# JRO RMG RSS SOP 12

## Standard Operating Procedure (SOP) for Study Closedown and Archiving

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<th>SOP ID Number</th>
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<td>1.0</td>
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**Author:**
Daniel Heather, R&D Archivist and Records Manager

**Approved by:**
Dr Susan Kerrison, Head of Risk and Regulation
21/03/2012

**Target Trusts:**
UCLH NHS Foundation Trust

**Target Audience:**
All Investigators, Research Nurses and Data Managers involved in archiving research records based at UCLH

**Related SOPs:**
JRO RMG RSS SOP 13 Site File

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**SOP e-Document kept:**
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# Revision Chronology

<table>
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Joint Research Office

Standard Operating Procedure (SOP) for Closedown and Archiving of Studies

1. SUMMARY

This SOP describes the procedures surrounding trial completion, end of trial reporting requirements and preparation for trial close out prior to archiving. It also includes guidance on the physical preparation of the records for archiving, relevant legislation and best practice and long-term storage solutions used by UCLH.

2. DEFINITIONS

No SOP specific definitions

3. PURPOSE and SCOPE

This SOP forms part of the suite of SOPs which will implement the NIHR Research Support Framework. This SOP describes the procedure for archiving investigator site documentation produced as a result of clinical research hosted at UCLH 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).

Trial records must be kept so that the data can be accessed after the trial has finished. It is a requirement that all clinical trial information should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification. Essential documents need to be archived in a way that ensures they are readily available to the competent authorities, and are stored in accordance with the requirements of the Data Protection Act 1998, the Freedom of Information Act 2000 and the UK Clinical Trial Regulations.

This SOP does not apply to SOPs for UCL sponsored CTIMPs. A list of published UCL sponsored CTIMP SOPs are available at: http://www.ucl.ac.uk/jro/

This SOP does not apply to the archiving of the main patient health record. This should be managed via UCLH’s centralised Health Records System. More details are available via the UCLH intranet at: http://insight/departments/other/ICT/ICTRecords/MedicalRecords/Pages/default.aspx

4. RELATED SOPs

JRO RMG RSS 13 Site File

5. JOINT RESEARCH OFFICE (JRO) POLICY

All SOPs produced from the JRO must be used in conjunction with local NHS Trust and UCL policies and procedures. Where applicable there is also a requirement to include stakeholder engagement as appropriately identified.
The JRO represents both UCL, UCLH and RF as the Sponsor and UCLH and RF as Participating Sites, depending on the type of research study. The JRO is responsible to ensure that appropriate research management and governance processes are in place. The RM&G SOPs will provide a quality assurance system for these requirements.

6. BACKGROUND

This SOP complies with

- NIHR RSS framework

The following may be applicable to this SOP, depending on the type of research:

- Good Clinical Practice (GCP)
- European Directives for CTIMPs as 2001/20/EC and 2005/20/EC (these Directives were transposed into UK law as statutory instruments SI2004/1031, SI2006/1928) and subsequent amendments incorporating elements of ICH GCP tripartite guidelines (E6).
- Human Tissue (Quality and Safety for Human Application) 2007
- Medical Devices Regulations 2002
- Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER)
- Human Tissue Act 2004
- Data Protection Act 1998
- Mental Capacity Act 2005
7. RESPONSIBLE PERSONNEL AND THEIR DUTIES

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<th>Responsible person</th>
<th>Summary of duties</th>
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<tr>
<td>1 CI, PI or designated representative</td>
<td>To follow the requirements of this SOP when records are ready to be archived.</td>
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<tr>
<td>2 R&amp;D Archivist and Records Manager</td>
<td>Oversight of the archiving process for research including providing training and guidance where required.</td>
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<tr>
<td>3 UCL Records Manager</td>
<td>Physical storage of investigator site records for trials in some instances.</td>
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<tr>
<td>4 Sponsor</td>
<td>To determine the retention period for investigator site records and to provide financial assistance (where applicable) to facilitate archiving. Additionally to approve the destruction of records once the agreed retention period has expired.</td>
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8. PROCEDURE

8.1 Closing the site

A site should be closed as soon as is practicable to do so. A site will be deemed to be closed once all study-related activities at a site are reconciled or complete. It should be ensured that:

- Investigator files should be reviewed and all essential documentation should be located in the appropriate files.
- All site data should be collected, entered and validated and all data queries resolved.
- All finance matters are resolved and all site payments completed as agreed in the study contracts/agreements/approvals.
- All unused trial supplies are returned or destroyed according to the study protocol, agreement and/or requirements of the Sponsor.
- Unused IMPS are returned to the Sponsor or destroyed locally onsite (as pre-arranged in the study Contract/Agreement and/or other arrangements with Pharmacy onsite). If IMP is destroyed onsite the destruction should be documented in the site file.
- Investigators should comply with the study publication policy, as outlined in either the study protocol and/or study contracts/agreements.

8.2 Chief Investigator (CI) specific responsibilities

8.2.1 Notifying the REC

It is the responsibility of the CI, acting on behalf of the Sponsor, to notify the REC which gave a favourable opinion of the research (the ‘main REC’) in writing of the conclusion or early termination of a study using the appropriate form.

The relevant form is available at:
You should send the appropriate form within 90 days of the end of the study, or within 15 days if the study is terminated early. If the study has been terminated early you should provide reasons. More detailed information is available at the web address provided above.

In the case of CTIMPS it is the responsibility of the sponsor, or the (sponsor’s representative) to notify the main REC of the end of trial.

The relevant form is available at: http://www.nres.npsa.nhs.uk/applications/after-ethical-review/endofstudy/

8.2.2 Notifying the JRO

The JRO should be notified as soon as practicable that the research has ended.

8.2.3 Notifying the sponsor

The sponsor should be notified as soon as practicable that the research has ended.

8.3 Initiating Archiving

Once the conditions outlined above have been met research records should be archived at the site as soon as it is viable to do so. Prior to commencing archiving the sponsor should be notified and any final invoices should be raised.

Please note: In instances where the sponsor has provided their own designated archiving SOP for the trial this will take precedence over this SOP.

8.3.1 Who is responsible for archiving the records?

UCLH NHS Foundation Trust maintains responsibility for archiving of investigator site records. This in turn will be delegated to the PI, Data Manager (DM) or Research Nurse (RN) within the department undertaking the research. It is a requirement that the PI, DM or RN is aware of the archiving requirements agreed in the study protocol or site agreement. Staff should consult these documents to ensure they are aware of:

- The minimum retention period stipulated by the sponsor
- What financial agreements (if any) have been put in place to facilitate the storage of the records? This will frequently have been negotiated by JRO Finance/Contracts

In instances where there is any uncertainty around either of these points confirmation should be sought from R&D. The R&D Archivist can be contacted via: Daniel.Heather@nhs.net

8.4 What records should be archived?

The minimum list of essential documents that must be retained at a site will differ depending on the type of clinical research being conducted. Please see the JRO RSS RMG SOP 13 Site File. This contains lists of the minimum essential documents required for different study types.
Consideration should be given to the following record types where applicable to the research (e.g. CTIMPS)

8.4.1 Pharmacy Records

In instances where a pharmacy file has been generated (e.g. a CTIMP), the PI or delegated DM/RN 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) and transfer these into the custody of the PI. These should then be archived alongside the investigator site documents.

8.4.2 Patient Hospital/Medical Notes

All trial patient hospital/medical notes should be clearly labelled to indicate that the patient was involved in a clinical trial. Records should be retained in accordance with the maximum period of time permitted by the hospital. After being appropriately labelled, the files should be transferred back into UCLH’s centralised Health Records System. More details are available via the UCLH intranet at: http://insight/departments/other/ICT/ICTRecords/MedicalRecords/Pages/default.aspx

8.5 How should records be archived?

Depending on the nature of the research (sponsor identity, status of the CI etc.) records should either be transferred offsite into external storage (via the Trust’s commercial storage provider Iron Mountain) or into the custody of UCL Records Office.

**Please note:** You will require access to a UCL managed computer and a UCL account in order to use the UCL Records Office software for transferring records.

In the first instance please contact Daniel.Heather@nhs.net who will be able to provide advice on the relevant archiving route for your study.

8.6 Archiving electronic documents

The majority of records produced as a result of research will be in hard-copy (paper format) and should be retained in hard-copy format for the duration of their archiving period. To ensure the completeness of the research records any relevant communications (containing evidence of decisions) held in electronic format (e.g. email) should be printed prior to archiving.

For additional guidance on records held on electronic media e.g. DVD-R/CD-R please contact the JRO.

**Please note:** In no circumstances should patient notes be transferred offsite with investigator site documents (either to UCL or Iron Mountain). Instead these should be stored via UCLH’s centralised Health Records System.

In all instances, whether the site file is archived on-site or off-site, the sponsor should be made aware of the location where the records have been archived.

8.7 For how long should records be retained?

It is the responsibility of the sponsor to determine how long the investigator site should retain their records. The minimum applicable retention period should be stipulated in the site agreement or study protocol. In all instances the site should not destroy any records without
the explicit permission of the sponsor and should take measures to ensure the accidental
destruction of records does not occur.

In instances where investigator site records are transferred into the custody of UCL they will
determine when the records are ready for disposal. They will seek the investigator’s
approval prior to destruction.

Specific retention guidance applies to clinical trials of investigational medicinal products
(CTIMPS). If further clarification is required please contact the R&D Archivist via
Daniel.Heather@nhs.net

9. IMPLEMENTATION & TRAINING

This SOP will be implemented according the procedure agreed by the Approvals
Development Group. It will also be disseminated via face-to-face training delivered to PIs,
Research Nurses and Data managers as appropriate. For ad-hoc training requests please
contact Daniel.Heather@nhs.net.

10. PUBLICATION & COMMUNICATION

This SOP is published on the JRO website: http://www.ucl.ac.uk/jro/ and can also be found
at G:\RM&G Team\NIHR RMG RSS SOPs\ Final; and S:RMG\NIHR RSS SOPs

11. REVIEW

SOPs will be reviewed every 2 years unless an earlier review is required.

12. REFERENCES

JRO Website
http://www.ucl.ac.uk/jro/

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digita
lasset/dh_4122427.pdf

NIHR RSS Framework (including Appendix 1 – Glossary of Terms and Acronyms)
http://www.nihr.ac.uk/systems/Pages/RSS_Documents.aspx

13. SIGNATURE PAGE

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