# Index Investigator Site File NA = Only to be ticked if not applicable

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|  | **NA** |
| 1. **Contact Information Study**   Contact information regarding study team. |  |
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| 1. **Regulatory and Ethical documents** |  |
| * 1. Positive judgement Research Committee (METC or CCMO), Approval Executive Board for the study to be carried out in its own centre and Research Declaration, incl. cover letters |  |
| * 1. **FDA form 1572 (copy)** | **X** |
| * 1. Progress report |  |
| * 1. End of study report / letters |  |
| * 1. Correspondence |  |
|  |  |
| 1. **Financial Contracts / Signed Agreements** |  |
| * 1. Clinical Study contract with sponsor (copy/original) |  |
| * 1. Financial disclosure |  |
| * 1. Other agreements (confidentiality for the monitor, pharmacy, laboratory, CRO etc.) |  |
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| 1. **Study Protocol** |  |
| * 1. Protocol (incl. protocol signature page) |  |
| * 1. Amendments (incl. protocol signature page) |  |
| * 1. Confidentiality Agreement |  |
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| 1. **Research Subject Information** |  |
| * 1. Approved (central and local) versions of Research Subject Information and Informed Consent |  |
| * 1. Original signed Informed Consents |  |
| * 1. Other written information given to the subject   (e.g. Flyer, news letters, diaries, appointment cards etc.) |  |
| * 1. Advertisements used for recruitment |  |
| * 1. Subject Screening and/or Enrolment Log |  |
| * 1. Subject ID code list |  |
| * 1. Subject reimbursement forms |  |
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| 1. **WMO Subject Insurance** |  |
| * 1. WMO subject insurance |  |
| * 1. Liability insurance |  |
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| 1. **Site personnel** |  |
| * 1. Authorization Form |  |
| * 1. CVs (signed and dated) |  |
| * 1. Training logs |  |

**NA**

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| 1. **Monitoring / Audit / Inspection documents** |  |
| * 1. Monitoring Plan |  |
| * 1. Monitoring Visit Log (completed) |  |
| * 1. Monitoring Visit correspondence (including Initiation Visit report / Close-out Visit report) |  |
| * 1. Relevant (telephone) contact reports and correspondence |  |
| * 1. Audit / Inspection report(s) / letter(s) |  |
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| 1. **Working Procedures** |  |
| * 1. Investigator / Site manual |  |
| * 1. Randomisation procedure |  |
| * 1. Archiving location overview |  |
| * 1. Other manuals / protocols |  |
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| 1. **Product Information / Pharmacy** |  |
| * 1. Drug accountability form / Drug dispensing log (completed) |  |
| * 1. Decoding procedures |  |
| * 1. Temperature log (or at pharmacy) |  |
| * 1. Investigator Brochure (IB)/ Investigational Medicinal Product Dossier (IMPD)/ Summary of Product Characteristics (SPC) / Investigational Medical Device Dossier (IMDD) |  |
| * 1. Labelling of study medication |  |
| * 1. Trial receipt(s) |  |
| * 1. Instruction for handling investigational product(s) |  |
| * 1. Shipping records for investigational product(s) (or at pharmacy) |  |
| * 1. Certificate of analysis of investigational product(s) (or at pharmacy) |  |
| * 1. Import licences (or at pharmacy) |  |
| * 1. Drug destruction forms |  |
| * 1. Correspondence |  |
| * 1. Accreditation / Certificate |  |
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| 1. **Laboratory** |  |
| * 1. Accreditation / Certificate |  |
| * 1. Normal ranges |  |
| * 1. Correspondence |  |
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| 1. **Safety** |  |
| * 1. SAE / SUSAR forms (example and completed) |  |
| * 1. Safety reports (Development Safety Update Report (DSUR) incl line-listing) |  |
| * 1. Correspondence regarding safety with investigators and sponsor |  |
| * 1. Correspondence regarding safety with local Research Committee if required |  |
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| 1. **Case report Form (CRF)** |  |
| * 1. Example CRF |  |
| * 1. Guidelines |  |
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| 1. **File Notes** |  |
| * 1. Protocol Violation Forms |  |
| * 1. Note to File Forms |  |
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| 1. **Documents of attended meetings** |  |
| * 1. Investigator meeting (incl. signature log) |  |
| * 1. Training (incl. training log and certificates) |  |
| * 1. Other meetings (incl. signature log) |  |
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| 1. **Lab Labels, request forms, shipment forms** |  |
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| 1. **Correspondence** (chronological) |  |
| * 1. Sponsor / CRO |  |
| * 1. Other |  |
| * 1. Newsletters |  |

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| 1. **Other** |  |
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