRF		☐ ☐ ☐	
12.5 Instructions for CRF completion		☐ ☐ ☐	
12.6 Copies of Completed CRFs		☐ ☐ ☐	*Or file note to where located*
13.0 LABORATORY RELATED DOCUMENTS – IF APPLICABLE (if applicable to study type)			
13.1 List of Labs used with contact details		☐ ☐ ☐	
13.2 List of Study specific equipment used		☐ ☐ ☐	
13.3 Lab technical procedure/test certification of accreditation	CTIMP	☐ ☐ ☐	*Or file note to where located*
13.4 Normal Lab reference ranges for any tests or medical procedures in the protocol	CTIMP	☐ ☐ ☐	*Or file note to where located*
13.5 Calibration records for technical equipment		☐ ☐ ☐	
13.6 Arrangements for collection, storage and shipment of blood and tumour tissue specimens	Tissue	☐ ☐ ☐	
13.7 Record of collected body fluids/tissue samples	Tissue	☐ ☐ ☐	
13.8 Record of retained body fluids/tissue samples	Tissue	☐ ☐ ☐	

13.9 Example letter requesting pathology sample	Tissue	☐☐☐	
14.0 STUDY CLOSURE AND ARCHIVING			
14.1 Declaration of the End of Study		☐☐☐	
14.2 Archiving arrangements		☐☐☐	
14.3 Summary of study findings		☐☐☐	
15.0 MISCELLANEOUS			
		☐☐☐	
		☐☐☐	