|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Study Name: |  | | | | | |
| Sponsor Code: |  | Chief Investigator: |  | | | |
| Location of TMF: |  | Sponsor File: | Yes |  | No |  |

**This checklist should be made trial specific at the beginning of the trial and used as a tool to mark the location of each essential document. Some documents may not be applicable to a trial and should be marked as such below. Comments can be recorded in the Comment column as required.**

The document checklist should be updated as documents are added to the file and the version/ date of the document added when appropriate. The document checklist can also be used to document a review of the file by completing the review section below. A sponsor file will exist for trials where the TMF is delegated to the trial team. Documents which should not be held in the sponsor file, trial master file (TMF) or investigator site file (ISF) are greyed out. Some documents may be held electronically, only on electronic media e.g. CD or memory stick within the paper file. The location of electronic documents must be file noted within the paper file.

Please complete:

|  |
| --- |
| Update of file and checklist only □ Full file review □ *If a full file review was conducted please complete review section at end of index* |

| Section | Sub-Section | Document | Version/ date | Location | | | | | Comment |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sponsor file | TMF | ISF | Electronic only | N/A |  |
| 1. Study Documents | 1.1 Current | Clinical Investigational plan (CIP) – *fully signed* |  |  |  |  |  |  |  |
| PIS |  |  |  |  |  |  |  |
| Consent |  |  |  |  |  |  |  |
| GP letter |  |  |  |  |  |  |  |
| Other study specific docs (list) |  |  |  |  |  |  |  |
| 1.2 Superseded | CIP – *fully signed* |  |  |  |  |  |  |  |
| PIS |  |  |  |  |  |  |  |
| Consent |  |  |  |  |  |  |  |
| GP letter |  |  |  |  |  |  |  |
| Other study specific docs (list) |  |  |  |  |  |  |  |
| 1.3 | Correspondence |  |  |  |  |  |  |  |
| 2. Approvals | 2.1 Ethics | Approvals *(Final favourable opinion)* |  |  |  |  |  |  |  |
| Cover letter *(or equivalent which lists document versions submitted)* |  |  |  |  |  |  |  |
| Correspondence *(may incl. acknowledgement of submission, request for further information, response to REC. Must include list of REC members. Make list study specific, full documentation required in TMF, ensure it is clear what will be located in ISF )* |  |  |  |  |  |  |  |
| IRAS form |  |  |  |  |  |  |  |
| Submitted documents |  |  |  |  |  |  |  |
| 2.2 Regulatory | Approvals *(letter/notice of no objection)* |  |  |  |  |  |  |  |
| Cover letter *(or equivalent which lists document versions submitted)* |  |  |  |  |  |  |  |
| Correspondence *(incl. acknowledgement of application, grounds for non-acceptance, response to MHRA. Make list study specific. Full documentation required in TMF, ensure it is clear what will be located in ISF )* |  |  |  |  |  |  |  |
| Clinical Investigation Application form *(IRAS form)* |  |  |  |  |  |  |  |
| Submitted documents (*incl technical file, CVs for clinical investigators, REC opinion if available)* |  |  |  |  |  |  |  |
| 2.3 R&D | Approvals / Capacity and Capability |  | Lothian only |  |  |  |  |  |
| Cover letter *(or equivalent which lists document versions submitted)* |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| IRAS form |  |  |  |  |  |  |  |
| SSI form / OID |  | Lothian only |  |  |  |  |  |
| Submitted documents |  |  |  |  |  |  |  |
| 2.4 Amendments | Amendment log *(if multi-site)* |  |  |  |  |  |  |  |
| Substantial Amendment *(delete if not applicable to study)*  NUMBER: 01  DATE:  *(approvals required will depend on the amendment, please make amendment specific)* | Ethics approval |  |  |  |  |  |  |  |
| Regulatory approval |  |  |  |  |  |  |  |
| R&D approval |  | Lothian only |  |  |  |  |  |
| HRA/NRSPCC acknowledgement emails |  |  |  |  |  |  |  |
| Amendment tool |  |  |  |  |  |  |  |
| Cover letter *(or equivalent which lists document versions submitted)* |  |  |  |  |  |  |  |
| Submitted documents (*tracked changes if applicable)* |  |  |  |  |  |  |  |
| Sponsor classification email |  |  |  |  |  |  |  |
| Sponsor implementation email |  |  |  |  |  |  |  |
| Substantial amendment checklist |  |  |  |  |  |  |  |
| Site level implementation email |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| Non Substantial Amendment *(delete if not applicable to study)*  NUMBER: 01  DATE:  *(approvals required will depend on the amendment, please make amendment specific)* | Regulatory approval |  |  |  |  |  |  |  |
| R&D approval/acknowledgement *(as applicable)* |  | Lothian only |  |  |  |  |  |
| HRA/NRSPCC acknowledgement emails |  |  |  |  |  |  |  |
| Amendment tool |  |  |  |  |  |  |  |
| Sponsor classification and implementation email |  |  |  |  |  |  |  |
| Site level implementation email |  |  |  |  |  |  |  |
| Submitted documents *(tracked changes if applicable)* |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 2.5 Progress Reports | APR |  |  |  |  |  |  |  |
| Evidence of submission |  |  |  |  |  |  |  |
| Acknowledgement |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 2.6 End of Trial | Declaration of the end of a study form |  |  |  |  |  |  |  |
| Notification to REC and acknowledgement |  |  |  |  |  |  |  |
| Notification to regulatory body and acknowledgement |  |  |  |  |  |  |  |
| Notification to R&D and acknowledgement |  |  |  |  |  |  |  |
| End of study report |  |  |  |  |  |  |  |
| 2.7 NHS Lothian R&D Documents | Documents and correspondence specific to R&D procedures |  |  |  |  |  |  |  |
| 3. Contracts and Funding | 3.1 Sponsorship and Insurance | Co-sponsorship agreement |  |  |  | Lothian only |  |  |  |
| Facilitation checklist |  |  |  |  |  |  |  |
| Sponsor Regulatory Checks Complete email |  |  |  |  |  |  |  |
| Insurance letter/statement |  |  |  |  |  |  |  |
| * 1. Agreements | Technical agreements |  |  |  |  |  |  |  |
| Site agreements |  |  |  |  |  |  |  |
| Other (list) |  |  |  |  |  |  |  |
| * 1. Funding | Funding application |  |  |  |  |  |  |  |
| Award letter |  |  |  |  |  |  |  |
|  | Correspondence |  |  |  |  |  |  |  |
| 4. Participant Documents | 4.1 | Subject log |  |  |  |  |  |  |  |
| 4.2 | Consent forms |  |  |  |  |  |  |  |
| 5. Safety | 5.1 Unblinding | Unblinding procedure |  |  |  |  |  |  |  |
| Documentation of Broken Blinds |  |  |  |  |  |  |  |
| 5.2 Safety reporting | Vigilance work instructions |  |  |  |  |  |  |  |
| Blank vigilance reporting forms |  |  |  |  |  |  |  |
| SAE/SAR/SUSAR/SADE/ASADE/USADE and device deficiency reports |  |  |  |  |  |  |  |
| SAE summary sheet *(filed for each SAE, produced by PV team, filed by sponsor only)* |  |  |  |  |  |  |  |
| Correspondence (*incl Sponsor acknowledgement of receipt for SAEs/SADEs, onward reporting to Regulatory as required)* |  |  |  |  |  |  |  |
| Line listings |  |  |  |  |  |  |  |
| 5.3 Required regulatory safety reporting *(please make study specific)* | Quarterly summary report of SAEs |  |  |  |  |  |  |  |
| Evidence of submission |  |  |  |  |  |  |  |
| Acknowledgement |  |  |  |  |  |  |  |
| 5.4 Protocol Deviations | Deviation logs |  |  |  |  |  |  |  |
| Sponsor Correspondence (*including notification and acknowledgement of receipt)* |  |  |  |  |  |  |  |
|  | Regulatory Correspondence *(including notification and acknowledgement of receipt)* |  |  |  |  |  |  |  |
| 6. Research Team | 6.1 | Delegation log |  |  |  |  |  |  |  |
| 6.2 | Chief Investigator CV  Chief Investigator GCP certificate |  |  |  |  |  |  |  |
| PI and Site Team CVs  PI and Site Team GCP certificates |  |  |  |  |  |  |  |
| 6.4 | Other relevant training *(training logs)* |  |  |  |  |  |  |  |
| 6.5 | Site contact list *(if multi site)* |  |  |  |  |  |  |  |
| 7. Monitoring and Audit | 7.1 Risk Assessments | ACCORD combined RA |  |  |  |  |  |  |  |
| Superseded combined RAs |  |  |  |  |  |  |  |
| Other risk assessment (list) |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 7.2 Monitoring Plan | Monitoring and SDV plan |  |  |  |  |  |  |  |
| Superseded monitoring and SDV plans |  |  |  |  |  |  |  |
| Source data plan |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 7.3 Monitoring Reports | Feasibility form |  |  |  |  |  |  |  |
| Site risk indicator tool |  |  |  |  |  |  |  |
| SIV (report and letter) |  |  |  |  |  |  |  |
| Regulatory green light |  |  |  |  |  |  |  |
| SATO |  |  |  |  |  |  |  |
| Monitoring visit report |  |  |  |  |  |  |  |
| Monitoring visit follow up letter |  |  |  |  |  |  |  |
| Action logs |  |  |  |  |  |  |  |
| Monitoring visit correspondence |  |  |  |  |  |  |  |
| Site level close out checklist |  |  |  |  |  |  |  |
| Close out visit report |  |  |  |  |  |  |  |
| Close out visit follow up letter |  |  |  |  |  |  |  |
| Close out visit action log (signed) |  |  |  |  |  |  |  |
| Final close out letter |  |  |  |  |  |  |  |
| Study level close out checklist |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| Contact reports |  |  |  |  |  |  |  |
| Documentation of recruitment checks |  |  |  |  |  |  |  |
| 7.4 Audit | Observations |  |  |  |  |  |  |  |
| Certificate |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 7.5 Vendors | Vendor assessment and approval |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 8. Medical Device and Labs | 8.1 Medical Device | Current IB |  |  |  |  |  |  |  |
| Superseded IBs |  |  |  |  |  |  |  |
| Instructions for use of device |  |  |  |  |  |  |  |
| Device labels *(or data allowing identification of device)* |  |  |  |  |  |  |  |
| Statement/Declaration of device conformity *(specify what document includes this)* |  |  |  |  |  |  |  |
| General description of product (if not in CIP) |  |  |  |  |  |  |  |
| Summary of testing conducted and clinical experience with the device to date |  |  |  |  |  |  |  |
| Device Risk analysis |  |  |  |  |  |  |  |
| Device accountability log templates |  |  |  |  |  |  |  |
| Device accountability log completed |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 8.2 Labs | Lab accreditations |  |  |  |  |  |  |  |
| Reference ranges |  |  |  |  |  |  |  |
| Laboratory/sample handling instructions |  |  |  |  |  |  |  |
| Sample accountability logs |  |  |  |  |  |  |  |
| Sample storage logs |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 9. Data management | 9.1 CRFs *(requirements for paper and eCRF will differ, please make study specific)* | Blank copy of current CRF *(pCRF)* |  |  |  |  |  |  |  |
| Superseded versions of CRF *(pCRF)* |  |  |  |  |  |  |  |
| Completed CRFs *(pCRFs or eCRF - consider at end of trial)* |  |  |  |  |  |  |  |
| CRF Tracker |  |  |  | pCRF only |  |  |  |
| CRF review |  |  |  |  |  |  |  |
| Blank copy of current source data worksheet |  |  |  |  |  |  |  |
| Superseded source data worksheet |  |  |  |  |  |  |  |
| Data Management Plan |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 9.2 Computer Systems | Validation checklist |  |  |  |  |  |  |  |
| Validation documents |  |  |  |  |  |  |  |
| System release history |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 9.3 Statistics | Master randomisation list *(consider blinding, may be added at end of trial)* |  |  |  |  |  |  |  |
| Statistical Analysis Plan |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 10. Meeting Minutes | 10.1 DMC | DMC charter |  |  |  |  |  |  |  |
| DMC minutes |  |  |  |  |  |  |  |
| DMC report |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 10.2 TSC | TSC charter |  |  |  |  |  |  |  |
| TSC minutes |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 10.3 TMG | TMG minutes |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |
| 10.4 Other (list) | Minutes |  |  |  |  |  |  |  |
| Correspondence |  |  |  |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Full file review | | | |
| Review of | Sponsor File □ | TMF □ | ISF □ |
| Review completed by |  | | |
| Date of review | DD MMM YYYY | | |
| List of documents required |  | | |