

**University Sponsored Clinical Research Example Checklist for SMF Contents**

|  |  |
| --- | --- |
| **Title of Research:** |  |
| **Chief Investigator:** |  |
| **Sponsor Reference:** |  |
| **REC Reference:** |  |
| **IRAS Reference (if applicable):** |  |
| **Funder Reference (if applicable):** |  |
| **Location of SMF:** |  |

**PLEASE NOTE**

* This checklist is not appropriate for Clinical Trials of Investigational Medicinal Products (CTIMPs). Guidance for maintaining a Trial Master File for CTIMPs can be found in SOP015[[1]](#footnote-1).
* Documents/sections marked with an asterisk (\*) may not be relevant for all projects.
* Please use this checklist in conjunction with SOP005[[2]](#footnote-2).

| **Folder Number** | **Section No/ Item/Title** | **Filed in SMF**  **(✓/N/A)** | **Original or copy?** |
| --- | --- | --- | --- |
|  | Study Protocol |  |  |
| 1.1 | Current Study Protocol |  |  |
| 1.2 | Superseded protocol |  |  |
| 1.3 | Protocol deviations |  |  |
| 1.4 | Related correspondence |  |  |
|  | Study Documents |  |  |
| 2.1 | Patient Information Sheet (PIS) |  |  |
| 2.2 | Previously Approved PIS |  |  |
| 2.3 | Informed Consent Form (ICF) |  |  |
| 2.4 | Previously Approved ICF |  |  |
| 2.5 | Other Study Documents |  |  |
| 2.6 | Previously Approved Other Study Documents |  |  |
| 2.7 | Related correspondence |  |  |
|  | REC |  |  |
| 3.1 | Original REC Application/IRAS Form |  |  |
| 3.2 | REC Approval |  |  |
| 3.4 | Related correspondence |  |  |
|  | HRA Approval/Site Approval |  |  |
| 4.1 | IRAS Form |  |  |
| 4.2 | HRA Approval |  |  |
| 4.3 | Confirmation of Capacity and Capability / Site Approval |  |  |
| 4.4 | Related correspondence |  |  |
|  | Trial Registration\* (only relevant for studies fitting into the first four categories on the IRAS filter page i.e. clinical trials) |  |  |
| 5.1 | Registrations |  |  |
| 5.2 | Related correspondence |  |  |
|  | MHRA\* (only relevant for Clinical Investigations of Medical Devices) |  |  |
| 6.1 | Original MHRA Application |  |  |
| 6.2 | MHRA Notice of No Objection |  |  |
| 6.3 | Related correspondence |  |  |
|  | Sponsorship |  |  |
| 7.1 | Sponsorship Letters |  |  |
| 7.2 | Evidence of Indemnity and or Insurance letter |  |  |
| 7.3 | Sponsorship Application |  |  |
| 7.5 | Related correspondence |  |  |
|  | Contracts\* |  |  |
| 8.1 | Signed Contracts/Agreements |  |  |
| 8.2 | Related correspondence |  |  |
|  | Finance\* |  |  |
| 9.1 | Award Letters |  |  |
| 9.2 | Related Correspondence |  |  |
|  | Annual Reports |  |  |
| 10.1 | REC/Sponsor Annual Report |  |  |
| 10.2 | REC/Sponsor Acknowledgment |  |  |
| 10.3 | Related Correspondence |  |  |
|  | Amendments |  |  |
| 11.1 | Urgent Safety Measures |  |  |
| 11.2 | Amendment 1 (Amendment form/request; Amendment documents clean and tracked changes versions; Amendment approvals) |  |  |
| 11.3 | Related Correspondence |  |  |
|  | CVs and GCPs |  |  |
| 12.1 | CVs |  |  |
| 12.2 | GCP Certificates\* |  |  |
| 12.3 | Delegation log |  |  |
| 12.4 | Related correspondence |  |  |
|  | Peer Review |  |  |
| 13.1 | Evidence of Peer Review |  |  |
| 13.2 | Related correspondence |  |  |
|  | Risk Assessment\* |  |  |
| 14.1 | Risk assessment |  |  |
| 14.2 | Related correspondence |  |  |
|  | Monitoring\* |  |  |
| 15.1 | Monitoring Plan |  |  |
| 15.2 | Monitoring Reports |  |  |
| 15.3 | Serious Breaches |  |  |
| 15.4 | Data Protection Breaches |  |  |
| 15.5 | Related correspondence |  |  |
|  | Oversight Committees\* |  |  |
| 16.1 | Trial management Group (TMG) |  |  |
| 16.2 | Trial Steering Committee (TSC) |  |  |
| 16.3 | Independent Data and Safety Monitoring Committee (IDSMC) |  |  |
|  | Safety Reporting\* |  |  |
| 17.1 | SAE reports |  |  |
| 17.2 | Related and unexpected SAEs submitted to Sponsor and REC |  |  |
| 17.3 | Pharmacovigilance Plan |  |  |
| 17.4 | Related correspondence |  |  |
|  | Data Management\* |  |  |
| 18.1 | Data Management Plan |  |  |
| 18.2 | Related correspondence |  |  |
|  | Close of Study |  |  |
| 19.1 | End of Study Declaration |  |  |
| 19.2 | End of Study Report |  |  |
| 19.3 | Early Termination\* |  |  |
| 19.4 | Related Correspondence |  |  |
|  | Archiving |  |  |
|  | Miscellaneous |  |  |

1. Maintaining a Trial Master File for Clinical Trials of Investigational Medicinal Products (CTIMP) studies [↑](#footnote-ref-1)
2. Maintaining a Study Master File for University Sponsored Clinical Research [↑](#footnote-ref-2)