Trial Master File / Investigator Site File Index
For studies NOT involving Investigational Medicinal Products

SECTION	TITLE	DOCUMENTS
1.	Contact List	Including details of relevant study site staff, responsible HRA/ REC, R&D / R&I contacts, laboratory and pharmacy staff involved in the study
2.	Protocol	Current Protocol signed and dated by Principal Investigator Superseded Protocol(s) Protocol Deviation Log Master Template Completed Protocol Deviation Log Evidence of peer review File note template *At TMF site level file:* *Signed protocol signature page* *- If applicable, local version and approval of translated version*
3.	Health Research Authority/ Ethics Committee	Signed and dated IRAS Application Statement of Activities /Schedule of Events HRA Initial Assessment Letter (Where applicable) 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 letter Non Substantial Amendments: Minor Amendments application form 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 *<u>At Trial Master File level:</u>* *Completed Feasibility Form* *Copy of completed Site Specific Assessment / Statements of Activities/ Schedule of Events and relevant HRA approvals / REC favourable opinion* *Evidence of receipt of amendment from all collaborating centres* *Correspondence where appropriate with Sponsor / HRA & REC*
4.	R & D / 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 *<u>At Trial Master File level:</u>* *Collaborating sites R&I/R&D submission and approval/ authorisation documentation.* *Notification / receipt of all subsequent amendments/approvals / authorisation* *Local R&I / R&D correspondence*
5.	Investigator Site Personnel	Template of Delegation of Authority Log Delegation of Authority Log

		Original signed and dated current CVs for all study personnel Evidence of GCP training/consent training e.g. certificate Evidence of study specific training *<u>At TMF site level file:</u>* *Copy of completed delegation of duties / authorised signatures forms, original CV for PI, CVs for other site staff* *Trial Training documentation:-* *- GCP Training* *- Protocol-related training / Investigator Meeting documentation*
6.	Study Documentation	Template of all current approved Participant Information Sheets and Informed Consent Forms- approved versions printed on Host Institution headed paper (make sure the version number and date is entered) Superseded Participant Information Sheets and Informed Consent Forms Template of GP letter Any other study related material eg invitation letters, posters questionnaires) Sample Case Report Form *<u>At TMF site level file:</u>* *Sample of Participant Information Sheets and Informed Consent Forms (local version)*
7.	Subject Documentation	Template Screening Log Completed Screening Log/s containing non identifiable participant data only Template Subject Enrolment/Identification log Completed Subject Enrolment/Identification log (not to be removed from site).

		<u>At Trial Master File level:</u> *Details of Subject enrolment numbers utilised for individual collaborating sites. No patient identifiable data.*
8.	Standard Operating Procedures	Current UoL Standard Operating Procedures are available on the UoL College of Medicine, Biological Sciences and Psychology Website, Research Governance pages.
9.	SAE Reporting	SAE reporting Guidelines Please refer to the SOP relating to safety reporting Current SAE form template Serious Adverse Events/ Serious Adverse Reactions/Suspected Unexpected Serious Adverse Reactions (SUSARs). SAE /SUSAR reports and associated acknowledgement correspondence SAE Tracking Log
10.	Informed Consent	Copies of all completed consent forms
11.	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 *<u>At Trial Master File level:</u>* Details of Randomisation process and relevant contact details for all collaborating centres.
12.	Data	Statistical Analysis Plan Details of electronic/paper case report form storage/security
13.	Monitoring	Agenda and minutes from Initiation/ Pre-trial Meeting Study Specific Monitoring Plan Initiation visit report

		Master monitoring log template Completed monitoring log Interim 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 <u>*At Trial Master File level:*</u> Copies of all monitoring reports and associated site responses for all centres. External audits and responses. Data query requests and response.
14.	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

		<u>At Trial Master File level:</u> *Certificates of accreditation and normal Reference Ranges for local labs of all participating sites* *Inventory of samples/specimens storage and temperature logs as applicable* *Contact details of all relevant personnel responsible for sample management*
15.	Study Related Supplies	Shipment/delivery Collection/return Supplies Re-order form templates Evidence of maintenance/calibration certification of all applicable equipment *<u>At Trial Master File level:</u>* *Copies of all relevant supply documentation and evidence of equipment maintenance/calibration for all collaborating centres*
16.	Financial / Legal	Contracts / Contract Addendums with all investigators and Sub-contractors Confirmation of Sponsorship Funding Letter(s)/ Financial Agreement Insurance and Indemnity Statement for all investigators Financial Correspondence Records of subject expenses *<u>At TMF Site Level File:</u>* *Copies of all agreements*
17.	Annual /Final report	Annual Reports to REC / HRA , Competent Authority and R&D/ R&I Notice to REC/ HRA, Competent Authority and R&D /R&I of trial completion *<u>At Trial Master File level:</u>* *Evidence of supply and acknowledgement of documentation to all collaborating centres*

18.	Publications	Copies of all study analysis publications
19.	Correspondence	Correspondence with CI / Sponsor and internal site correspondence, including Newsletters and other study specific correspondence. Meeting Agendas and Minutes General correspondence *At TMF Site Level File:* *Relevant correspondence/notifications to sites*
20.	Miscellaneous	