Archive Process Map

	• Confirm close-out process is complete, data base locked and permission to archive has been received from Sponsor, or evidence of an attempt to gain permission (with a clear deadline of no less than one month) and retention period confirmed.
	• Request archiving via rdoffice@nnuh.nhs.uk using heading "Request for Archiving and IRAS/R&D study number'' • R&D to issue checklist, inventory and Archiving Chain of Custody Form. See SOP 900 App 2, App 3 and App 4 • Documentation to be prepared as per below/overleaf
	• CI/PI/Research Delivery Team or delegated other to complete checklist and inventory See SOP 900 App 2 and App 3 • Inventory to be placed in the top of the box with evidence to archive and retention period from sponsor underneath
	• Request Quality Control check via rdoffice@nnuh.nhs.uk • R&D will perform the QC check in-situ, errors shall be rectified at this time • If any errors cannot be rectified straight away then a second QC check will be required
	• Chain of Custody Form (SOP 900 App 4) to be completed, signed & dated by both parties • R&D will allocate box numbers, seal all boxes in-situ and arrange a date for boxes to be collected from their current location or brought to R&D office ready to be sent to the archive facility. • If not collected from R&D office, the holder of the archive boxes must ensure Chain of Custody form is signed by the archive facility driver. This must then be scanned and emailed to rdoffice@nnuh.nhs.uk • CI/PI/Research Delivery Team or delegated other will receive confirmation of completion of archiving via email from R&D

One study only per archive box unless the sponsor is the same then multiple studies may be archived in the same box

Preparation of Documentation for Archiving

- Ensure all study documents are archived; this must include documentation from supporting departments, such as Pharmacy if applicable. You will need to provide R&D with assurance (via App 4 Chain of Custody form) that the study documentation going for archiving is complete and prepared appropriately.

- Ensure that patient identifiable data is stored separately in brown envelopes or a separate box (marked as '***confidential - patient identifiable data'***, with study name & IRAS / R&D study number) - these should not be sealed until QC is complete

- Remove documents from folders or files ensuring removal of staples, bulldog clips, paperclips and plastic wallets

- Documentation on thermal paper (such as ECGs) should be removed (photocopies can be inserted in their place)

- Redact any staff identifiable personal data i.e. often found on CVs e.g. home address, home telephone number, date of birth, marital status, number of children

- Transfer records to plastic archiving clips. Do not overfill the clips. Content in envelopes does not necessarily need to be on archiving clips

- For each archive clip include a printed cover sheet which identifies the content and numbering i.e. 1 of 2, 2 of 2

- It is not GCP compliant to store electronic media i.e. CDs / memory sticks, in the boxes. However, if contents must be archived, the CI/PI/Research Delivery Team or delegated other should either:

    - arrange for contents to be printed and filed in the boxes; or

    - contact the Sponsor and state that: '*We have reviewed the archiving of the above study. We note that the records contain portable electronic media (e.g. usb drives and/or CDs). It is not our usual policy to archive portable media such as this as it is not a recognised GCP compliant medium for archiving electronic data. However, we note that responsibility to ensure readability of the data at any point in the future rests with the Sponsor and we will therefore leave the portable media in the box with the paper documentation. If you wish to implement an alternative solution please contact us not later than (one month)'*

    - Before placing the CD/USB in the box the delivery team should access the data and print an inventory describing the data contained.

- If the electronic media is not required on file (because it already exists) then the holder of the records should raise a job via Digital Health to destroy the electronic media. Select 'Can' I have' and 'General Queries' in the Digital Health application. Request 'secure destruction of CDs/USBs that contain confidential data'. Digital Health should be asked to acknowledge receipt of the media and the documentation (detailing destruction of the electronic media) should be placed with the material to be archived.

- If a Sponsor wants to email records for data download, please note that NNUH cannot currently offer electronic archiving. Storage on the NNUH S:drive is not a GCP compliant storage mechanism. Records should therefore either be printed or the Sponsor should be asked to provide the material via CD/USB noting that it is not NNUH policy to store data by that means either (as above) however that media will be placed in the box for storage noting that the Sponsor accepts responsibility for readability of the data.