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Standard Operating Procedure (SOP) 011

Archiving

Scope

To outline the procedure for archiving PICnIC study documentation.

Arrangements for archiving

- On completion of the study, defined as once all follow up data and queries have been completed, you will be informed by the Sponsor that all study documentation must be archived. This is to ensure that documents are not mislaid, damaged or destroyed.
- The archiving arrangements (e.g. location), resources to support them, and period of archiving should be organised by the site research staff prior to commencing patient recruitment. Details of your sites archiving arrangements should be stored in Section 9: Quality Assurance, of the Investigator Site File, using a file note if most appropriate.
- Records should be kept for 10 years in such a way that ensures they are complete, legible and available to anyone with a legitimate need to access them.

Documents to be archived

- All documents in the Investigator Site File should be archived.
- Any essential study documentation that was kept somewhere other than the ISF during the study should be returned to the PI once the study has finished so that all documents can be archived together.

Off-site archiving

- A log of any documents archived should give the location, name of archived documents and date the documents were archived. This log should be retained by the PI or the individual(s) delegated this responsibility (see SOP 002: Delegation of study duties). Any change to the location or off-site location should be clearly documented to allow tracking of the records.

Access to archived documents

- Access to archived documents should be restricted to those with a legitimate need to view these.
- In the event of a monitoring visit by the Sponsor or ICNARC CTU, any requested archived study documentation should be made available.

Destruction of archived documents

- After the archiving period is complete, sites are responsible for the confidential destruction of all archived documents.