Appendix 2

Investigator Site File Index

For studies NOT involving Investigational Medicinal Products

Investigator Site file index template has been produced with regards to the documentation required by UHL, as a Host organisation. This index can be modified to suit individual study requirements.

SECTION	TITLE	DOCUMENTS
1.	Contact List	Including details of relevant study site staff, responsible HRA/REC, R&I contacts, laboratory and other relevant staff involved in the study
2.	Protocol	Current Protocol signed and dated by PI Signed and dated protocol signature page(s) for all protocol versions. Superseded Protocol(s) Completed protocol training records Protocol Deviation Log Master Template Completed protocol deviation log File note template
3.	Health Research Authority / Ethics Committee	Signed and dated IRAS application Organisation Information Document/Statement of Activities / Schedule of Events as applicable HRA Initial Assessment Letter (where applicable) REC letter of Acknowledgement REC letter of Provisional /Full Favourable Opinion HRA Approval letter Substantial Amendments: Substantial amendment application form (via IRAS) to HRA/REC HRA /REC confirmation of submission email HRA categorisation email HRA Approval letter / REC favourable opinion Non Substantial Amendments: Minor Amendments application form (via IRAS) to HRA/RE HRA /REC confirmation of submission email

		HRA approval /REC favourable opinion GCP Compliance / REC Constitution /Composition / List of members (forms part of REC favourable opinion) HRA / Ethics Correspondence
4.	R&I	R&I application R&I approval/Authorisation Submission / Notification and R&I acknowledgement/approval/authorisation of all Substantial and Non-Substantial Amendments R&I Correspondence
5.	Investigator Site Personnel	Template of Delegation of Authority Log Completed Delegation of Authority Log(s) Original signed and dated current CVs for all study personnel named on the Delegation Log, covering the period of the study Evidence of GCP training/consent training e.g. certificate covering the period of the study Evidence of study specific training
6.	Standard Operating Procedures	Details of where current Sponsor and Host organisation Standard Operating procedures can be accessed. UHL Host Standard Operating procedures are available on R&I Website https://www.leicestersresearch.nhs.uk/
7.	Study Documentation	Template of all current approved Participant Information Sheets and Informed Consent Forms- approved versions printed on UHL headed paper Superseded Participant Information Sheets and Informed Consent Forms Template of GP letter (where applicable) Any other study related material eg invitation letters, posters questionnaires Sample Case Report Form

8.	Subject Documentation	Template Screening Log (non identifiable data) where applicable Completed Screening Log/s containing non identifiable participant data only, where applicable Template Subject enrolment/Identification log Subject enrolment/Identification log (not to be removed from site)
9.	Randomisation	Documentation of Randomisation process Details of randomisation process and all relevant guidance documentation if utilised. Master Randomisation List (in sealed envelope)/ details of electronic randomisation process/details of where master randomisation list is held and relevant contact details.
10.	Informed Consent	Original copies of all completed consent forms with associated patient information sheets
11.	SAE Reporting	SAE reporting Guidelines Please refer to the Sponsor SOP relating to safety reporting Current Sponsor SAE form template Completed Serious Adverse Events/ Serious Adverse Reactions/forms and associated acknowledgement correspondence SAE Tracking Log (where applicable) Evidence of Data Monitoring Committee meetings – agenda/minutes (where applicable)
12.	Monitoring/Audit	Minutes from Initiation/ Pre Study Meeting where applicable

		Monitoring log where applicable Monitoring/Audit Documentation eg Monitoring visit report and responses Associated correspondence
13.	Clinical Laboratory	Central Laboratories Certificates of accreditation, if applicable Central Laboratories Normal Reference Ranges (including revisions) if applicable Local Laboratories Certificates of accreditation, if applicable Local Laboratories Normal Reference Ranges (including revisions) if applicable Current signed and dated CV s for relevant laboratory staff Lab Manual/sample processing instructions Sample Shipment Receipt/ Tracking Temperature logs for sample storage Sample storage instructions Inventory/destruction of samples/specimens
14.	Financial / Legal	Contracts / Contract Addendums Funding Letter(s) Financial Agreement Insurance and Indemnity Statement for all investigators Financial Correspondence Records of subject expenses
15.	Study Related Supplies	Shipment/delivery Collection/return Supplies Re-order form templates Evidence of maintenance/calibration certification of all applicable equipment

16.	Annual /Final report	Annual Reports and to HRA/REC and R&I Notice to HRA/REC and R&I of trial completion
17.	Publications	Copies of all study analysis publications
18.	Correspondence	Correspondence with CI / Sponsor including Newsletters and other study specific correspondence. Meeting Agendas and Minutes General correspondence
19.	Data	*Statistical analysis plan* *Details of electronic/paper case report form storage/security*
20.	Miscellaneous	