Appendix 1a

Investigator Site File Index for Non UKCA/CE Marked Medical Device 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 MHRA/HRA/REC, R&I contacts, Device Manufacturer/Supplier, pharmacy (where applicable), laboratory and other relevant departments 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 Superseded CIP/ protocol(s) Completed CIP/protocol training records CIP/Protocol Deviation Log Master Template Completed CIP/Protocol deviation log File note template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 Organisational Information Document / Schedule of Events/ statement of activities 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 letter / REC favourable opinion letter 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.	Competent Authority	Clinical Trial Authorisation (CTA) application CTA acceptance letter Submission / Acknowledgement / Approval of amendment/s letter/s MHRA Correspondence
5.	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
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 covering the total period of the study

		Evidence of study and device 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 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
9.	Subject Documentation	Template Screening Log (where applicable) Completed Screening Log/s containing non identifiable participant data only (where applicable) Template Subject Enrolment/Identification log Completed Subject Enrolment/Identification log (not to be removed from site).
10.	Randomisation	Documentation of randomisation/ Decoding process Details of randomisation/ decoding 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.	Informed Consent	Copies of all completed consent forms including all re consent forms where applicable with associated patient information sheets
12.	Data Management	Details of electronic/paper case report form storage/security Superseded Data Management Plan Electronic Data Capture (EDC)/ eCase Report Form (eCRF) training records, where applicable
13.	Source Data	Source Data Schedule where applicable Data query/response documentation
14.	Medical Device/ Study Related Supplies	Details of Labelling/Master copy of label (where applicable) Investigator Brochure(IB)(signed and dated) and/or Manufacturer Instructions/Manual Superseded versions of IB/Manufacturer Instructions/Manuals Shipment/Receipt records Device Accountability Log Template 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

15.	Safety Reporting	Sponsor Serious Adverse Event (SAE)/ Serious Adverse Device Effect (SADE) reporting Guideline/Event Sponsor SAE/SADE/USADE form template Completed SAE/SADE/USADE forms and Sponsor acknowledgement documentation Sponsor Unexpected Serious Adverse Device Effect (USADE) reporting Guidelines Evidence of notification of USADE/ to MHRA and REC 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 Evidence of notification of Device Deficiency (where applicable) to MHRA. Device safety alert updates
16.	Monitoring/Audit	Agenda and minutes from Initiation/ Pre-trial Meeting Study Specific Monitoring Plan Initiation visit/site/pharmacy(where applicable) report Template monitoring log template Completed monitoring log Interim Monitoring Documentation e.g.Site/ Pharmacy(where applicable) monitoring visit report and PI responses Final trial close out/site/pharmacy monitoring reports External Audit reports and responses Associated correspondence

17.	Clinical Laboratory	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, where applicable 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
18.	Financial / Legal	Contracts / Contract addendums Funding Letter(s)/ Financial Agreement Insurance/Indemnity for all investigators Financial Correspondence Records of subject expenses
19.	Annual Report /End of study declaration/Clinical Investigation Report	Annual Reports to HRA / REC and Sponsor Notice to HRA / REC, MHRA and R&I / R&D of trial completion (end of study declaration) Final Clinical Investigation Report and acknowledgement from HRA/REC/ MHRA/Sponsor

20.	Publications	Copies of all study analysis publications
21.	Correspondence	Correspondence with CI / Sponsor and internal site correspondence, including Newsletters and other study specific correspondence. Meeting agendas and minutes General correspondence
22.	Miscellaneous (detail documents where applicable)	