

Pre-archiving check list

The purpose of this document is to ensure that all archiving is completed to an approved standard, that all archived materials are stored appropriately and for the correct period of time.

Please note that archived documents must NEVER be sent to the Sponsor and must be facilitated by an intermediary e.g. Sponsor Monitors.

Please complete the form clearly and if not using typescript, please **PRINT** the words to enable legibility.

Full Study Title	
Study Reference Number	
Chief Investigator	
Point of Contact (contact details)	

	Yes/No/Comments
Has the Sponsor confirmed close out?	
Do you have copies of the close out documentation to evidence Sponsor close out?	
Have all patient completed all treatments & visits?	
Has all data been collected?	
Where appropriate, has all drug accountability been performed?	
Have all outstanding issues been resolved?	
Are all data queries resolved?	
Is the site file complete?	
Has the Sponsor stipulated length of archive?	
Have all documents relating to the study been collected from all other departments e.g. Laboratory, Pharmacy etc?	
Have all records on thermal paper been transferred to normal paper e.g. ECGs, faxes etc?	
Have all plastic / metal clips, rubber bands and plastic wallets been removed?	
Have files been removed from Lever arch files or Manilla wallets?	
Has a cover sheet been created for each section?	
Has an index been created for each box and a complete archive index retained?	
Have dates of destruction been recorded?	

Chief Investigator:.....Date:

Sponsor:Date: