RD&I	NHS University Hospitals Plymouth NHS Trust **STANDARD OPERATING PROCEDURE**

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

The definitive versions of all UHPNT RD&I Dept SOPs appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Trust's website: https://www.plymouthhospitals.nhs.uk/researchers

Archiving

SOP No: SC2

Version No: 5.1

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Page: **1** of **15**

Last Review Date: Jan 2019 Next review date: Aug 2020

	APPROVED BY
Name:	Chris Rollinson
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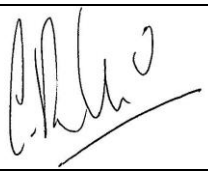
Signature:	
Date:	18th Jan 2019

1 Purpose and Scope

The purpose of this SOP is to define the local procedure for preparing clinical study records at an investigational site conducting a study sponsored, co-sponsored or hosted by one of more of the Partner Organisations, and for their subsequent transfer to archive as required in the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments and the UK Policy Framework for Health and Social Care Research (2017).

All essential documents relating to the clinical study must be archived in accordance with this SOP and the requirements of the UK Regulations.

1.1 For Clinical Trials of Investigational Medical Products (CTIMPs) and Devices carried out under MHRA authorisation:

- For at least 5 years after the completion* of a clinical study, as defined by the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006

Marketing authorisation holders must arrange for essential clinical trial documents (including case report forms) other than subject's medical files, to be kept by the owners of the data:

- for at least 25 years after completion or discontinuation of the trial,

or

- for at least two years after the granting of the last marketing authorisation in the European Community and when there are no pending or contemplated marketing applications in the European Community,

or

- for at least two years after formal discontinuation of clinical development of the investigational product as defined by the Medicines for Human Use (Fees and Miscellaneous Amendments) Regulations 2003).

or

- for 30 years in the case of an Advanced Therapy Medicinal Product (ATMP), as defined in SI 2010/1882. Advanced therapy products and miscellaneous amendments.

or

- As defined in the sponsor's protocol (as long as this supersedes the requirements of National law).

1.2 For non-CTIMPs the relevant documentation will be archived for a minimum of five years after the conclusion* of the study unless the funding body stipulates otherwise.

Documents can be retained for a longer period, if required by other applicable regulatory requirements or by educational establishments e.g. if a research project is part of a

student's study for a higher degree this maybe longer. Extensions of archive retention periods will be agreed with the study sponsor. It is the responsibility of the sponsor to inform the hospital, institution or practice as to when these documents no longer need to be retained.

A Clinical Trial participant's medical files should be retained in accordance with applicable legislation and in accordance with the maximum period of time permitted by the hospital, institution or private practice.

The sponsor or other owner of the data shall retain all other documentation pertaining to the trial for as long as the product is authorised.

- The final report shall be retained by the sponsor or subsequent owner, for five years after the medicinal product is no longer authorised.

It is vital that all study essential documents are maintained in a legible condition. Thus, plans for archiving should be made in the design phase of the study. Cost of storage may be appreciable over time and therefore these costs should be included in the study finances.

In scope: research hosted by, and/or sponsored by UHPNT.

Definitions

PI	Principal Investigators
CI	Chief Investigator
ATMP	Advanced Therapy Medicinal Product
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HCA	Health Care Assistants
HRA	Health Research Authority
MHRA	Medicines and Healthcare products Regulatory Agency
REC	Research Ethics Committee
RD&I	Research Development & Innovation
RO	Research Office
SOP	Standard Operating Procedure
Source data	Consists of all information contained in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies) and are specific to each study. Documentation of source data is necessary for the reconstruction, evaluation,

	and validation of clinical findings, observations and other activities during a clinical trial. In multi-centre Sponsored CTIMPs, it is important for the documentation of source data to be standardised across all sites to ensure consistency of the trial data.
Source documents	include original documents, data and records such as hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial. Case Report Forms (CRFs) may be used as source documents only if specified in protocol.
Named Archivist	The person responsible for ensuring archiving requirements are met as defined and required in the Regulations.
Deputy Archivists	Appropriately trained individuals which support and cover the Named Archivist
End of Study	The completion or conclusion of a study will be the date of the study closure letter to the Research Ethics Committee (REC) or if a multi-site trial, where UHPNT is one of the research sites, the date of close out letter from the sponsor.
UHPNT	University Hospitals Plymouth NHS Trust

2 Who should read this document?

All staff involved in conducting research e.g. Chief Investigators (CI), Principal Investigators (PI), Research Nurses & Midwives, Health Care Assistants (HCA), RD&I Managers and Clinical Trial Administrative staff.

3 Procedure to Follow

3.1 Responsibility

It is the responsibility of the study sponsor and investigators to ensure that essential study documentation is retained after a study is completed.

The individual study protocol will outline the responsibilities of the team members for archiving and will detail for how long data must be retained. All studies conducted on trust premises will have their essential study documents stored in the Trust archive facility unless otherwise stated in the protocol. The Trust Named Archivist is the RD&I Research Governance Manager, and the Deputy Archivists are the Senior Research Support Facilitators.

3.2 Archiving procedure

At the end of the study after the closedown procedures have been completed and an end of study letter has been received.

When the Chief Investigator / Principal Investigator (CI/PI) has decided that it is appropriate to archive the study the Trust Named Archivist, or Deputy Archivists will be informed, by a member of the study team.

The Trust Named Archivist or Deputy Archivists will arrange for the delivery of the requisite number of storage boxes and box labels.

The actual archiving is to be carried out by a member / members of the study team under the direction of the CI / PI. All study documents should be archived together including pharmacy, laboratory, radiology and any other supporting documents (the only exception are medical records which will be held for the requisite time by the Medical Records Dept.). The Trust Named Archivist or Deputy Archivists will offer all reasonable advice / assistance to ensure that the task is carried out in accordance with this SOP.

For each study an Archive Document Log is required to be completed to record all documents that are archived in each box used, this should also include the expected date for the documents destruction (Appendix 2).

Only essential documents are to be archived. All files, folders and outer protective coverings, paperclips, and adhesive tape need to be removed before placing in the archive box.

Only one study should be archived per box.

For each study a copy of the completed Archive Document Log is to be filed within the relevant archiving box prior to being deposited with the Trust Named Archivist, or Deputy Archivists.

Once the CI / PI is satisfied that all relevant documents for the study have been archived, the Trust Named Archivist, or Deputy Archivists are to be informed in order to arrange for the boxes to be collected (see Appendix 1 Flowchart of archiving procedure).

3.3 Duration of Archiving

The Sponsor and Investigator should consider whether the results of a study will, or may be included in a marketing authorisation application (CTIMP and Medical Device Studies) and should take the necessary steps to ensure the retention of the essential documents for the requisite time.

Studies that are not to be used in regulatory submissions.

Essential documents from studies that are not to be used in regulatory submissions should be retained for a minimum of five years after completion of the trial. This is the minimum retention period and may be extended if required. This maybe at the request of the funding body, University (in the case of research done for the higher degrees) or if a

researcher or research group thinks that the source study data may be revisited at some in the future for further analysis.

3.4 Retrieval and Return of Archived Items

Only the Trust Named Archivist and Deputy Archivists can authorise and arrange the retrieval of any item and / or box from the Trust's archive facility, on receipt of a request from the CI, PI, or designated team member by e-mail or letter.

The CI, PI, or designated team member is to advise, by e-mail or letter to the Trust Named Archivist or Deputy Archivists when the item / box is ready to be re-archived.

Study documents must be available at all times for inspection by the Competent Regulatory Authority i.e. the MHRA.

3.5 Destruction of Archived data

For UHPNT Sponsored studies, the Trust Named Archivist, or Deputy Archivists will endeavour to notify investigators in writing before study records are destroyed. It is not always possible to contact the investigators as they may have left the Trust in which case the Trust as sponsor will authorise the records destruction.

For studies that UHPNT host, but do not sponsor, on reaching the agreed retention period if a sponsor does not contact UHPNT, a destruction request will be sent by the Trust Named Archivist, or Deputy Archivists to the last identified sponsor contact. If they have not responded within the timeline stated then the request for destruction will be implemented.

Documentation will be destroyed by security shredding by the Trust's Incinerator Department. A certificate of destruction will be issued by RD&I. The certificate of destruction should be retained for a further five years from the date of destruction.

Care should be given in particular to the storage and destruction of personal data which is subject to the applicable terms of the Data Protection Act 2018.

3.6 Disaster Recovery

In the event of:

a. Fire
b. Water damage or
c. Pest infestation

The Named Archivist, and Deputy Archivists will see if any documents can be recovered. In some cases documents may be recoverable with the assistance of a document restoration service. The Named Archivist, or Deputy Archivists will arrange collection of all documents that may be recovered or restored. For all records that have been lost a file note will be produced and forwarded to the sponsor and regulatory authority (if study

required regulatory approval) explaining what happened and which documents have been lost.

3.7 Closure of the Archive

In the event of the closure of the currently used archive facility, it is the responsibility of the Trust Named Archivist, or Deputy Archivists to ensure that an alternative facility is found in good time, and the archive is safely transferred to the new facility.

3.8 Location of the Trust Research Archive:

Bush Park Central Medical Records, Bush Park, Estover, Plymouth, PL6 7RG

4 Document Ratification Process

The review period for this document is set as ***default of three*** years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the ***RD&I Manager or their Deputy***.

Non-significant amendments to this document may be made, under delegated authority from ***a Senior RD&I manager***, by the nominated author. These must be ratified by ***a Senior RD&I manager***.

Significant reviews and revisions to this document will include a consultation with ***appropriately knowledgeable staff***. For non-significant amendments, informal consultation will be restricted to ***staff*** who are directly affected by the proposed changes.

Dissemination and implementation

4.1. Dissemination of this SOP

4.1.1. New SOPs and new versions of existing SOPs: The Research Governance Manager will be responsible for ensuring authorised SOPs are uploaded on the RD&I intranet site. Internal Trust Staff are expected to use the RD&I intranet site to access latest versions of SOPs and to check the website regularly for updates.

Notice of new or amended procedural documents that have undergone a major amendment will be given *via* the following routes:

- Inclusion in the Trust weekly e-bulletin Vital Signs
- Direct email to Trust Researchers and or teams

4.2. Training in this SOP

4.2.1. All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

5 Reference material

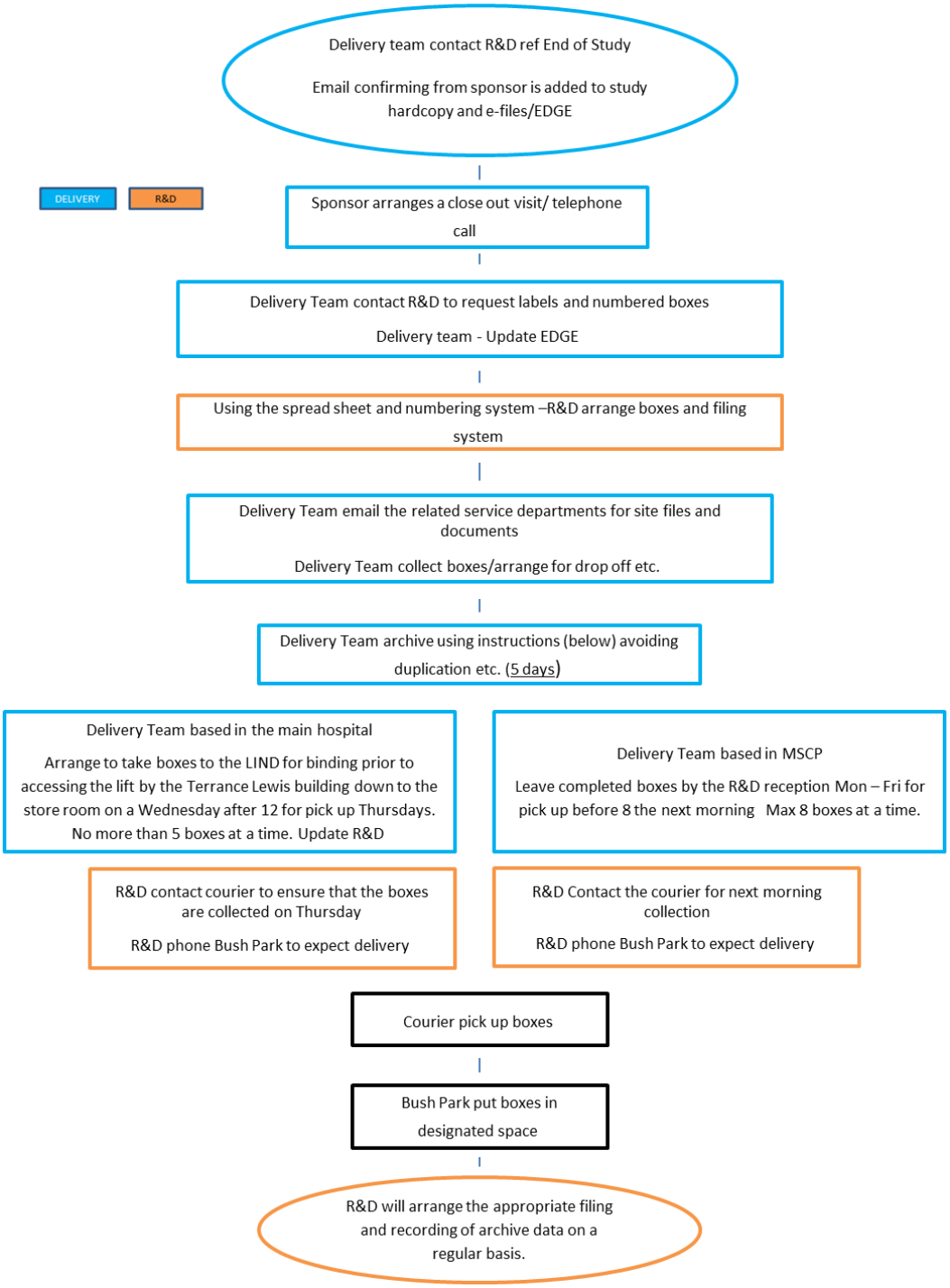
The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006

The Medicines for Human Use (Fees and Miscellaneous Amendments) Regulations 2003)

DoH - Research involving the NHS: retention of records, March 2007

DoH - Records Management NHS Code of Practice Part 2 (2nd Edition)

Appendix: Flowchart of Archiving procedure | Appendix 1



DELIVERY R&D

1. Delivery team contact RD&I ref End of Study – Delivery team should have confirmation by email letter from the sponsor to confirm this. If the study is due to close on EDGE, the delivery team should contact the sponsor to confirm the actual close date before archiving anything.
2. Once received - the email/letter confirming from End of Study from the sponsor should be added to study hardcopy and e-files and uploaded to EDGE (delivery team)
3. RD&I generates a 'Close Out Letter' confirming the actual archive date (e.g. in 25 years) – RD&I sends to the sponsor/delivery team to be signed during the close out visit.
4. Sponsor arranges a close out visit/ telephone call directly with the delivery team. 'Close Out Letter' is signed – copy is taken and added to the archive box. Original 'Close Out Letter' sent to RD&I for filing
5. RD&I file original 'Close Out Letter'
6. RD&I sort through RD&I file and keep only RD&I related documents to be added to the box (the site file will have all the related study documents)
7. E-files will be destroyed or have limited access applied (Delivery Team and RD&I)
8. Delivery Team contact RD&I to request labels and numbered boxes and arrange to collect boxes (RD&I will help out where possible) and RD&I file
9. Using the spread sheet and numbering system –RD&I number the boxes correctly for filing at Bush park
10. Delivery team - Update the actual information and dates on EDGE
11. Delivery Team email the related service departments to prepare related documents for archive
12. Service departments sort the files so that only service department related study documents are stored (collect/dropped off)
13. Delivery Team archive using SOP /instruction (below) - avoiding duplication etc. (5 days)and adds signed copy of 'Close Out Letter'

For staff based in the main hospital

14. Move boxes to the Lind Centre
15. The Binding machine is used to secure the boxes
16. Delivery team access lift by the Terrence Lewis Building INSERT DETAILS HERE (under hospital near stores) **for after 12 on a Wednesday**
17. The delivery Team update RD&I that the boxes are waiting to be taken to Bush Park
18. RD&I contact courier to ensure that the boxes are collected on the next day (Thursday) Ring 35460 to arrange a collection
19. RD&I phone Bush Park to update them and to expect delivery - Bush Park contact is Jon Rowland's 37096

For Staff Based in the MSCP

14 The Binding machine is used to secure the boxes
15 Boxes are left, to the left hand side of the RD&I reception for pick up next morning (pre 8am)
16 The delivery Team update RD&I that the boxes are waiting to be taken to Bush Park
17 RD&I contact courier to ensure that the boxes are collected on the next day (Thursday). Ring 35460 to arrange a collection
18 RD&I phone Bush Park them to update them and expect delivery - Bush Park contact is Jon Rowland's 37096
19 Courier pick up boxes
20 Bush Park put boxes in designated space – over on the far wall @Bush Park
21 RD&I go over with the IPAD once a month to file in the correct place – final check to boxes (return if not completed correctly)
22 RD&I check to see which boxes can be destroyed
23 RD&I contact the sponsor to confirm (if 'Close Out Letter' is not generated) – 2 weeks given to respond
24 RD&I destroys relevant outdated boxes monthly.

Archiving Instructions (*aide-memoire*)

- Any faxes/e-mails that are on thermal paper to be copied onto standard paper prior to archiving
- Check other departments for documents- pharmacy, nuclear med, RD&I etc

The following **MUST** be removed prior to archiving:

- Lever arch files
- Plastic wallets
- Paper clips
- File dividers (card and plastic)
- Rubber bands
- **All** duplicate documents
- **Bind boxes using the binding machine**

Please ensure that **ALL** study documents are archived at the same time, as our archiving facility is offsite, and filing documents at a later date is an inconvenience.

Please ensure boxes are **NOT** overfilled.

*Please contact 39992 or 32196 for help

Appendix: Archive Document Log — Appendix 2

Study Name:

Unique box reference no:	Sponsor:
MREC no: UKCRN:	EudraCT number:

CI / PI:	RD&I number: IRAS number:

Packer's name / job title:	Signature & date:
Expected date for study document destruction: _ _ _ / _ _ _ _ (Month / Year)	

DATED DOCUMENTED APPROVALS	Tick if archived	DATED DOCUMENTED APPROVALS	Tick if archived
Protocol Current Previous versions	☐ ☐	**Consent Forms** Sample Signed versions	☐ ☐
CRFs Sample Signed versions	☐ ☐	**Patient Information Sheets** Sample Signed versions	☐ ☐
Correspondence	☐	**GP Letter**	☐
Investigator Brochure/SMPC Current IB Previous IB's Current SmPC Previous SmPC	 ☐ ☐ ☐ ☐	**Personnel Docs** CVs GCP certs Delegation log Training log Letter of access/honorary contract	 ☐ ☐ ☐ ☐ ☐
UHPNT RD&I Approval Letter	☐	**IRAS Form/s** (Including, NHS RD&I, REC, IRAS, SoA and SoE)	☐
Regulatory Approvals MHRA REC Other	 ☐ ☐ ☐	**Screening** Screening log template Completed screening log	 ☐ ☐

DATED DOCUMENTED APPROVALS	Tick if archived	DATED DOCUMENTED APPROVALS	Tick if archived
Enrolment Enrolment log template Completed enrolment log	☐ ☐	**Randomisation/Unblinding procedures**	☐
Recruitment Advertising Approved advert material	☐	**File notes**	☐
Safety Reporting SAEs SUSARS Protocol violations Monitoring Annual Reports End of study notification	 ☐ ☐ ☐ ☐ ☐ ☐	**Legal Documentation** CTA/Contract MTA Insurance Sponsorship letter Finance schedule Matrix of responsibilities	 ☐ ☐ ☐ ☐ ☐ ☐
Pharmacy file Including samples of labels/prescription/instructions, return forms, SOP's on destruction etc	☐	**RD&I Office File** Including all study set up documents	☐
Laboratory Accreditation certificate Ranges Other relevant lab documentation	 ☐ ☐ ☐	**CT Office File** Including CTA, invoices and correspondence	☐
Please use the space below for any additional documents			

6 Amendment History

Version Number:	5.1
Date Of Amendment:	Jan 2019
Details Of Amendment:	Updated Trust and Dept. name. Reduce signature requirement to single senior RD&I Manager. Updated references to the Data Protection Act 2018 and the UK Policy Framework for Health and Social Care Research (2017).

Version Number:	5.0
Date Of Amendment:	Aug 2017
Details Of Amendment:	Updated SOP template and numbering system. Reviewed and updated SOP.

Version Number:	4.4 (minor amendment)
Date Of Amendment:	Apr 2017
Details Of Amendment:	Sections 3.0 and 3.1 relating to procedure have been updated for clarity, and section 6.2 removing the word ‘barcodes’ Appendix 1 Archiving log has been updated. The entire document has been updated and an audit finding as to who the SOP applies to and who should read it has been addressed.

Version Number:	4.3 (minor amendment)
Date of Amendment	Nov 2015

Details of Amendment	Updated. Added the following definition in section 4.0 Deputy Archivists- Appropriately trained individuals which support and cover the Named Archivist. Updated the document throughout with 'Deputy Archivists' Updated section 6.15 to clarify destruction of archiving data Redesigned the Archiving Document Log (see Appendix1) to help improve the archiving process for the research study teams.

Version Number:	4.2 (minor amendment)
Date of Amendment:	Nov 2014
Details of Amendment:	Change - The Trust Named Archivist is the RD&I Research Governance Manager also added Archive Facility location

Version Number:	4.1 (minor amendment)
Date of Amendment:	Nov 2010
Details of Amendment:	Cover page - Change of SOP location address.