Exemplar Investigator Site File for non-statutory sites (non-medicinal products)

Investigator Site File Index

Study Title:

Principal Investigator:

Section	Title	Content	Comments
1	Current – Protocol / Patient Information sheet / Informed Consent / GP letter Signed Patient Information Sheet and Informed Consent	Current Protocol Current - Headed Patient Information sheet / Informed Consent / GP letter Signed patient Information sheet(s) and Informed Consent	
2	Ethics	Original approval letter Correspondence Approval letters for amendments Letter from University confirming approval (Postgraduate Study)	
3	Historical – Protocol /Patient Information sheet / Informed Consent / GP letter Amendments	Historical Protocols (Filenote if filed elsewhere) Historical - Headed Patient Information sheet / Informed Consent / GP letter Amendments	
4	Host organisation i.e. Hospice	Submission request Completed study checklist Study approval letter copy Amendment approval letters Study interim reports	
5	Contracts	Study acknowledgement Letter of confirmation from Sponsor Indemnity Site agreements – if required Financial schedule / summary	
6	Evidence of study initiation	Evidence that all staff involved are aware of the study and understand their role – sign and date initiation log	
7	Delegation log	Site signature / responsibility log	

8	Curriculum Vitae's / GCP certificates	Signed and dated CV's for all research personnel listed in the signature / responsibility log (to be updated every 2 years) Up to date GCP certificates if study involves use of a CT IMP	
9	Patient Identification form Patient recruitment / Screening log		
10	Study data capture form	Might include questionnaires or data capture proforma. For larger studies this would be in the format of a Case Report Form (CRF). (Filenote if too bulky and stored elsewhere)	
11	Correspondence	File in reverse chronological order – All correspondence to / from the co-ordinating research body Email communication (signed & dated when read) Notes of any telephone calls	
12	Newsletters Annual report		
13	Study training materials		
14	Randomisation details	Instructions / Information if applicable	
15	Miscellaneous (Specify documents)		

<u>After the completion of the trial the following must also be filed in the study site file</u>

15	Final report	Sent from Investigator to ethics	
16	Study report	To document results and interpretation of study	
17	Archiving	(Filenote if too bulky and stored elsewhere)	