






## Research Delivery Team Archive Process Map

	<ul style="list-style-type: none"> <li>• Confirm close-out process is complete, data base locked and permission to archive has been received from Sponsor, or evidence of two attempts to gain permission and retention period confirmed.</li> </ul>
	<ul style="list-style-type: none"> <li>• Request archiving via <a href="mailto:rdoffice@nnuh.nhs.uk">rdoffice@nnuh.nhs.uk</a> using heading “Request for Archiving and IRAS/R&amp;D study number”</li> <li>• R&amp;D to issue checklist, inventory and Archiving Chain of Custody Form. See SOP 900 App 2, App 3 and App 4</li> <li>• Research Delivery Team to prepare documentation as per below</li> </ul>
	<ul style="list-style-type: none"> <li>• Research Delivery Team complete checklist and inventory See SOP 900 App 2 and App 3</li> <li>• Inventory to be placed in the box with evidence to archive and retention period from sponsor</li> </ul>
	<ul style="list-style-type: none"> <li>• Request Quality Control check via <a href="mailto:rdoffice@nnuh.nhs.uk">rdoffice@nnuh.nhs.uk</a></li> <li>• R&amp;D will perform the QC check in-situ with the Research Delivery Team, errors shall be rectified at this time</li> <li>• If any errors cannot be rectified straight away then a second QC check will be required</li> </ul>
	<ul style="list-style-type: none"> <li>• Chain of Custody Form to be completed by Research Delivery Team, signed &amp; dated by both parties</li> <li>• R&amp;D will allocate box numbers, seal all boxes in-situ and arrange a date for boxes to be collected by Archive Vault from their current location or brought to R&amp;D office ready to be sent to the archive facility.</li> <li>• If not collected from R&amp;D office, Research Delivery Team must ensure Chain of Custody form is signed by the Archive Vault driver. This must then be scanned and emailed to <a href="mailto:rdoffice@nnuh.nhs.uk">rdoffice@nnuh.nhs.uk</a></li> <li>• Research Delivery Team will receive confirmation of completion of archiving via email from R&amp;D</li> </ul>

**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 are stored separately in brown envelopes or a separate box (identified as patient identifiable data, 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) must be photocopied
- Transfer to blue archiving clips. Do not overfill the clips.
- For each archive clip include a printed cover sheet which identifies the content and numbering i.e. 1 of 2, 2 of 2
- Electronic data i.e. CDs / memory sticks, cannot be stored in the boxes. If contents need to be archived, the Research Delivery Team should arrange for contents to be printed and filed in the boxes. When all information from the electronic media has been placed in the box or if content is not required on file (because it already exists) then the Research Delivery Team should raise a job via Digital Health to destroy the electronic media. Digital Health should be asked to acknowledge receipt and the documentation (detailing destruction of the electronic media) should be placed with the material to be archived.