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| **Notes** |
| * As per ICH GCP 8.1, it is a requirement that a record is maintained of the location(s) of all essential documents (refer SOP 8.0 Essential Documents).
* The table below can be adapted to use in order to log the location of source documents related to a trial.
* This log is to be located in a prominent position within the Investigator Site File (ISF).
* During the archive period, this log must be updated and retained within the archived ISF.
* Post the archive period, if any documents are deemed ‘permanent retention’, this log is to be filed within the permanent record.
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| **Essential Documents Log** |
| Protocol Code: [insert] | Site: [insert details] | Hospital/Organisation: [insert details] |
| **Source Document** | **Location within the Organisation** | **Source document location** | **Contact person** |
| *Patient Medical Records* | *Medical Records, level 5, building 10* | *All clinical notes* | *Head of Medical Records* |
| *Patient Medical Records* | *Electronic system – EPAS* | *Login to EPAS required* | *Head of Medical Records* |
| *Pharmacy Records* | *Level 2* | *Clinical Trials Pharmacy* | *Clinical Trials Pharmacist* |
| *Radiology Records* | *Building 3* | *Electronic Records* | *Head of Radiology* |
| *Pathology Records* | *Level 5* | *Electronic Records* | *Head of Pathology* |
| *Completed Data Collection Worksheets* | *Clinical Trials Centre, Level 1, Building 4* | *Participant Study File* | *Study Co-ordinator* |
| *Signed Consent Forms* | *Clinical Trials Centre, Level 1, Building 4* | *Participant Study File* | *Study Co-ordinator* |
| *Investigator CV* | *Human resources department* | *Paper or Electronic location* | *HR manager* |