Appendix 1

Investigator Site File Index

Clinical Trials of Investigational Medicinal Products

This 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/EudraCT/ R&I contacts, pharmacy, laboratory and other relevant departments 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 Superseded protocol(s) Sponsor protocol training records Protocol Deviation Log Master Template Completed Protocol deviation log File note template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 Statement of activities / Organisation Information Document/ schedule of events as applicable HRA Initial assessment letter (where applicable) REC letter of acknowledgement REC letter of provisional/ full favourable opinion (listing documents reviewed) 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 letter

		Non-substantial amendments: Minor Amendments application form (via IRAS) to HRA/REC 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.	Competent Authority	Clinical Trial Authorisation (CTA) application (paper copy and electronic copy) CTA acceptance letter Submission / Acknowledgement/Approval of amendment letter/s (paper copy and electronic copy) MHRA Correspondence
5.	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
6.	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 (where applicable), covering the total period of the study Evidence of study specific training
7.	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/
8.	Study Documentation	Template of all current approved Participant Information Sheets and Informed Consent Forms printed on UHL headed paper(make sure the versions and date number is entered) Superseded Participant Information Sheets and Informed Consent Forms Template of GP letter Template of any other study related material e.g. invitation letters, posters, questionnaires) Sample Case Report Form
9.	Subject Documentation	Template Screening Log (if applicable) Completed Screening Log/s containing non identifiable participant data only (if applicable) Template Subject Enrolment/Identification log Completed Subject Enrolment/Identification log/s (not to be removed from site).
10.	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. Evidence (where applicable) of randomisation i.e. envelopes/email/IVRS
11.	Data Management	Data Management Plan Superseded Data Management Plan Statistical Analysis Plan Electronic Data Capture (EDC)/-eCase Report Form(eCRF) Training records

12.	Source data	Source Data Schedule Data queries and resolution documentation
13.	Informed Consent	Copies of all completed consent forms with associated patient information sheets
14.	Pharmacovigilance/Safety reporting	SAE reporting and Pharmacovigilance contact details. Sponsor SAE form template Completed Serious Adverse Events/ Serious Adverse Reactions/Suspected Unexpected Serious Adverse Reactions (SUSARs) forms and sponsor acknowledgement documentation. SAE/SAR/SUSAR tracking log (where applicable) Annual Development Safety Update Report and acknowledgement correspondence (MHRA & REC) Evidence of Data Monitoring Committee meetings - agenda/minutes
15.	Reference Safety Information	Investigator Brochure / Summary of Products Characteristics with evidence of annual review and update by CI/PI(signed and dated) Superseded IB/SMPC documents Safety alert updates
16.	Monitoring	Agenda and minutes from Initiation/ Pre-trial Meeting Study Specific Monitoring Plan Initiation visit report Master monitoring log template Completed monitoring log Monitoring Documentation e.g. Monitoring visit report and CI/PI responses Final Trial Close out monitoring report External Audit reports and responses Associated correspondence Data management/Source document clarification Data query management

17.	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 Lab Manual/sample processing instructions, if applicable Details of sample storage facilities/processes/relevant personnel contact details Sample Shipment Receipt/ Tracking, if applicable Temperature logs for sample storage Sample storage instructions,/Inventory of samples/specimens, if applicable Inventory/destruction log of all samples/specimens Details of sample storage arrangements (where applicable) for all samples held for future research
18.	Pharmacy	Sponsor Green Light approval documents Investigational Medicinal Product packaging (label specification, copies of labels) Instructions for handling and storage of trial medication and trial related materials (randomisation, re-supply, return / destruction. Code breaking (unblinding) documentation(IVRS if applicable) Master template prescription form Completed prescription forms Template of Accountability forms / Inventory Forms / Dispensing logs / Temperature logs for all sites. Drug Destruction documentation. Completed Accountability/Inventory/Dispensing Forms Drug destruction template Completed drug destruction forms

		The following is applicable when Pharmacy is involved with Investigational Medicinal Product Manufacturing: - GMP certificate - Certificate of Analysis - Authorisation of release by Qualified Person
19.	Financial / Legal	Contracts / Contract addendums with all investigators and Sub-contractors Funding Letter(s)/ Financial Agreement Insurance / Indemnity Statement for all investigators Clinical Trial Agreement with all investigators Financial Correspondence Records of subject expenses
20.	Study Related Supplies	Shipment/delivery Collection/return Supplies re-order form templates Evidence of maintenance/calibration certification of all applicable equipment
21.	Annual Report/End of Study Declaration	Annual Reports to HRA/REC, Competent Authority and relevant acknowledgements Notice to HRA/REC, Competent Authority and R&I of trial completion
22.	Final Study Report/ Publications	Copy of Final Study Report Acknowledgement of receipt by HRA Copies of all study publications on file
23.	Correspondence	Correspondence with CI / Sponsor, including Newsletters and other study specific correspondence. Meeting agendas and minutes General correspondence

24.	Archiving	Documentation of archiving arrangements (as per Sponsor SOP) Confirmation from Sponsor that records can be destroyed Completed Record destruction form
25.	Miscellaneous	