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| Form number | **Form 50.011B** | Version | **2.0** |
| Title | **Innovation Projects E-Folder Index** | | |

**Section 1: Study documentation**

**Section 2: Ethics**

**Section 3: R&I approval (sub folder - Other HB sites)**

**Section 4: Sponsor**

**Section 5: Legal**

**Section 6: Finance**

**Section 7: Amendments**

**Section 8: Project Management (sub folder - Meetings)**

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

**Section 1: Study documentation**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| Protocol or  Clinical Investigation Plan | 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 |
| GP letter | SReDA and E-folder | GP letter, version, date |
| Invitation letter | SReDA and E-folder | Invitation letter, group, version, date |
| Sample diary card | SReDA and E-folder | Diary card, version, date |
| Questionnaires | SReDA and E-folder | Questionnaire title, version, date |
| Advertising materials | SReDA and E-folder | Title of material, version, date |

**Section 2: Ethical approval**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| LPAC or PBPP application | SReDA and E-folder | Application, date |
| Biorepository Management Group | SReDA and E-folder | Application, date |
| Conditions met letter | SReDA and E-folder | Conditions met, date |
| Favourable opinion | SReDA and E-folder | REC approval, date |
| Provisional opinion | SReDA and E-folder | REC provisional, date |
| REC meeting letter | SReDA and E-folder | REC meeting, date |
| Notification of end of study | SReDA and E-folder | End of Study form, date |
| Other correspondence | E-folder | Subject, date |
| Final report | SReDA and E-folder | Final report, date |
| **IRAS submission – folder** |  |  |
| IRAS full submission | SReDA and E-folder | IRAS application and supporting docs, date |

**Section 3: R&I approval**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| **NHS GG&C** |  |  |
| OID | SReDA and E-folder | OID form, date signed |
| OID appendix email | SReDA and E-folder | OID appendix email, date |
| NHS head of department approvals (emails) | E-folder | HofD Approval dept name |
| R&I Approval for all NHS GG&C sites | SReDA and E-folder | Approval, date |
| **Sub folder - Other HBs** |  |  |
| OID for other sites | SReDA and E-folder | OID form, date signed |
| R&I approvals for other sites | E-folder | R&I approval, HB name, date |
| **Generic R&D documents** |  |  |
| Study Wide Review/Generic Review | SReDA and E-folder | Study Wide Review |
| IRAS application form | SReDA and E-folder | IRAS form, date signed |

**Section 4: Sponsor**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| Risk Assessment | Upload to SReDA and/or E-folder | RA (study or Trial) |
| Draft documents reviewed by Sponsor (work up documents) | E-folder only | For e.g. ‘Protocol, number, draft version, date’ |
| Vendor Assessment | Upload to SReDA and/or E-folder | VA, date |

**Section 5: Legal**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| Collaboration Agreement(s) | SReDA and E-folder | Collaboration agreement |
| Data Transfer Agreement(s) | SReDA and E-folder | DTA |
| Data Processing Agreement(s) | SReDA and E-folder | DPA |
| Material transfer agreement | SReDA and E-folder | MTA |
| Other contracts | SReDA and E-folder | Contract - Contractor name |
| Insurance | SReDA and E-folder | Insurance certificate |
| DPIA/SSP | SReDA and E-folder | Signed forms or evidence that not required |
| Third Party Access Agreement | SReDA and E-folder | Signed off or evidence that not required – if accessing network |

**Section 6: Finance**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| Original NHS grant costing | E-folder | R&I number, grant costing request, date |
| Other Costings | E-folder | R&I number, XX costs, date |
| SoECAT | SReDA and E-folder | SoECAT, date |
| Funding award letter | SReDA and E-folder | Funding award |
| Waiver to Tender | E-folder | Waiver to tender, date |
| New Supplier documentation | E-folder | Supplier info, date |
| Purchase orders | E-folder | Purchase order, date |

**Section 7: Amendments**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| Amendment checklist | E-folder | AMD checklist |
| R&I acknowledgement email | SReDA and E-folder | AMD number, R&D app |
| REC amendment opinion | SReDA and E-folder | AMD REC opinion |
| Amendment submission cover letter | SReDA and E-folder | AMD number, cover letter |
| Notification of amendment form | SReDA and E-folder | AMD number form |

**Section 8: Project Management**

|  |  |  |
| --- | --- | --- |
| **Document** | **Upload to SReDA and/or E-folder** | **Naming convention** |
| **Sub folder - Meetings** |  |  |
| Agendas | E-folder | Meeting name, agenda, date |
| Minutes | E-folder | Meeting name, minutes, date |
| Action Logs | E-folder | Meeting name, action log, date |
| Any other project management documents | E-folder | As appropriate |

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