Royal Papworth Hospital NHS Foundation Trust

Document Title: Archiving of Research Studies

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Summary of Amendments

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

Version 11.0	Major changes to the document Section 4.3 Discussion with Information Governance Manager: Documents to be archived no longer have to be anonymised prior to sending to MHRA accredited archiving facility Section 4.3 eTMF's for archiving will be moved from N drive R&D projects to N drive R&D Projects archive by eTMF lead or Monitoring & Audit Co-ordinator. Section 4.3 Asset Register – defines process for Asset Register Archiving
Version 12.0	Addition of detail at section 4.1j regarding archiving a full download of the trial database
Version 13	Administrational changes made to 4.3 d)6
Version 14	Section 4.1 Clarification around the data sharing agreement for NHS digital data and the archiving of data from OpenClinica. Section 4.3 Clarification for when to use the scanner and generating certified copied for archiving Section 5 changes to where the destruction of records can take place

Key related documents:	Trust Research Policy DN662 Record Appraisal and Disposal Procedure SOP063: Research and Development: Internal Good Clinical Practice (GCP) Audit GD057 OpenClinica Database Hosting and Storage FRM059 Archive Retrieval Form FRM060 Archiving Destruction Certificate

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 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 be 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.

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 and non-CE marked device studies, 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. NHS digital data: On or before the effective date of termination or expiry of any DSA (Data Sharing Agreement), the Recipient must ensure that all Data licensed under that DSA is securely and permanently destroyed or erased, save where agreed in a replacement DSA for the Data to be retained. On completion of the activity in Clause 14.1, the Recipient shall promptly, and in any event within 28 days of the date of termination or expiry of this Contract, or any DSA, provide confirmation of the secure and permanent destruction to NHS England in the form of a Certificate of Destruction. (The maximum term of a DSA is 3 years only. You can apply for a renewal of the DSA if you can justify needing to have the data for an extended length of time, however this is very costly).

g. 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).

h. Electronic media should be documented on the archiving database. The following should be documented:

- Format (e.g. hard drive, CD, USB Drive/memory stick)
- The contents of the media
- Which numbered box the electronic media has been placed in
- If the electronic media is password protected

i. 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.

j. 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.

k. 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.

l. For studies managed by Papworth Trials Unit Collaboration (PTUC) or sponsored by Royal Papworth NHS Foundation Trust, a full download of the database must be made once the database is locked for analysis and this must be filed within the eTMF to ensure a back-up of the trial dataset (GD057 OpenClinica Database Hosting and Storage). This will be archived within the eTMF in line with the procedure detailed below at section 4.3e.

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

n. 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.

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

p. Unless otherwise specified the documentation should be retained for the period specified in the contract and / or the period required by the regulatory authorities (whichever is the longest).

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

r. 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 consent forms, identification code list/enrolment log and randomisation log 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 placed in brown archiving envelopes, labelled with the contents.

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. For a CTIMP using the paper format that has a corresponding electronic e-TMF, the e-TMF must be electronically archived (please see section e below) once all relevant paper documents have been printed and filed in the paper sponsor and site file (this should include correspondence, and any relevant document from the working documents folder).

7. Conduct a final QC of the paper file/s to check: all paper documents are filed in the appropriate sections of the sponsor/site file. No essential documents remain in the working documents folder. All correspondence has been filed. Ensure paper documents with unavoidable patient identifiable data have been scanned and saved to EDMC where possible or redacted where possible.

8. A complete 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 shredded – this needs to be agreed on a study by study basis. (see section 4.3.e.5 for the list of paper documents to be retained - these can be scanned for storage in the eTMF but MUST NOT be shredded). Case report forms (CRF's) can be scanned and then shredded (ONLY if applicable).

2. The patient recruitment logs will be printed off for paper archiving and the electronic version retained and electronically archived. These paper logs are to be archived in accordance with 4.3.d.3.

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

4. 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).

5. The following minimum paper documents must be archived:

   Signed patient Informed Consent forms
   Delegation Log
   Screening Log / Randomisation Log (see e.2. above)
   Signed protocol signature page/acceptance 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.

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

7. If the e-TMF has a corresponding working documents folder, the EOS team should reconcile the documents in the working documents area to ensure all essential documents have been filed in the Sponsor or Site File.

8. Governance (for gov team only) folder must also be archived along with the eTMF (can remain as a standard working documents folder without the need for conversion to pdf etc.).

9. 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 either the TMF lead or the QA Team. The Archiving Administrator will be informed by the eTMF lead or the QA Team when this happens. An up-to date list is kept by the R&D Admin team (papworth.randdadmin@nhs.net).

10. Papworth Sponsored multi-centre studies: If sites are using the Papworth eTMF or their own version of an eTMF, sites may archive this locally. Advice provided to the site on filing in a secure location on their computer drives, with limited access for the specified archiving period.

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 asset administrator must mark the study as archived on the R&D Asset register.

k. **The study team must inform Research Governance of the study end date to update EDGE.**

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 in section 4.4

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

a. If an Investigator wants to retrieve a study from the archive, they must co-ordinate 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.

b. The Archive Administrator will co-ordinate the retrieval of boxes from the off-site archive and/or from the R&D Projects Archive on the N drive 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.

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

d. 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.

c. Paper documentation for destruction can either be completed in house using the shred station or via Kellys.

d. Paper study documentation will be destroyed in accordance with Royal Papworth's policy on confidential waste (DN662).

e. If boxes contain digital data (disks/flash drives/memory sticks), they will be destroyed in line with the study risk assessment.

f. Boxes for destruction held by Kellys: The Archive Administrator will contact Kellys and provide a list of barcodes for the boxes to be destroyed.

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

h. A certificate of destruction, if required, will either be provided by Kellys or is available from the R&D Department (FRM060).

i. Destruction of archived boxes and/or eTMF's will be logged on the Archive database by the Archive Administrator.

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). 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.

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

Further Document Information

Approved by: *Management/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 (2023)

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:	April 2028

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	

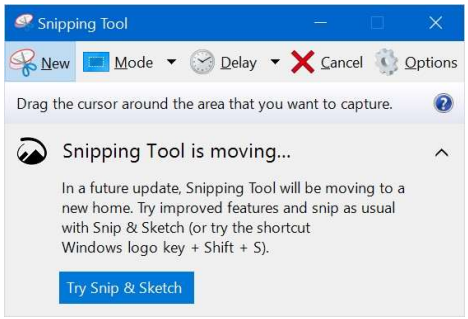
CONTENTS:

Appendix 2

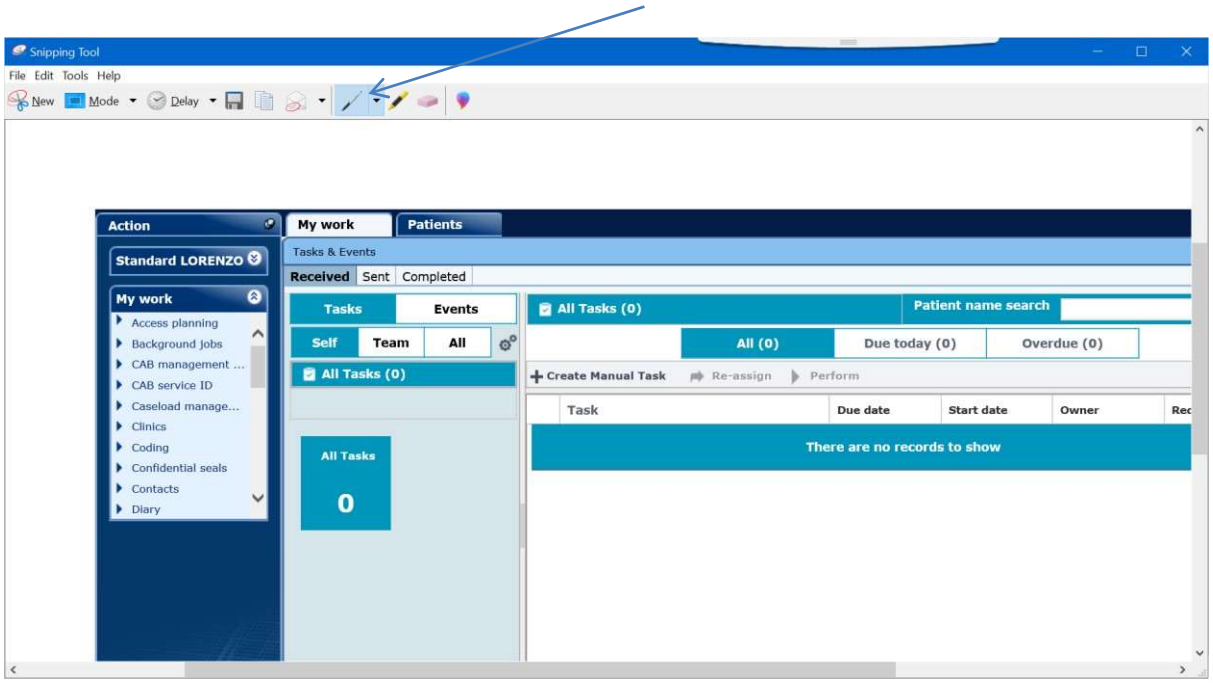
Easy way to anonymise screenshots.

Make sure the screen you want to copy is visible.

Use the SNIP tool  to copy the screen area you want. Click on “New”

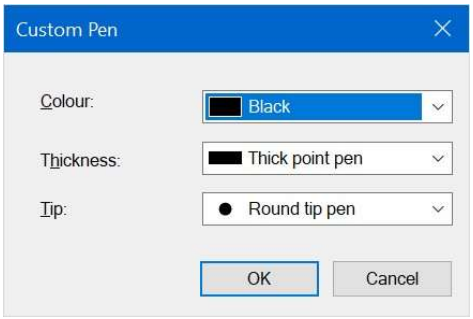


Use the cursor to highlight the area you want to copy and you will see the area in the snipping tool.

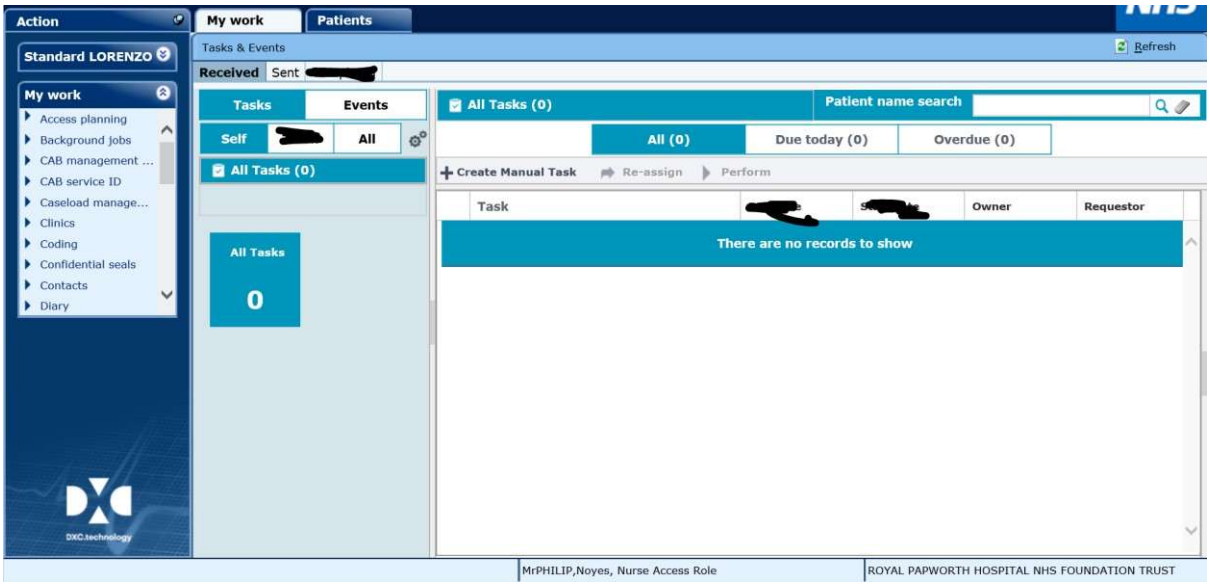


There are several edit tools you can use, click on pen here Select

Custom Pen, then Customise. Select these choices:

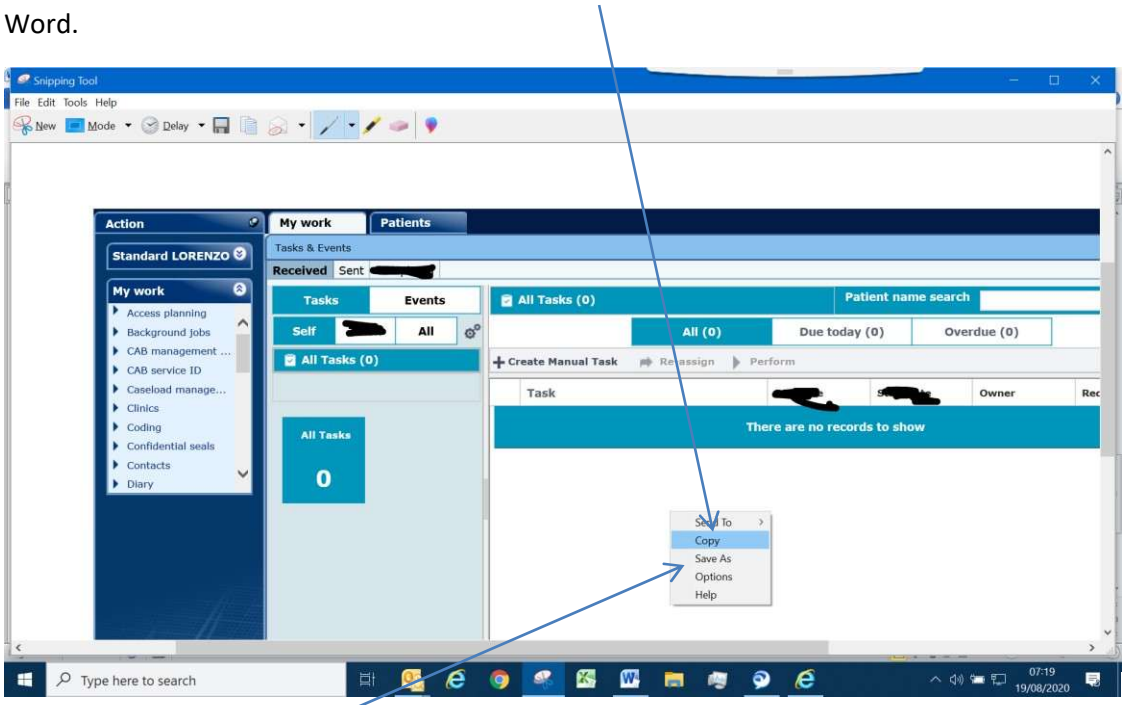


You can then blank out the areas you want



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

Word.



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