

Guidance document for researchers

Archiving essential documents for Clinical Trials of Investigational Medicinal Products (CTIMPs) sponsored by the Trust or jointly with the University

This 'best practice' document is to be used by researchers for archiving of research related documents. It has been written to comply with relevant regulations and guidelines. The content should be reviewed in conjunction with any guidelines/procedures which are unique within your department.

1 Archiving

Further to the guidance from the MHRA¹, the Chief Investigator, on behalf of the Trust as the Sponsor, will arrange archiving of the trials master file and associated documents. This guidance from the MHRA and any other Trust Policies and Procedures and Department of Health legislation relating to storage and retention of data must be followed. Please ensure that you familiarise yourself with the guidance available.

2 What and when to archive

All hard copies of the essential documents contained within the Trials Master File and any associated documents must be archived at the completion of the Trial (end of study definition will be stated clearly in the protocol for the Trial). If the CI for the trial decides to transfer hard-copy correspondence to other media, then they would need to be able to demonstrate that the integrity of any transcription had been preserved.

All essential documents should be retained for at least 15 years* after the completion of a clinical trial or for a longer period where so required by other applicable requirements e.g. for marketing authorisation applications.

Any local retention and destruction policies should also be referred to.

* any requests to store documentation for a shorter period will be reviewed on a case-by-case basis by the r&d department

3 Where to archive

Documents should be archived in an appropriate room or locked cupboard with suitable fire protection without water sprinkler systems; water protection; for humid conditions; pests etc. The room or cupboard must be secure with access only by authorised personnel.

If appropriate, an external archive site may be utilized. Please contact the patient's record manager for details of archiving off site.

4 Costs

When costing a study, archiving costs should be considered and budgeted. Ensure that there are sufficient funds to pay for any off site storage space and archiving materials i.e. boxes, staffing time etc.

5 For Principal Investigators

For studies where an Addenbrooke's researcher will be a PI they will be responsible for archiving of essential documents at this site in accordance with the requirements of the Sponsor (or CI if appropriate), the institution and local regulations.

Useful archiving links

<http://www.ct-toolkit.ac.uk/db/documents/Archiving.pdf>

[http://www.ct-toolkit.ac.uk/db/documents/DH_073514\[1\]_reten_of_records.pdf](http://www.ct-toolkit.ac.uk/db/documents/DH_073514[1]_reten_of_records.pdf)

1 - 2006 No. 1928 – Medicines - The Medicines for Human Use (Clinical Trials) Amendment Regulations
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