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| * Protocols (current and superseded) |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| **All versions of current and superseded:-**   * Participant information sheet (PIS) and consent forms * GP letter (if any) * Any other written documentation / information provided to subjects.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 |