This index should be used as a guide only. Not all documents listed below will be applicable to all trials. If documents are filed elsewhere, a note to file should be placed within the ISF to record where these documents are located.

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| **Section 1: Study Contacts** |
| * Study identifiers
* Principal Investigator and Research team contact details
* Sponsor/R&D Contact Details
 |
| **Section 2: Protocol**  |
| * Protocols (current and superseded)
 |
| **Section 3: Amendments** |
| * Amendment Log
* Submissions and approvals
 |
| **Section 4: Participant Documentation** |
| **All versions of current and superseded:-*** Participant information sheet (PIS) and consent forms
* GP letter (if any)
* Any other written documentation / information provided to subjects.
* Original signed consent forms (should be kept in separate folder if completed data sheets/CRFs are kept in Site File).
* Subject Log
 |
| **Section 5: Data Collection/Case Report Forms (CRF)** |
| * Sample Case Report Forms (CRFs), questionnaire, data recording sheets etc.
* Data queries
 |
| **Section 6: Sponsorship** |
| * Sponsorship
* Monitoring/Audit
* Funding
 |
| **Section 7: Ethics** |
| * Ethics application, approval
* Ethics correspondence
* Signed IRAS Form
* Annual progress reports
 |
| **Section 8: Research and Development** |
| * Applications - Local Information Pack documentation
* Approvals
* Research passport and/or Letter of Access (if appropriate)
* Caldicott Guardian (if required)
 |
| **Section 9: Site Staff** |
| * Staff CVs, GCP certificates and training logs
* Site delegation of responsibilities log (if applicable)
 |
| **Section 10: Adverse Events / Serious Adverse events (If applicable).** |
| * Reporting procedure (SOP)
* Blank AE/SAE forms
* SAE Reports / correspondence
* SAE Log (if applicable)
 |
| **Section 12: Breaches & Deviations** |
| * Log of Deviations
* Log of Breaches and Urgent Safety Measures
 |
| **Section 13: Laboratories ( if applicable)** |
| * Guidelines for handling and preparing samples
* Storage / logs of samples
* Local Lab reference ranges
 |
| **Section 14: Additional Approvals** |
| * Patient Benefit and Public Protection (PBPP)
* Confidentiality Advisory Group (CAG) – *applicable to* *England and Wales only*
 |
| **Section 15: General Correspondence** |
| * Non regulatory letters, faxes, emails etc.
 |
| **Section 16: Miscellaneous** |
| * Conference presentation/abstracts
* Publications
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