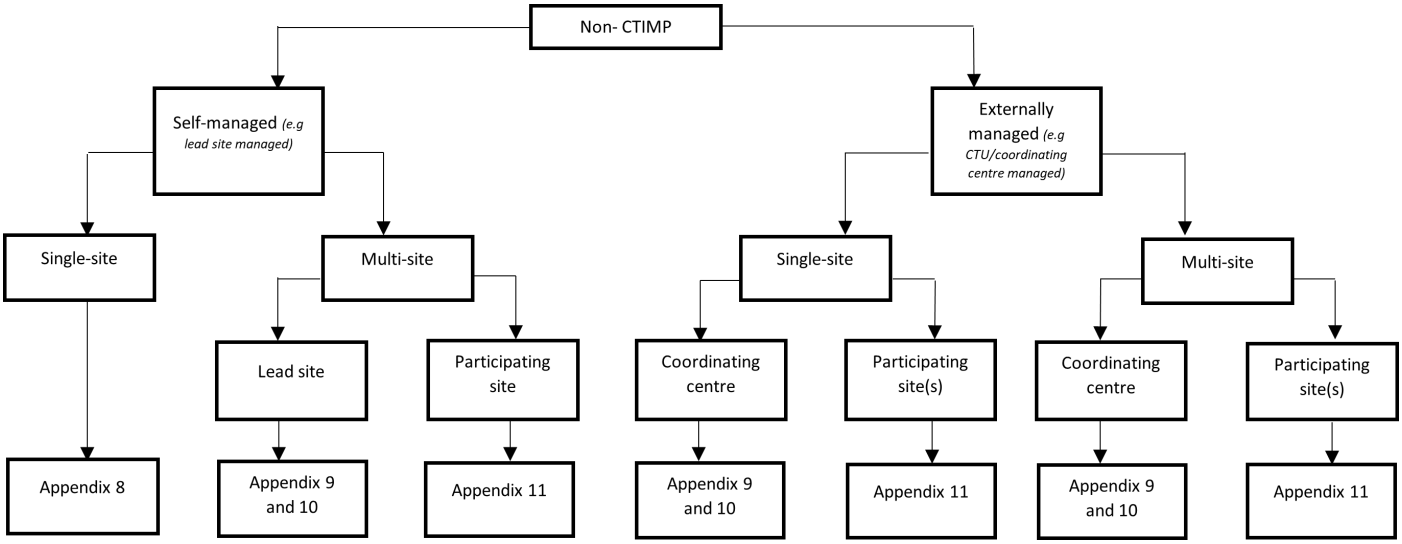
UNIVERSITY OF LEICESTER

Site Specific File (SSF) Contents List for studies not involving Investigational Medicinal Products (non-CTIMP) – Guidance Page

This contents list should be used by the lead site in a self-managed multi-centre CTIMP, or by the external coordinating centre for a single or multi-site CTIMP to create a SSF per participating research site. In addition to this SSF, a Trial Master File (TMF) should be created and maintained using Appendix 9.

All site documents should relate to the participating (research) site named on page 1.

Please use the decision tree below to check which contents list(s) is/are required for your study



Tips for using this contents list:

1. Not all documents/sections listed below will be applicable to all studies.
   Where an entire section is **not applicable**, it should be marked as such, but the original numbering of the section should be retained, this ensures a consistent filing system across all University of Leicester sponsored studies.

2. If a listed document is stored elsewhere, a note to file should be included to record its location and confirm how access can be gained. Where a document is stored electronically, please include the file path.

3. Documents should be filed in reverse chronological order (newest on top) with superseded documents marked as such.

4. To supersede a document you should;
   - Strike a single line through the front page of the document
   - Write superseded by and add the version and date of the updated document i.e. Superseded by v2.3 01/01/2023
   - Initial or sign and date next to the annotation (please note that anybody undertaking TMF maintenance should be delegated this task on the Delegation of Authority and Signature Log)

5. A copy of the relevant contents list should be placed at the front of each TMF/ISF folder. The guidance pages do not require filing.

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Site Specific File (SSF) Contents List for studies not involving Investigational Medicinal Products (non-CTIMP)

Study Title	
Site number/name:	
Principal Investigator:	

Section 1: Trial Management	
1.1	List of relevant site contacts *e.g. research team members, laboratory departments, R&D/I departments etc*
Section 2: Protocol and Associated Documents	
2.1	Current Protocol signature page *signed and dated by the Principal Investigator*
2.2	Superseded Protocol signature page(s) *signed and dated by the Principal Investigator*
2.3	Current site Protocol Deviation Log (S-1013 Appendix 2)
2.4	Site CAPA/Serious Breach *notifications and correspondence (if applicable)*
2.5	Current site File Note Tracking Log *(if applicable)* (S-1013 Appendix 4)
Section 3: Study Documentation	
3.1	Current, site localised study documents *e.g. Participant Information Sheets, Template Informed Consent Forms, Letters, Posters, Questionnaires etc*
3.2	Superseded, site localised study documents *e.g. Participant Information Sheets, Template Informed Consent Forms, Letters, Posters, Questionnaires etc (where applicable)*
Section 4: Initial Site Approvals	
4.1	Site Sponsor Green Light
4.2	Site R&D/I approval *(Confirmation of Capacity and Capability)*
4.3	Site Feasibility Assessment
4.4	Relevant correspondence
Section 5: Amendments	
5.1	**Substantial Amendments (repeat per substantial amendment)** • Site Sponsor Green Light for the implementation of the amendment • Site R&D/I amendment approval (Confirmation of Capacity and capability) *(if applicable)* • Evidence of site research team and R&D/I notification of amendment • Relevant correspondence
5.2	**Non substantial Amendments (repeat per non-substantial amendment)** • Site Sponsor Green Light/Approval for the implementation of the amendment • Site R&D/I amendment approval *(Confirmation of Capacity and Capability) (if applicable)* • Evidence of site research team and R&D/I notification of amendment *(stating 35-day implementation date)* • Relevant site Correspondence
Section 6: Investigator Site Personnel	
6.1	Site Delegation of Authority and Signature Log(s) *(S-1010 Appendix 2)*
6.2	Site personnel documents *(covering the duration of involvement with the study)* *The following documents should be filed as relevant per person listed on the DoA;* ***Lead site only*** • Signed and dated research CV *(HRA template recommended)* • Evidence of GCP training • Evidence of consent training *(if applicable)* • Evidence of study specific training *e.g. Logs showing protocol training* (S-1020, Appendix 1) • Sponsor SOP read logs (S-1011, Appendix 3) • Study Specific SOP read logs *(if applicable)* ***For all other sites***

	• Investigator tracking log (*A spreadsheet must be maintained which lists all the individuals involved in the study at the site and the dates of relevant documents and training)* (S-1015 Appendix 13) • A copy of the PI's GCP certificate and signed CV
Section 7: Participant Documentation	
7.1	Copy of site Screening log (S-1011 Appendix 5)
7.2	***Lead site only*** Site Participant Enrolment log
7.3	***For all other sites*** details of Participant enrolment numbers including a list of allocated participant IDs for participating sites (No patient identifiable data)
Section 8: Informed Consent	
8.1	***Lead site only*** Original Completed Consent Forms
8.2	***For all other sites*** this section should be blank
Section 9: Statistics and Analysis	
9.1	Details of site randomisation process *(if applicable)*
9.2	Relevant contact details for a code break *(if applicable)*
Section 10: Safety Reporting	
10.1	Site SAE/SAR/SUSAR Tracking Log (S-1009 Appendix 2)
10.2	Site SAE/SAR/SUSAR reports *and associated acknowledgement correspondence*
Section 11: Clinical Laboratory (if applicable)	
11.1	Site laboratories Certificates of Accreditation
11.2	Site laboratories Normal Reference Ranges *(including revisions)*
11.3	Details of site sample storage facilities/processes
11.4	Site Sample Shipment Receipt(s)/Tracking Log(s) *(if applicable)*
Section 12: Monitoring	
12.1	Signed site Source Data Agreement (S-1007 Appendix 4)
12.2	Site Initiation Visit (SIV) documentation *e.g. agenda, signed closed SIV report and outstanding actions list, signed SIV log and relevant correspondence (if applicable)*
12.3	Site Monitoring documentation *e.g. signed closed monitoring visit report(s)/CAPAs and relevant correspondence (if applicable)*
12.4	Site External Audit documentation *e.g. signed closed monitoring visit report(s)/CAPAs and relevant correspondence (if applicable)*
12.5	Site data query management documentation *e.g. copies of internal audits/quality control checks*
12.6	Site Close out Visit (CoV) documentation *e.g. signed closed COV report and outstanding actions list and relevant correspondence*
Section 13: Financial/Legal	
13.1	Signed site agreements e.g. OID/mNCA *(including any updates)*
13.2	Schedule of Events (SoE)/Validated SoECAT *(including any updates)*
13.3	Participant Identification Centre (PIC) documents *(if applicable)* • PIC site tracker (S-1015 Appendix 12) Site to PIC site documents *(repeat per PIC site)* • Site to PIC site(s) Sponsor Green Light • PIC site Confirmation of Capacity and Capability *(if applicable)* • Signed agreement(s) *e.g. site to PIC mNCA* • Relevant Correspondence
13.4	Other financial documents/correspondence
Section 14: Correspondence	
14.1	Important site correspondence
Section 15: Miscellaneous	
15.1	