Appendix 2a

Investigator Site File Index

For studies of UKCA/CE Marked and Proof of Concept Studies

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, R&I contacts, laboratory and other relevant staff involved in the study
2.	Clinical Investigation Plan (CIP)/Protocol	Current CIP/protocol signed and dated by PI Signed and dated CIP/protocol signature page(s) for all CIP/protocol versions. Superseded CIP/protocol(s) Completed CIP/protocol training records (as applicable) CIP/protocol deviation log master template Completed CIP/protocol deviation log File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/ template to HRA/REC

		HRA /REC confirmation of submission email HRA categorisation email HRA approval / REC favourable opinion Non Substantial Amendments: Minor amendments application form/ template 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.	R&I	R&I application/capability assessment R&I authorisation Submission / notification and R&I acknowledgement/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 Original signed and dated current CVs for all study personnel named on the delegation log Evidence of GCP training/consent training covering the total period of the study Evidence of study and device specific training

6.	Study Documentation	Template of all current approved participant information sheets and informed consent forms- approved versions printed on UHL headed paper Superseded documentation e.g. participant information sheets and informed consent forms Template of GP letter Template of any other study related material e.g. invitation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
7.	Subject Documentation	Template screening log (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)
8.	Standard Operating Procedures	Details of where and how to access current Sponsor standard Operating procedures UHL Host Standard Operating procedures are available on R&I Website https://www.leicestersresearch.nhs.uk/
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. Evidence (where applicable) of randomisation i.e. envelopes / email / IVRS

10.	Informed Consent	Original copies of all completed consent forms including re consent forms where applicable Copy of consent form audit record where applicable.
11.	Data Management	Details of electronic/paper case report form storage/security Electronic Data Capture (EDC)/ eCase Report Form (eCRF) training records, where applicable.
12.	Source Data	Source Data Schedule where applicable Data query/response documentation
13.	Medical Device/ Study Related Supplies	Details of labelling/master copy of label (where applicable) Manufacturer instructions/manual Superseded versions of manufacturer instructions/manuals Shipment/receipt records Device accountability log master Completed device accountability logs Component supplies order form templates Completed supply request forms Temperature logs (where applicable) Evidence of maintenance/calibration certification of all applicable equipment

14.	Safety Reporting	Sponsor Serious Adverse Event (SAE)/ Serious Adverse Device Effect (SADE) reporting guideline/event categorisation flow chart Sponsor SAE/SADE form template Completed SAE/SADE forms and Sponsor/ REC acknowledgement documentation Adverse Event/Device Effect record template Competed Adverse Event/Device Effect record(s) Medical Device Deficiency report form template Completed Medical Device Deficiency report forms Device safety alert updates
15.	Monitoring/Audit	Agenda and minutes from initiation/ pre study meeting (where applicable). Study specific monitoring plan (where applicable) Initiation visit report Template monitoring log Completed monitoring log Interim monitoring documentation e.g. monitoring visit report and CI/PI responses Final trial close out report Audit reports and responses Associated correspondence
16.	Clinical Laboratory (where applicable)	Central laboratories certificates of accreditation, where applicable Central laboratories normal reference ranges (including revisions) where applicable Local laboratories certificates of accreditation, where applicable

		Local laboratories normal reference ranges (including revisions) where applicable Lab manual/sample processing instructions, where applicable Details of sample storage facilities/ processes/relevant personnel contact details Sample shipment receipt/ tracking Temperature logs for sample storage Sample storage instructions/ inventory of samples/specimens, where applicable Inventory/destruction log of all samples/specimens Details of sample storage arrangements (where applicable) for all samples held for future research
17.	Financial / Legal	Contracts / contract addendums Funding letter(s)/ financial agreement Insurance/ indemnity statement for all investigators Financial Correspondence Records of subject expenses
18.	Annual /End of study declaration/Final report	Annual reports to HRA/REC Notice to HRA/REC and R&I of trial completion Final study report and acknowledgement from HRA/REC
19.	Publications	Copies of all study analysis publications
20.	Correspondence	Correspondence with CI / Sponsor and internal site correspondence, including newsletters and other study specific correspondence. Meeting agendas and minutes

		General correspondence
21.	Miscellaneous (detail documents where applicable)	