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| Form number | **Form 50.011A** | Version  | **5.0** |
| Title | **E-Folder Index** |

**Section 1: Contact Information**

**Section 2: Funding**

**Section 3: Study documents**

**Section 4: REC/HRA/GTAC/ARSAC**

**Section 5: Regulatory - MHRA**

**Section 6: Amendments**

**Section 7: Legal**

**Section 8: Pre/post RGL documents and relevant correspondence**

**Section 9: End of trial documentation**

**Section 10: Additional documents not part of TMF**

**Documents to be uploaded to E-folders and SReDA**

**Section 1: Contact information**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| Sponsor and coordinating centre contact information | E-folder | Contact information |
| Chief investigator details (CV and GCP) | SReDA and E-folder  | CI CV / CI GCP |

**Section 2: Funding**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| Peer review documentation | E-folder | Peer review form |
| Funding application (all documents) | E-folder | Document name, date, R&I reference |
| Funding award letter | E-folder | Award letter, funder name |
| Reports to funding body | E-folder | Report, date |
| Other correspondence with funding award body | E-folder | Subject, date |
| File notes | E-folder | File note, date |
| NHS costing sheet (Form 51.010A) | E-folder | Costing form, date |
| SoECAT/Schedule of events | SReDA and E-folder | Study name, R&I reference, SoECAT/Schedule of events, date |
| Funding correspondence  | E-folder | Subject, date |

**Section 3: Study documents**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| Protocol | SReDA and E-folder | Protocol, number, version, date |
| Patient Information Sheet | SReDA and E-folder | PIS, group (i.e. carer, child) version, date |
| Consent form | SReDA and E-folder | Consent form, group, version, date |
| Translated PIS/Consent form (if applicable) | SReDA and E-folder | Translated PIS/Consent form, version, date |
| GP letter | SReDA and E-folder | GP letter, version, date |
| Outline OID | SReDA and E-folder | Outline OID, date |
| Sample Handling Manual/Laboratory Manual/Imaging Manual | SReDA and E-folder | Sample Handling Manual/Laboratory Manual/Imaging Manual, version, date |
| Other study documentation e.g. advertisement material, questionnaires, patient diaries | SReDA and E-folder | Diary card, version, date |
| Relevant correspondence  | E-folder | Email subject, date |
| File notes | E-folder | File note, date |

**Section 4: REC/HRA/GTAC/ARSAC**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| IRAS form (initial ethics submission) | SReDA and E-folder | IRAS form, date |
| REC application (cover letter with all documents) | SReDA and E-folder | Cover letter, date |
| Caldicott/PBPP approval/ARSAC assessment letter (if applicable) | SReDA and E-folder | Caldicott/PBPP/ARSAC approval |
| Ethics correspondence | SReDA and E-folder | Email subject, date |
| Conditions met letter | SReDA and E-folder | Conditions met, date |
| Provisional opinion | SReDA and E-folder | REC provisional, date |
| REC favourable opinion letter | SReDA and E-folder | Favourable opinion letter |
| HRA favourable opinion letter (if applicable) | SReDA and E-folder | HRA approval |
| Site specific assessments (if applicable) | E-folder | Site specific assessment |
| File notes | E-folder | File note, date |
| Annual reports  | E-folder | REC annual report. date |

**Section 5: Regulatory - MHRA**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| MHRA application (cover letter with all documents) | SReDA and E-folder | End of Study form, date |
| CTA Notice of Non-Acceptance  | SReDA and E-folder | CTA Non-Acceptance |
| Regulatory correspondence  | E-folder | Subject, date |
| MHRA approval (Regulatory CTA Letter) | SReDA and E-folder | CTA Acceptance |
| CIMD documentation | E-folder | Document name, date |
| Additional CIMD documentation (if required) | E-folder | Document name, date |
| File notes | E-folder | File note, date |

**Section 6: Amendments**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| Amendment Log | E-Folder | Amendment Log |
| Sponsor amendment checklist  | E-folder | Sponsor amendment checklist |
| Amendment tool | SReDA and E-folder | Locked amendment tool, date |
| Amendment Cover letter (REC/MHRA) | SReDA and E-folder | Cover letter, date |
| Amendment documentation (e.g. protocol, study documents, summary of changes etc.) | SReDA and E-folder | Document name, version, date |
| Sponsor decision of amendment type  | SReDA and E-folder | Sponsor decision on amendment type |
| Sponsor amendment review correspondence | E-folder | Subject, date |
| REC amendment favourable opinion letter | SReDA and E-folder | Favourable opinion letter, date |
| HRA amendment approval  | SReDA and E-folder | HRA approval, date |
| REC and HRA relevant correspondence  | E-folder | Subject, date |
| MHRA amendment approval | SReDA and E-folder | CTA Notice of Acceptance |
| MHRA relevant correspondence  | E-folder | Subject, date |
| File notes | E-folder | File note, date |

**Section 7: Legal**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| Coversheet detailing all contracts required | E-folder | Contractual arrangement overview |
| Contractual arrangements (including amendments and correspondence) | E-folder | Document/subject name |
| Insurance | E-folder | Insurance |
| Sponsor authorisation letter for international parties (if applicable) | E-folder | Sponsor authorisation letter |
| File notes | E-folder | File note, date |

**Section 8: Pre/post RGL documents and relevant correspondence**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| Trial adoption/extended review submission and correspondence (if applicable) | E-folder | Adoption to portfolio |
| TSC documentation (list of members, letters of invitation, email confirmation from members, signed charter, confirmation from funder of acceptance of TSC members) | E-folder | Document name, date |
| IDMC documentation (list of members, letters of invitation, email confirmation from members, signed charter, confirmation from funder of acceptance of IDMC membets, DMC reports) | E-folder | Document name, date |
| Public database registration (e.g. ClinicalTrials, ISCRCTN) | E-folder | Registration on \*database name\* |
| Risk assessment | SReDA and E-folder | Risk assessment |
| eCRF user acceptance correspondence | E-folder | eCRF, subject, date |
| Signed CI delegation of responsibilities  | E-folder | CI delegation of responsibilites |
| Sponsor oversight checklist | E-folder | Sponsor oversight checklist |
| Sponsor RGL letter | SReDA and E-folder | RGL letter, date |
| Co-enrolment documents (protocol of study, signed agreement, sponsor authorisation email, relevant correspondence) | E-folder | Co-enrolment, document name, date |
| Archiving arrangements/destruction | E-folder | Document name, date |
| Publications | E-folder | Document name, date |
| Other relevant email correspondence  | E-folder | Email subject |
| File notes | E-folder | File note, date |
| Complaints | E-folder | Subject, date |

**Section 9: End of trial documentation**

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| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| End of trial declaration and acknowledgement REC | E-folder | Declaration end of study  |
| End of trial declaration and acknowledgement MHRA | E-folder | End of trial declaration |
| Final report | E-folder | Final report |
| Other relevant email correspondence  | E-folder | Email subject, date |
| File notes | E-folder | File note, date |

**Section 10: Additional Documents not part of TMF**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| Archiving documentation | E-folder | Archiving |
| Project e-file checklist (Form 52.009D) | E-folder | Project e-file checklist |
| CPMS minimum dataset | E-folder | CPMS minimum dataset, version, R&I reference |
| QC report | E-folder | QC report, R&I reference |
| Localised OID | SReDA and E-folder | Study name, localised OID, site name, date authorised |
| OID appendix | E-folder | OID appendix email, R&I reference |
| Head of department approval | E-folder | HoD approval |
| Delegation log | E-folder | Study name, delegation log |
| Site pharmacy approval | E-folder | R&I reference, local pharmacy confirmation |
| CVs/GCPs of PI | SReDA and E-folder | CV/GCP, name of PI |
| Management approval email of amendments | E-folder | R&I reference, protocol number & version, amendment number & date |
| Change to study team form | E-folder | Change to study team form, date |
| Research passports | E-folder | Research passport, researcher name |
| Assessment tool (generic review) | SReDA and E-folder | Assessment tool |
| Management approval letter | SReDA and E-folder | R&I reference, management approval, site name |
| IRAS form | SReDA and E-folder | IRAS form, date |
| IRAS xml | SReDA and E-folder | IRAS xml |
| Meeting minutes | E-folder | Meeting name, date |
| Data management documentation | E-folder | Document name, date |
| Monitoring plan | E-folder | Study name, monitoring plan |
| Participating site documentation (site agreement, OID, confirmation of capacity & capability, green for go, site approval letter) | E-folder | Document name, version, date |
| Pharmacovigilance plan (Form 55.001A) | E-folder | Form 55.001A, Study name PV plan, version |
| Pharmacy documentation (clinical information sheets, intervention sheets, file notes) | E-folder | Document name, version, date |

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