**Essential Documents to be maintained within a TMF**

**PLEASE NOTE:** Whether each separate document must be filed in a TMF will depend on the exact nature of the research project. Those documents marked with an asterisk (**\***) may not be required for all projects.

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| **Title of Document** | | **Further Details** |
| **1. Protocol and Consent** | | |
| Final, signed research protocol and amended protocols, with version numbers | | To document the Chief Investigator and Sponsor agreement to the protocol/amendment(s). |
| Confirmation of peer review | | To provide evidence that the scientific quality of the project has been independently assessed. |
| Example of Informed Consent Form and any amendments | | To provide evidence of how informed consent will be logged. |
| Examples of any other written information provided to subjects and any updates | **\*** | To document that research subjects will be given sufficient written information (content and wording) to enable them to give fully informed consent.  It should also include any documents the subject needs to complete themselves e.g. diary cards, patient handbook, questionnaires. |
| Copy of advertisement for subject recruitment and any amendments | **\*** | To document that recruitment measures are appropriate and not coercive. |
| Copy of any letter/information for a patient’s GP or Consultant | **\*** |  |
| Investigator’s Brochure and updates | **\*** | To document that relevant and current scientific information about a medicinal product has been provided to Investigators (for example, by the Chief Investigator to Principal Investigators in multi-centre trials). |
| **2. Ethics** | |  |
| **HRA Approval letter and approval for all amendments** | | To document that the trial has received HRA approval. Approvals to any amendments need to be stored alongside originals. |
| Final Ethics application and any amendments | |  |
| Ethics approval letter(s) | | To document that the trial has received Ethics Committee approval and to identify the version number and date(s) of the approved documents. Approvals to any amendments need to be stored alongside originals. |
| Ethics Committee composition where study was approved (if not already included in ethics approval letter) | | To document that the Ethics Committee is constituted in agreement with GCP.  NB. All NHS Ethics Committees that are approving clinical trials encompassed by the Clinical Trials Regulations will have been granted “authorised” status from the National Research Ethics Service, NRES and will therefore work in compliance with GCP. |
| Any Ethics Correspondence | |  |
| Ethics Reports | | For example, annual reports, safety reports, final report by CI. |
| **3. Research and Development** | |  |
| Confirmation of local Capacity and Capability (CCC) | | To document that the trial has received confirmation from the NHS organisation where the research is being conducted that it has the capacity and capability in place to deliver the study and will do so. |
| Copy of financial information relating to the study (funding application/award letter/costings) | | To document that financial arrangements for the study are in place. |
| Insurance Statement (copy of any certificate/letter/agreement) | | To document provisions to the subject(s) for any study-related harm they might experience. This includes cover for negligent and non-negligent harm. |
| Copy of Sponsor agreement and allocation of responsibilities | | To document that a research Sponsor has been identified to ensure appropriate arrangements are in place for the initiation, management and financing of the project. |
| Copy of any signed agreement(s) between involved parties | | To document agreements and responsibilities for the preparation, conduct and closure of the trial. |
| **4. Regulatory** | |  |
| Regulatory Application Form(s) (if applicable) | \* | e.g. MHRA, CAG |
| Regulatory Approval(s) (if applicable) | \* | To document that appropriate authorisation by the Regulatory Authority (such as, MHRA, CAG) has been issued prior to the project commencing. |
| **5. Correspondence (except Regulatory and Ethics/HRA)** | |  |
| Relevant written correspondence | | i.e. letters, meeting notes and minutes, records of telephone conversations, emails. |
| **6. Research Team – Staff and Training** | |  |
| Signed and dated CVs evidencing the qualifications and experience of the Chief Investigator/research team (or other relevant documents) | | To document the qualifications and eligibility of the CI/PI(s) and any key members of the research team to conduct the study, or to provide medical supervision of subjects. |
| Delegation of duty log | | To document roles and responsibilities of staff for the study. |
| Staff training records | | To document any study specific training or general competency training each member of the research team has undertaken. |
| Signature log | | To document signatures and initials of ALL persons authorised to make entries or corrections in the CRF or medical/research records. |
| Honorary Contract, Licence to Attend of Letter of Access for non-NHS Trust staff | | To demonstrate appropriate contractual arrangements and permissions are in place for study staff to attend the NHS premises where the study is being carried out and to have access to that organisation’s patients. |
| **7. Participant Information** | |  |
| Copies of original informed consent forms signed by each project participant | | This must include those forms from any screening failures. |
| Master randomisation list | | To document the actual randomisation of the trial subjects to different treatment arms. |
| Subject screening log | | Required to identify all subjects who entered pre-trial screening even if they were not entered into the study. Document reasons for non-entry as appropriate. |
| Subject ID code list | | To document that the CI/PI keeps a confidential list of all trial numbers allocated to subjects on enrolling into the trial. |
| Subject enrolment log | | To document the chronological enrolment of subjects into the trial. |
| **8. Data Collection** | |  |
| Sample Case Report Form and completion guidance | | To document how the Case Report Forms will record information. |
| Record of retained body fluids/tissue samples (if any) | \* | To document the location of any retained samples to comply with the Human Tissue Act (2004) and in case assays need to be repeated. |
| Normal laboratory reference ranges for any tests used or medical/technical procedures included in protocol (includes central labs) | \* | To document the normal values and/or reference ranges of the test results. |
| Lab/technical procedures/tests certification or accreditation | \* | To document competence of the facility to perform required test(s) and support reliability of results. |
| Copies of calibration records for technical equipment | \* | To support reliability of results by demonstrating that any equipment used for the study is performing correctly and to appropriate standards. |
| **9. Serious Adverse Events** | \* |  |
| Sample SAE form and copy of reporting procedures | \* | Required for all CTIMPs. |
| Completed SAE forms (if not included in the Case Report Forms) | \* | Required for all CTIMPs. |
| Copies of correspondence from CI to Sponsor/Regulatory Authority(ies) (e.g. MHRA, Ethics) reporting SAEs | **\*** | Required for all CTIMPs. |
| Development Safety Update Reports (DSUR) | **\*** | Required for all CTIMPs. |
| **10. Pharmacy/Product-Related** | \* |  |
| Instructions for handling of IMP(s) and trial related material(s) (if not included in the protocol) | \* | Required for all CTIMPs. To document instructions needed to ensure proper storage, packaging, dispensing and disposal of IMP(s). |
| Sample label for IMP(s) | \* | Required for all CTIMPs. To document compliance with labelling regulations (EU Good Manufacturing Practice (GMP) Directive) and appropriate instructions provided to the subject. |
| Shipping records for IMP(s) | \* | Required for all CTIMPs. To document shipment dates, batch numbers and methods of shipment of IMP(s) and trial-related materials and for tracking of product batch, review of the shipping conditions and accountability. |
| Certificate(s) of analysis of IMP(s) shipped | \* | Required for all CTIMPs. To document the identity, purity and strength of any IMP(s) to be used in the trial. |
| Decoding procedures for blinded trials | \* | Required for all CTIMPs. To document how, in the case of an emergency, identity of blinded IMP can be revealed without breaking the blind for the remaining subjects’ treatment. |
| IMP accountability at site | \* | Required for all CTIMPs. |
| IMP(s) destruction record(s) | \* | Required for all CTIMPs. To document the destruction of any unused IMP(s). |
| **11. Monitoring and Audit** | |  |
| Record(s) of all monitoring reports | | This could include a pre-trial report which documents the suitability of a site for conduct of the trial and also a trial initiation report which documents that trial procedures were reviewed with the investigator and the study staff. |
| Final close-out monitoring report | | To document that activities required for the study at closeout are completed and copies of essential documents are held in appropriate files. |
| Audit certificate (if available) | \* |  |
| Clinical trial report | \* |  |