Document Title: Archiving of Research Studies

Document Number: PTUC SOP011

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Summary of Amendments

Version Number	Modification:
Version 9.0	Minor changes throughout document.
Version 10.0	Minor changes throughout document.

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff who are involved in the archiving of research study documentation.
- It provides clear guidance on the archiving and recalling of all essential documents related to research studies where Royal Papworth Hospital is responsible for archiving.

1 Purpose and Contents

a. This document defines the Trust's procedures for the archiving of study related material for Research Studies managed by Royal Papworth Trials Unit Collaboration (PTUC), sponsored by Royal Papworth NHS Foundation Trust or for hosted studies where archiving responsibility is delegated to Royal Papworth Hospital.

b. This document details the requirements for demonstrating the appropriate archiving of research documents as described in Good Clinical Practice (GCP: 'a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of research studies that provides assurances that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected').

c. This document provides guidance on the process involved in the archiving of research documents upon completion of a study so as to comply with the Trust's policies on Information Governance, Data Protection, Case Note Retention and Storage of Patient Records.

2 Roles & Responsibilities

a. This Policy applies to research that is conducted at the Trust and studies managed by PTUC.

b. Staff involved in the archiving of research must comply with the requirements set out in section 4.

c. The Sponsor of a research study is responsible for arranging the archiving of the study related material. This can delegated to another organisation e.g. PTUC or Royal Papworth Hospital for non-Royal Papworth sponsored studies

d. The actual procedure will be delegated to an appropriately experienced member of the Royal Papworth Hospital R&D staff.

e. The exact arrangements for archiving will be decided on a study-by-study basis. Participating sites may be responsible for archiving their own site's records in accordance with any participating site agreement.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with may result in disciplinary procedures.

4 Procedure

4.1 Archiving Considerations

a. Arrangements for archiving should be agreed during the study set-up or contract negotiations prior to the commencement of the study. These will include who is responsible for the archiving for non-Royal Papworth sponsored studies, costs, duration and where study documents will be archived.

b. Source data within the patient health care record is stored in accordance with Trust Procedures. An alert must be placed on a patient's health record to show the patient is taking part in a study and the date destruction of the health record is allowed.

c. For studies where Royal Papworth Hospital is deemed responsible for the archiving the following SOP must be followed. For multi-centre studies managed by PTUC or sponsored by Royal Papworth Hospital, arrangements must be made for the data to be archived at each site. See section 4.4 below.

d. Paper materials and electronic media should be archived off-site with an archiving company that has been audited by Royal Papworth Hospital. This will ensure that the requirements for security, access, and protection against external damage are met. All media (both Paper and Electronic) should be stored in a suitably controlled environment and this should be documented in the pragmatic risk assessment.

e. For CTIMPs, if electronic media contain primary outcome data then they must be stored in an appropriate environmentally controlled archive facility. For secondary outcomes and all other studies a risk assessment should be undertaken to identify where the media can be stored.

f. If data are stored on electronic media, consideration should be given to storing in differing formats on different types of media or even on the same media from different manufacturers. The decision of how this is to be done, or a reason if not deemed necessary, should be documented on the pragmatic risk assessment (CTIMPs) or via a note to file (non-CTIMPs).

g. If the media used to store the data may potentially deteriorate or become obsolete; the transfer of data to new media should be taken into consideration. It is also advised periodic tests are undertaken to confirm the on-going availability of the data

h. Where data are required to be migrated to new media or a new format, then the transfer should be validated and fully documented, so that it could be subject to an audit, to ensure and demonstrate that there has been no loss, changes or corruption to the data and that authenticity is maintained.

i. For eTMF / electronic files, the data should be archived on the N Drive in accordance with section 4.3.e below; as this folder is subject to a backup, with the backup media stored in a separate location.

j. The electronic documents or data that have been archived must be protected from unauthorised changes to maintain authenticity.

k. Future access to records and data should be maintained. If migration of data is required IT may need to be contacted in order to assist with any formatting to ensure the continued access with new software.

l. All essential documents (as defined in the GCP Guidelines) must be archived.

m. Unless otherwise specified the documentation should be retained for a minimum of 15 years from the date of completion of the study.

n. Archiving arrangements should enable the prompt retrieval of records if required for any audit or inspections that may subsequently take place.

o. Access to archived data must be suitably restricted by user access.

4.2 Timing of Archiving

a. Research projects managed by PTUC or sponsored by Royal Papworth NHS Foundation Trust should be archived following study completion, database lock and publication.

b. All other studies should be archived as soon as possible after the trial close-down visit in accordance with the Sponsor's instructions.

4.3 Archiving Procedure

a. The Study Team must inform the Archiving Administrator of the intention to archive the study.

b. The R&D No., short title, Chief and Principal investigators, Sponsor, Funder(s), Research Group, Date the study closed, whether or not there are electronic media being archived

and the Destruction Date should be recorded on the R&D archive database by the Archiving Administrator.

c. An R&D Archive Number will be allocated by the Archive Administrator.

d. The paper and electronic media will be archived as follows:

1. All relevant paper documentation will be removed from box files, ring binders and plastic wallets.

2. All metal objects such as paperclips will be removed (except staples).

3. The only documents to be archived containing patient identifiable information should be the consent forms and the identification code list/enrolment log and randomisation log. These must be placed in a white archiving envelope, labelled with the contents. It will be sealed at both ends with a Royal Papworth R&D sticker which has been signed and dated to prove that it has not been tampered with during storage.

4. All other patient study documents should be anonymised ensuring they are labelled with at least the patients study ID number. Study ID, DOB and Initials are not considered patient identifiable information, so can be used on documents.

   For paper records patient identifiable information on a CRF must be redacted by scoring through with a black out marker. These should be placed in brown archiving envelopes, labelled with the contents.

   For electronic records patient identifiable information on a CRF should be redacted by either deleting the identifiable information or using one of the methods shown in Appendix 2.

5. In the event of the study having any media to be stored, these should be placed in an envelope within the archiving box unless there are special storage requirements. The archiving database must be updated with the type of media being held.

6. A complete a contents page (Appendix 1) must be placed in the archiving box.

e. For studies using the Royal Papworth Hospital eTMF system the data will be archived as follows:

1. Original paper documents that have been scanned on the eTMF scanner to generate a certified copy for retaining in the eTMF can now be discarded (if not done so already). Case report forms (CRF's) can be scanned with study ID, DOB and Initials on

ONLY. Any patient identifiable information on a CRF must be redacted prior to scanning.

2. The patient screening/randomisation logs will be printed off for paper archiving – these can be deleted from the eTMF once this has been completed. These are to be archived in accordance with 4.3.d.3. .

3. All emails must be saved as a PDF document before storage.

4. All electronic data to be archived must be anonymous. Study ID, DOB and Initials are not considered patient identifiable information, so can be used on documents. Copies of documents that have been uploaded to the patients electronic health record e.g patient letters, GP letters can be deleted from the eTMF prior to archiving.

5. Documents that may have been received from outside the Trust with unavoidable patient identifiable data should be saved to EDMC (previously called EMR), these should not be filed in the eTMF (e.g., GP summaries as part of an AE follow up).

6. The following minimum paper documents must be archived:

   Signed patient Informed Consent forms;
   Delegation Log;
   Screening Log / Randomisation Log (see 2 above);
   Signed protocol signature page (For all approved versions and amendments);
   Signed contracts (title page and signature page);
   Training Log;

   These should be archived in accordance with 4.3.d.3.

7. Electronic files and correspondence must be collated by a suitably qualified member of the study team.

8. Once the eTMF is ready for archiving it must be moved from N:\Shared\R&D PROJECTS to N:\Shared\R&D PROJECTS ARCHIVE by an authorised member of staff. An up-to-date list is kept by the R&D Admin team (papworth.randdadmin@nhs.net).

f. Only archiving boxes provided by the responsible party should be used. They will be secured with tape.

g. The archiving company's own labels, must be used following their instructions.

h. The R&D archiving database must be updated by the Archive Administrator and any retrieval forms kept in the Post Archiving file in R&D.

i. The status of the study should be updated to 'Archived' on the R&D database.

j. The study should be marked as archived on the Trust Asset register and the Information Governance team informed. **In order to archive and remove from the asset register there must be no patient identifiable information in the electronic study file or it must remain on the asset register.**

4.4 Archiving for a Royal Papworth sponsored multi-site study – Paper documents

a. For sites participating in studies managed by PTUC or sponsored by Royal Papworth Hospital this archiving SOP must be followed, unless an arrangement has been made with the site to follow their own archiving SOP. This discussion must be documented. The current archive storage is provided by Kelly's storage (Guildford).

b. The archiving administrator will provide each site with:

1. Labels;
2. A4 White envelopes;
3. Large brown archiving envelopes;
4. Contents page;
5. Kelly's storage box (es) depending on the archiving to be completed;
6. Kelly's bar code sticker for each box sent. These should be photocopied for reference;
7. Box seals.

c. All sites must comply with the procedures above.

d. Royal Papworth will require the Barcode numbers and the date of archiving for the archive database.

e. A contents list should be completed by each site. A copy must be taken of the contents list by each site for their records. All envelopes should be placed in the archive box along with a copy of the contents list. Once this is completed, the archive administrator should be contacted to arrange a date for collection by the archive company (papworth.randdadmin@nhs.net).

f. In the event of the sites requesting their documentation from Kelly's archives the sites are requested to inform the sponsor that they are doing so by emailing Royal Papworth: papworth.randdadmin@nhs.net. The cost of retrieving archived material is the responsibility of the individual site not the sponsor.

4.5 Audit

a. The archiving boxes, prior to submission to the offsite facility, will be subject to audit by R&D QA as part of the routine Audit programme. This is to ensure that the boxes contain the correct documentation and comply with the requirements of this SOP. This will be documented on the CAPA database under the audit tab as per the Auditing standard operating procedure SOP (SOP063: Research and Development: Internal Good Clinical Practice (GCP) Audit).

b. The offsite archive facility will be audited every three years. The visit will include, but will not be limited to:

1. Inspection of the site;
2. Inspection of a random selection of Royal Papworth archived boxes including both paper and electronic media; the results of this will be documented on the CAPA database under the audit tab;
3. Review of archive providers procedures;
4. Discussion regarding any issues experienced.

c. A report detailing the audit will be written by R&D QA and submitted to R&D Senior Managers' group for review where if any issues have been identified a strategy for resolution of these issues will be drawn up. The site audit report will be filed within the QA electronic folders.

4.7 Retrieval of Records

d. If an Investigator wants to retrieve a study from the archive, they must coordinate access through the R&D archive administrator (email: papworth.randdadmin@nhs.net) so as the whereabouts of archived material can be tracked via the R&D Archive database. Retrieval Form FRM059 should be completed.

e. The archive administrator will co-ordinate the retrieval of boxes from the off-site archive and delivery to the required location (whether Royal Papworth Hospital or the appropriate site location). All movement of archive boxes will be logged on the Archive database.

f. Any changes made to documentation in the archive box must be detailed.

g. The archive administrator will arrange for the box to be returned to the archive facility when requested by the investigator, and this will be logged on the archive database.

5 Destruction of Records

a. Study documentation will be kept until the agreed destruction date in line with GCP requirements. The archive administrator will contact the sponsor and chief investigator; to gain permission for destruction of documentation.

b. If the CI cannot be contacted for confirmation regarding the destruction of the records, then the sponsor will confirm this and the records will be destroyed after the allotted time. If in the event the sponsor or company no longer exist then the R&D clinical director will give permission for the destruction of records. A Destruction Certificate can be obtained from the intranet under FRM060.

c. Paper study documentation will be destroyed in accordance with Royal Papworth's policy on confidential waste.

d. Studies with an archived eTMF will be deleted from the N drive "R&D projects Archive".

e. A certificate of destruction, if required, is available from the R&D Department.

6 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual research studies and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Appendix 1

Archived Documents

R&D PROJECT NO	
PROJECT TITLE	
ETHICS NUMBER	
PROTOCOL ID	
CRO/SITE NUMBER	
SPONSORS	
PRINCIPAL INVESTIGATOR	
ARCHIVE BOX NUMBER (e.g. box 1 of 1)	
DATE STUDY CLOSED	
DO NOT DESTROY BEFORE	

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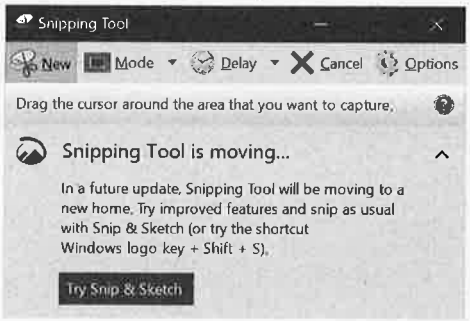
Appendix 2

Easy way to anonymise screenshots.

Make sure the screen you want to copy is visible.

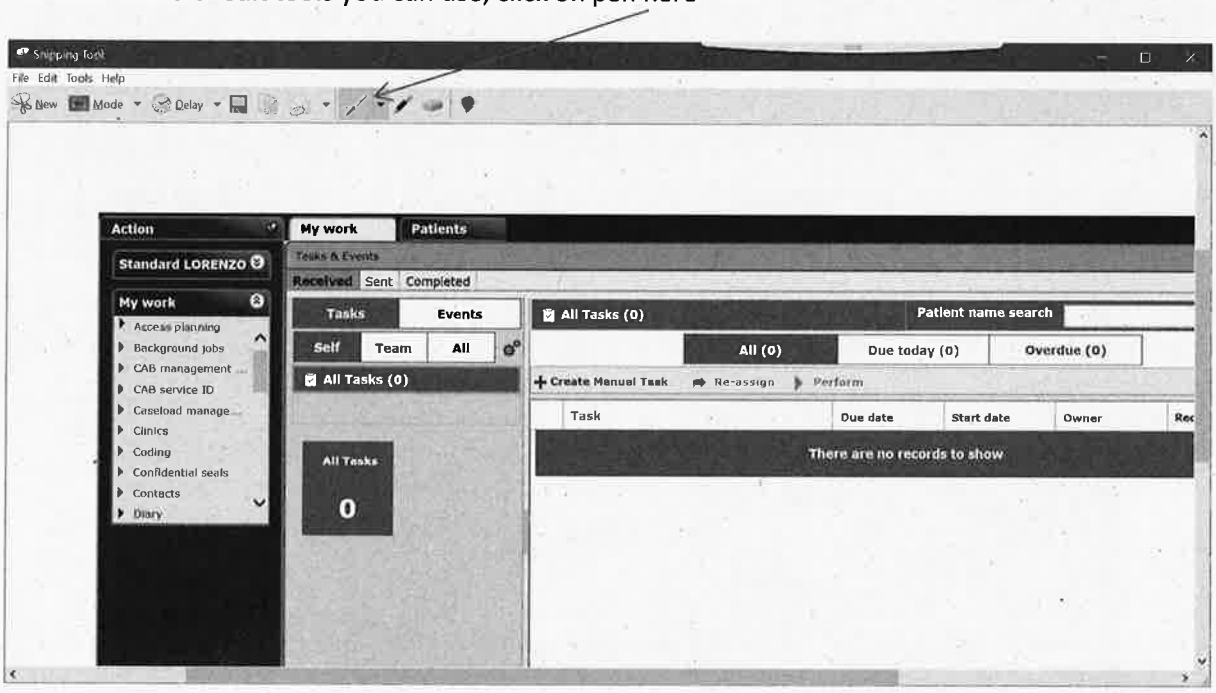
Use the SNIP tool  to copy the screen area you want.

Click on "New"

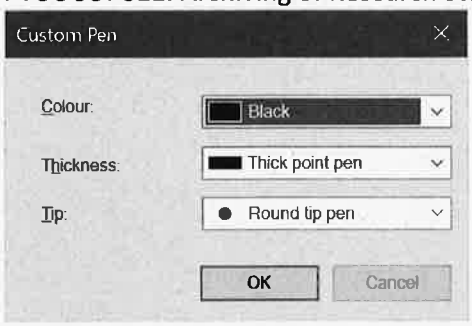


Use the cursor to highlight the area you want to copy and you will see the area in the snipping tool.

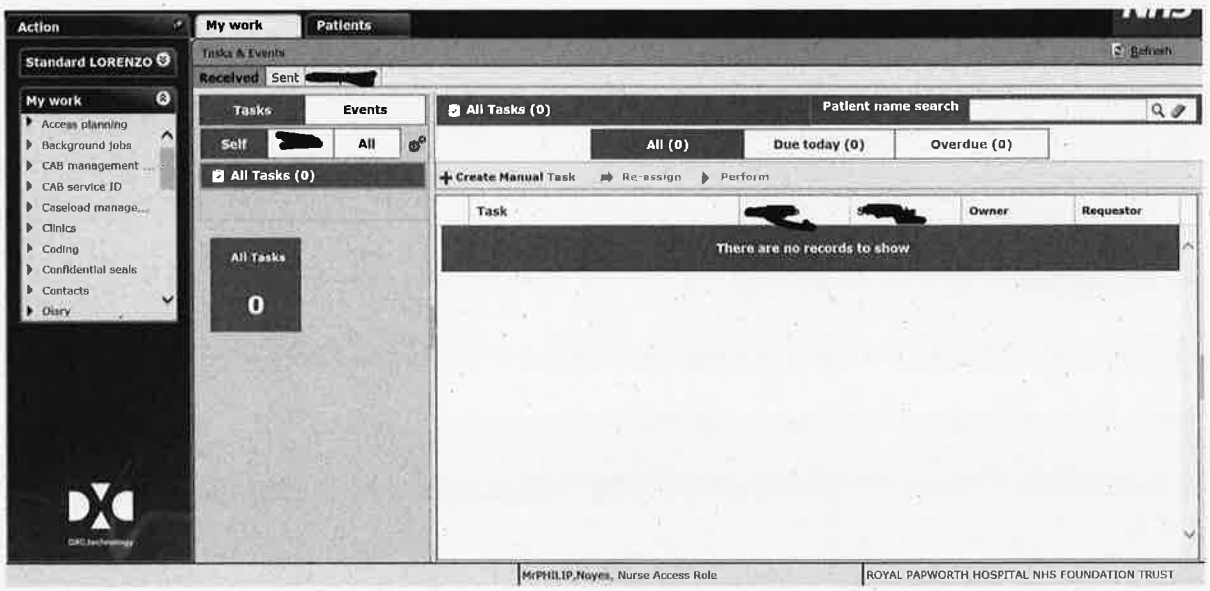
There are several edit tools you can use, click on pen here



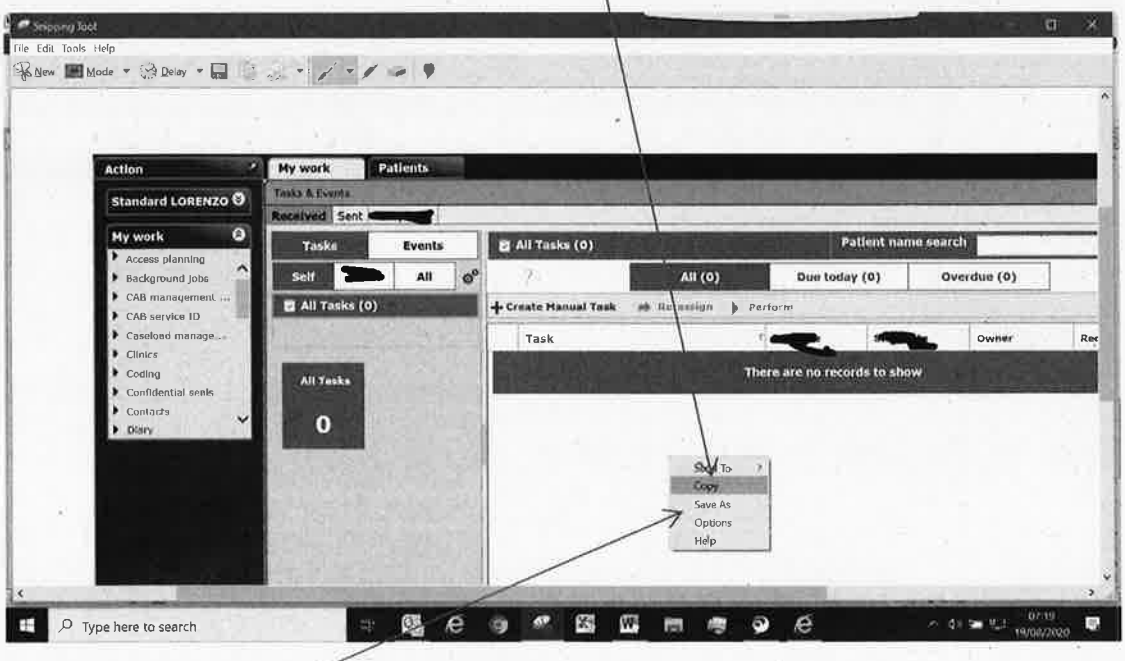
Select Custom Pen, then Customise. Select these choices:



You can then blank out the areas you want



Then either right click on the image and choose copy. You can then right click to paste directly into Word.



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Documents should then be **saved as a PDF** document for checking.

PTUC SOP011: Archiving of Research Studies
Further Document Information

Approved by: *Managment/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Research studies) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2018)
Key related documents:	Trust Research Policy

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	No	No	No	No	No	No	No
Positive/Negative							

Review date:	December 2023

I certify the contents of this SOP has been reviewed and ratified

..... 3rd December 2020.

Signed by Dr Ian Smith, Clinical Director of R&D Date

SOP release date: 16th December 2020