# 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**
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| * 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
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| * 1. **FDA form 1572 (copy)**
 | **X** |
| * 1. Progress report
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| * 1. End of study report / letters
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| * 1. Correspondence
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| 1. **Financial Contracts / Signed Agreements**
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| * 1. Clinical Study contract with sponsor (copy/original)
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| * 1. Financial disclosure
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| * 1. Other agreements (confidentiality for the monitor, pharmacy, laboratory, CRO etc.)
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| 1. **Study Protocol**
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| * 1. Protocol (incl. protocol signature page)
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| * 1. Amendments (incl. protocol signature page)
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| * 1. Confidentiality Agreement
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| 1. **Research Subject Information**
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| * 1. Approved (central and local) versions of Research Subject Information and Informed Consent
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| * 1. Original signed Informed Consents
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| * 1. Other written information given to the subject

 (e.g. Flyer, news letters, diaries, appointment cards etc.) |  |
| * 1. Advertisements used for recruitment
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| * 1. Subject Screening and/or Enrolment Log
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| * 1. Subject ID code list
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| * 1. Subject reimbursement forms
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| 1. **WMO Subject Insurance**
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| * 1. WMO subject insurance
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| * 1. Liability insurance
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| 1. **Site personnel**
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| * 1. Authorization Form
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| * 1. CVs (signed and dated)
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| * 1. Training logs
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 **NA**

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