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| **INVESTIGATOR SITE FILE CHECKLIST** |
| Administrative |
| Contact List *(Contact details for site staff and coordinating centre)* |  |  |  |
| Version Control Log |  |  |  |
| Study Protocol  |
| Current Approved Version (Signed), including acknowledgement of receipt |  |  |  |
| Superseded Approved Protocol(s) |  |  |  |
| Participant Information Sheet And Consent Form (ON LOCAL HEADED PAPER) |
| Patient Information Sheet (PIS) |
| Current Approved PIS Template  |  |  |  |
| Superseded Approved PIS(s) Templates |  |  |  |
| Informed Consent Form (ICF) |
| Current Approved ICF Template |  |  |  |
| Superseded Approved ICF Template |  |  |  |
| GP Letter |
| Current Approved Letter/Information for Patient’s GP |  |  |  |
| Superseded Approved GP Letter/Information for Patient’s GP |  |  |  |
| Other Ethics Approved Information Given to Patients  |
| Current Approved Recruitment Advertisement(s) |  |  |  |
| Superseded Approved Recruitment Advertisement(s) |  |  |  |
| REC (Ethics) |
| Ethics Application |
| Amendments (Full submission package and approval) |  |  |  |
| Original Ethics Application Submission Package (Full submission package and approval) |  |  |  |
| Ethics Annual Progress Report(s)  |  |  |  |
| Ethics Study Closure notification and acknowledgment including submitted Clinical Study Report |  |  |  |
| Sponsor / Research & Development |
| Sponsor |
| Letter of confirmation of Sponsorship |  |  |  |
| Insurance and Indemnity Certificate(s) |  |  |  |
| Trial Closure Notification and archiving documentation |  |  |  |
| Research and Development |
| Signed SSI Form and local approvals, including any amendments |  |  |  |
| NHS/HSC R&D Form |  |  |  |
| Completed Feasibility questionnaire |  |  |  |
| Finance and contracts |
| Finance |
| Copy of financial information relating to the study (invoices etc.) |  |  |  |
| Contract(s) |
| Contracts (e.g. signed Site Agreement) |  |  |  |
| Confidentiality Agreement(s) |  |  |  |
| Research Team – Staff and Training  |
| Delegation Duties Log for Site Team |  |  |  |
| Signed & Dated CVs & GCP Certificates for Site Team |  |  |  |
| Study-specific training records |  |  |  |
| Pharmacovigilance |
| AE Reporting Procedures  |  |  |  |
| List of Reported AEs and acknowledgements of AE form receipt by Sponsor |  |  |  |
| Intervention |
| Operation Manual  |  |  |  |
| Patient data |
| Patient enrolment |
| Randomisation or enrollment procedure/instructions |  |  |  |
| Patient Screening Log |  |  |  |
| Patient Enrolment Log |  |  |  |
| Completed Patient Consent Forms |  |  |  |
| Study Data |
| Completed CRFs /eCRFs  |  |  |  |
| Documentation of CRF corrections and data queries |  |  |  |
| Data management  |
| Case Report Forms |
| Sample Case Report Form(s) / eCRFs  |  |  |  |
| Superseded Case Report Form(s) /eCRFs |  |  |  |
| CRF completion guidelines |  |  |  |
| Deviations and Potential Serious Breaches |  |  |  |
| Monitoring and Audits |  |  |  |
|  Monitoring  |
| SIVdocumentationincl presentation, attendance log and updates |  |  |  |
| Monitoringdocumentationincl email, report, attendance log and updates |  |  |  |
| Close out visit documentation incl letter, report, attendance log and updates |  |  |  |
| Audit /Inspection Certificates  |  |  |  |
| Committees and Meetings |
| Investigator Meetings or other meetings as appropriate |
| Agenda, Presentations, Minutes |  |  |  |
| CORRESPONDENCE |