

Information Sheet: File notes and File note index

File notes

File notes should be used during all clinical trials to record any changes occurring with the documentation within the Investigator Site File. File notes provide auditors and study monitors with information concerning the management of the Investigator Site File.

This includes abnormalities such as wrong version numbers, signatures missing, consent forms missing, documents being relocated/replaced etc.

Each file note needs to be assigned a category from the following list:

- Document unaccounted for
- New Version of document or protocol
- Documentation relocated
- Other (please specify below)

There is also space to add any additional comments/remarks.

If an issue needs to be resolved, then there may be a need for a follow up and it should be documented on the file note when this has been resolved, accompanied by a signature and the date. An example of this is attached.

File note index

This should be kept at the front of the Investigator Site File. It should be filled in after every file note is created. This index provides a summary and the location of all the file notes within a particular Investigator Site File. This index can be used to check if all issues described by the file notes have been resolved. An example of this attached.

These documents are available from the SOS website.

EXAMPLE:

File note number: 1

Research Site and Location	Clinical Research Hospital		
Principal Investigator	A.N. Other		
Date	6/1/09		
Category	Document unaccounted for		X
	New Version of document or protocol		
	Documentation relocated		
	Other (please specify below)		
Note			
There is a patient consent form missing in the Investigator Site File. The patient notes are being checked to ensure that the consent form is present.			
Signed	A.N. Other		
Role in study	Researcher		
Follow up (if necessary)			
The consent form has been located in the patient notes and a copy has been placed in the Investigator Site File A.N. Other 10/1/09			
EXAMPLE			
Resolved			
Yes	X	n/a	

