**Trial Master File Checklist**

|  |  |  |  |
| --- | --- | --- | --- |
| **Title of Research:** |  | **INSERT TRIAL LOGO** | |
| **Chief Investigator:** |  | **Name of Lead Centre:** |  |
| **REC Reference:** |  | **Lead Trust Reference:** |  |
| **ISRCTN Reference:** |  | **RSO Reference:** |  |
| **Funder Reference:** |  | **Sponsor Reference:** |  |
| **UKCRN Reference:** |  | **Other References:** |  |
| **EudraCT Reference:** |  |  |  |
| **Start Date:** |  | **Proposed End Date:** |  |

Notes for using checklist and completion of TMF checklist/ electronic files:

1. This index is provided as a template document and should be amended to fit particular requirements of research.
2. TMF folders should be stored together where possible; if any subfolders need to be stored separately this should be noted in the index/checklist and a file note stating their location and how they can be accessed should be filed in the section where the subfolder would usually be. Providing a skeleton of the content of separate folders is advised.
3. Electronic records of the TMF should match this checklist in its structure.
4. As part of the electronic record **ONLY** ‘working documents’ subfolder should be added as required for each section for storage of draft versions of trial documentation. Subheadings for ‘working documents’ are not required in printed checklist.
5. Where applicable, additional subsections can be added but should read in chronological order. For international trials where translation was undertaken the finalised approved documents should be filed in appropriately labelled subsections (indicating the target language of the translation). Subfolders for translation should be created under the section where current approved documents in the original language are filed.
6. Documents stored in paper TMF should be filed by date with newest record at the front.
7. All study documents that are subject to version control must include a ‘Superseded’ (previous approved documents and associated correspondence) subsection (to enable a simplified checklist, these are not marked below), which should always follow the ‘Current’ section containing the most recent version. Regulatory or ethical approval should not be subjected to superseding. Instead such documents should be filed in reverse chronological order under appropriately labelled subsections. For example REC approvals can be filed under subsections title Amendment 2, Amendment 1, originally approved etc.
8. Please note that titles marked with a (\*) in the current checklist may not be required for all projects but this is given as an indication only. For sections that are not required please indicate N/A in the appropriate column. DO NOT remove not applicable sections from the checklist.
9. Column one of the checklist should be populated with the number of the file folder holding the documents for that section.
10. The final column in the checklist table need not be completed until trial closure, when the archive box reference should be entered.

**Guidance provided in blue should be reviewed and deleted prior to use**

| **Folder Number** | **Section No/ Item/Title** | **In File\***  **(✓/N/A)** | **Archived**  **(specify archive box reference)** |
| --- | --- | --- | --- |
|  | Administration |  |  |
|  | Trial Management Plan/Gantt Chart |  |  |
|  | Initiation/Greenlight Checklist |  |  |
|  | Signature and delegation log (an updated delegation log to be printed for inspection / audit) |  |  |
|  | CI & medical expert CVs and GCPs |  |  |
|  | Amendment tracker (include here is summary document produced to track chronology of ethics/regulatory submissions) |  |  |
|  | Templates \* (include here any templates associated to other SOPs that have been modified and needed approval and/or any other study specific templates including file note templates) |  |  |
|  | Contact list |  |  |
|  | Study Protocol |  |  |
|  | Signed Study Protocol |  |  |
|  | Supplementary documents (documents referenced but not retained in the protocol e.g. participating site list) |  |  |
|  | Feasibility (add subfolders as necessary for survey documents, responses, reports)\* |  |  |
|  | Trial Registration |  |  |
|  | EudraCT Number Issue Document \* |  |  |
|  | ISRCTN Application Form |  |  |
|  | ISRCTN Registration and Correspondence |  |  |
|  | UKCRN Portfolio Registration \* |  |  |
|  | UKCRN Accrual upload confirmation \* |  |  |
|  | E-DGE \* |  |  |
|  | Other registration (e.g. NCT)\* |  |  |
|  | Sponsorship |  |  |
|  | Application for Sponsorship to <insert sponsor name> |  |  |
|  | Intention to Sponsor: <insert sponsor name> |  |  |
|  | Sponsorship Approval Letter: <insert sponsor name> |  |  |
|  | Sponsor Permission to Proceed notification\*: <insert sponsor name> |  |  |
|  | Indemnity and or Insurance letter <insert sponsor name> |  |  |
|  | Sponsor correspondence <insert sponsor name> |  |  |
|  | Finance |  |  |
|  | Grant Application |  |  |
|  | Award Letter |  |  |
|  | Budget |  |  |
|  | Study Related Payments |  |  |
|  | Correspondence |  |  |
|  | Reports |  |  |
|  | Subvention application and correspondence |  |  |
|  | Risk Assessment |  |  |
|  | Signed risk assessment |  |  |
|  | Risk Assessment Correspondence |  |  |
|  | Patient Information Sheet and Consent/Patient Identification |  |  |
|  | PIS/ICF (ensure each type of PIS/ICF is listed on a separate row, with subsections for superseded version)   * Types of PIS/ICF: * Parent * Competent Adult * Adult lacking capacity (proxy consent/consultee) * Minor assent (add separate subfolder for each age group) |  |  |
|  | GP Letter/s |  |  |
|  | Contact cards (the cards issued to participants to carry with them with details of their trial participation and research team contact details) \* |  |  |
|  | Translational (for additional samples separate to the main ICF)\* |  |  |
|  | Contracts including Sponsor vendor selection documentation where applicable |  |  |
|  | External Sponsor and UoL Agreement\* |  |  |
|  | Co-Sponsorship Agreement\* |  |  |
|  | Internal Delegation Plan\* |  |  |
|  | Service Level Agreement\* |  |  |
|  | Subcontract\* |  |  |
|  | Template Material Transfer Agreement\* |  |  |
|  | Template Clinical Trial Site Agreement\* |  |  |
|  | Trial Supplies Agreement\* |  |  |
|  | Confidentiality Agreements\* |  |  |
|  | GCLP Laboratory Agreement\* |  |  |
|  | Biobank Agreement \* |  |  |
|  | Funder contract\* |  |  |
|  | Ethics Committee Documents |  |  |
|  | REC Applications |  |  |
|  | REC Approval Letters |  |  |
|  | REC correspondence (other than application related) |  |  |
|  | REC Reports |  |  |
|  | Competent Authority (MHRA or other regulator <insert regulator>) Documentation\* |  |  |
|  | CTA or other applications |  |  |
|  | CA Correspondence (other than application related) |  |  |
|  | Clinical Trials Authorisation or other approval |  |  |
|  | Reports (e.g. MHRA Annual Safety Report or DSUR) |  |  |
|  | HRA and Research & Development Documentation |  |  |
|  | IRAS Application form |  |  |
|  | HRA approval and related correspondance |  |  |
|  | Correspondence |  |  |
|  | CSP Portfolio Application \* |  |  |
|  | CSP Portfolio Adoption confirmation\* |  |  |
|  | Investigational Medicinal Product / Intervention (e.g. medical device) & Pharmacy \* |  |  |
|  | IMPD / IB / Summary of Product Characteristics |  |  |
|  | QP certification |  |  |
|  | CoRC (certificate of release and compliance) |  |  |
|  | Manufacturing Authorisation / GMP certification |  |  |
|  | Pharmacy Manual |  |  |
|  | Record of IB/SmPC update checks |  |  |
|  | Certificate of analysis (IMP quality batch tests) |  |  |
|  | Accountability documentation |  |  |
|  | Records of Temperature Excursion & Monitoring |  |  |
|  | Monitoring and Quality Assurance |  |  |
|  | Trial Monitoring Plan |  |  |
|  | TMF Quality Control Check Reports |  |  |
|  | Central Trial Monitoring Reports |  |  |
|  | Potential Serious Breach Reports |  |  |
|  | Data Protection Documentation (pDPB report) |  |  |
|  | Screening (logs) |  |  |
|  | Recruitment (graphs) |  |  |
|  | Quality Incident/CAPA Reports |  |  |
|  | Internal Audit Certificates |  |  |
|  | Site Monitoring |  |  |
|  | Oversight Committees |  |  |
|  | Trial management Group ( TMG) – Record of Members\*(for instances where a list of members is not part of the terms of reference /charter) |  |  |
|  | Trial management Group ( TMG) – Terms of Reference/Charter |  |  |
|  | Trial management Group ( TMG) – Record of meetings |  |  |
|  | Trial Steering Committee ( TSC) – Record of Members\* (for instances where a list of members is not part of the terms of reference /charter) |  |  |
|  | Trial Steering Committee ( TSC) – Terms of Reference/Charter |  |  |
|  | Trial Steering Committee ( TSC) – Record of meetings |  |  |
|  | Independent Data and Safety Monitoring Committee (IDSMC) – Record of Members\* (for instances where a list of members is not part of the terms of reference /charter) |  |  |
|  | Independent Data and Safety Monitoring Committee (IDSMC) – Terms of Reference/Charter |  |  |
|  | Independent Data and Safety Monitoring Committee (IDSMC) – Record of open meetings |  |  |
|  | Internal meetings (insert subsections as appropriate e.g. Internal Trial Team meetings) |  |  |
|  | Data Management |  |  |
|  | CRF Index |  |  |
|  | Approved CRF |  |  |
|  | Current approved Patient Reported Outcome Measures (PROMS) |  |  |
|  | CRF approval documentation |  |  |
|  | Data Management Plan |  |  |
|  | CRF completion guidance (for centres and/or CTU) |  |  |
|  | Returned completed CRFS, Data Queries and related supporting information – stored in separate files ordered by <<centre/randomisation number>> |  |  |
|  | Record of QC Checks of data |  |  |
|  | Information Systems |  |  |
|  | Database requirement specification |  |  |
|  | Database validation plan |  |  |
|  | Database validation report |  |  |
|  | Statistical Information |  |  |
|  | Statistical Analysis plan |  |  |
|  | Randomisation Checklist |  |  |
|  | Sample size calculations |  |  |
|  | IDSMC closed report |  |  |
|  | IDSMC closed minutes |  |  |
|  | Central Guidance (Any study specific instructions including training slides, user guides etc. that are not held elsewhere in the TMF.) |  |  |
|  | Add subsections as needed |  |  |
|  | Safety Reporting |  |  |
|  | Guidance for SAE Completion/PV/safety plan |  |  |
|  | Clinical Coordinators/key contacts for medical assessment of safety reports Contact list |  |  |
|  | SAE Labels |  |  |
|  | SAE Log |  |  |
|  | Telephone Log Template |  |  |
|  | Verbal SAE Report Template |  |  |
|  | Completed SAE CRFs /Report Forms (file note referencing location if not kept here) |  |  |
|  | Reports |  |  |
|  | Correspondence (associated with notification and receipt of safety reports) <add subsections for Sponsor, REC, Competent authority and Sites as appropriate> |  |  |
|  | Study Related Material (other than IMP/Intervention)\* |  |  |
|  | Label Templates |  |  |
|  | Shipment Records |  |  |
|  | Returns Records |  |  |
|  | Destruction Records |  |  |
|  | Sample Logs |  |  |
|  | Other |  |  |
|  | Trial Sites files (add separate subfolders for each site as needed) |  |  |
|  | See Example Skeleton for Contents at the end of checklist |  |  |
|  | Central Laboratory |  |  |
|  | Central Laboratory Documentation (including CPA) |  |  |
|  | Central Reference ranges |  |  |
|  | Laboratory Procedures |  |  |
|  | Publicity & Publications |  |  |
|  | Publications |  |  |
|  | Website (file note to specify location if kept separately) |  |  |
|  | Newsletters |  |  |
|  | Promotional material (e.g. conference presentation, posters etc.) |  |  |
|  | Close out |  |  |
|  | Close out plan |  |  |
|  | Archiving |  |  |
|  | Sub-Studies\* (subsections can be added as needed and should follow the structure of the current TMF checklist) |  |  |

# Trial Sites Sub Folder

|  |  |  |  |
| --- | --- | --- | --- |
| **Title of Research:** |  | **INSERT TRIAL LOGO** | |
| **Chief Investigator:** |  | **Name of Lead Centre:** |  |
| **REC Reference:** |  | **Lead Trust Reference:** |  |
| **ISRCTN Reference:** |  | **RSO Reference:** |  |
| **Funder Reference:** |  | **Sponsor Reference:** |  |
| **UKCRN Reference:** |  | **Other References:** |  |
| **EudraCT Reference:** |  |  |  |
| **Start Date:** |  | **Proposed End Date:** |  |

| **Folder Number** | **Section No/ Item/Title** | **In File\***  **(✓/N/A)** | **Archived**  **(specify archive box reference)** |
| --- | --- | --- | --- |
|  | <Site Name> |  |  |
|  | **22.1.1 Admin Records** |  |  |
|  | Site Initiation Checklist |  |  |
|  | Delegation Logs |  |  |
|  | Site Templates (include site file index) |  |  |
|  | Amendment tracker |  |  |
|  | CVs |  |  |
|  | GCP Certificates |  |  |
|  | **22.1.2 Receipt of Supplies**  **(For IMP/intervention use 21.1.6. For other study related material that requires special labelling/handling/tracking e.g. biological samples use 21.1.11)** |  |  |
|  | **22.1.3 ISF Index Checklist** |  |  |
|  | **22.1.4 PISC** |  |  |
|  | **22.1.5 Contracts/ Research & Development** |  |  |
|  | Contracts |  |  |
|  | SSI |  |  |
|  | R&D Approval |  |  |
|  | **22.1.6 IMP/ Intervention** |  |  |
|  | Site Labels |  |  |
|  | Logs |  |  |
|  | Shipments |  |  |
|  | Returns |  |  |
|  | Destruction |  |  |
|  | Unblinding |  |  |
|  | Temperature monitoring deviations |  |  |
|  | **22.1.7 Finance** |  |  |
|  | **22.1.8 Site Specific Guidance (where it is on local headed notepaper or instructions specific to this site only)** |  |  |
|  | **22.1.9 Data Collection** |  |  |
|  | **22.1.10 Laboratory accreditation/ certificates** |  |  |
|  | Site ranges |  |  |
|  | **22.1.11 Study Related Material** |  |  |
|  | Shipments |  |  |
|  | Returns |  |  |
|  | Destruction |  |  |
|  | **22.1.12 Monitoring** |  |  |
|  | **22.1.13 Meetings** |  |  |
|  | **22.1.14 Closeout (closure checklist/associated site closure documents)** |  |  |