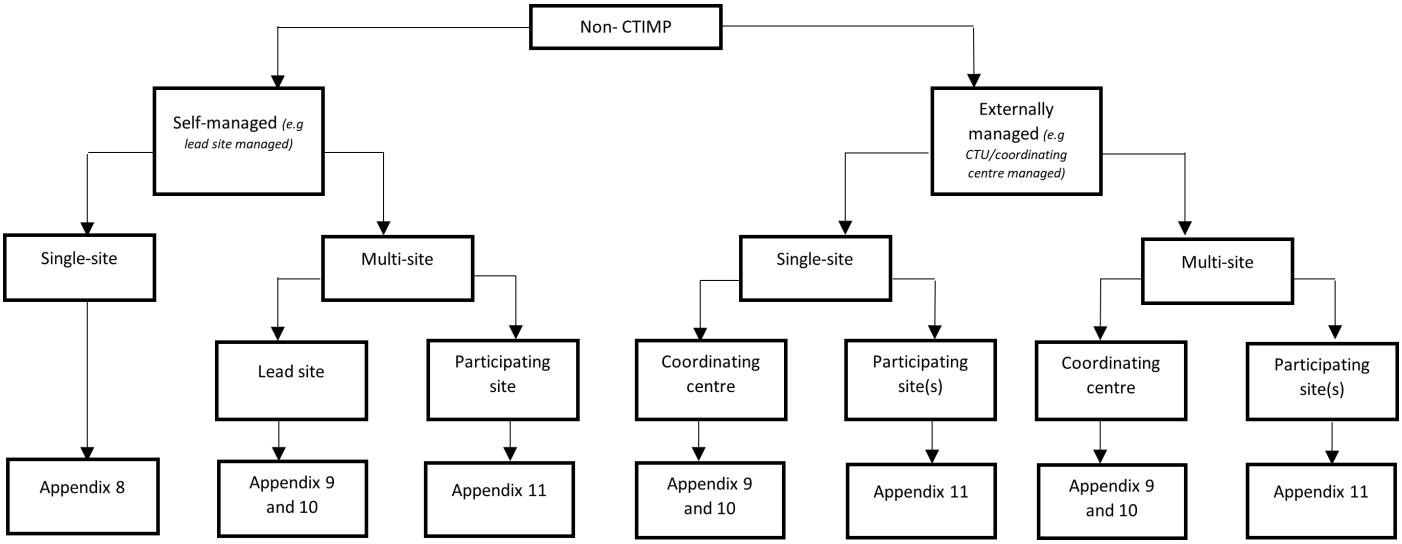
UNIVERSITY OF LEICESTER

# Investigator Site File (ISF) Contents List for studies not involving Investigational Medicinal Products (non-CTIMP) – Guidance Page

This contents list should be used by participating (research) sites in a CTIMP to create an ISF.

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 Documents should be filed in reverse chronological order (newest on top) with superseded documents marked as such.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   - Write superseded by and add the version and date of the updated document i.e. Superseded by v2.3 01/01/2023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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# Investigator Site File (ISF) Contents List for studies not involving Investigational Medicinal Products (non-CTIMP)

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|---|---|
| Study Title: | |
| Site number/name: | |
| Principal Investigator: | |

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| **Section 1: Study Management** | |
| **1.1** | List of relevant site contacts *e.g. research team members, laboratory departments, R&D/I departments etc* |
| **1.2** | List of relevant central study contacts *e.g Study Management team, CTU, CI, Sponsor* |
| **1.3** | Study Documentation version control log/tracker *(S-1015 Appendix 3)* |
| **Section 2: Protocol and Associated Documents** | |
| **2.1** | Current Protocol *signed and dated by the Principal Investigator* |
| **2.2** | Superseded Protocol *signed and dated by the Principal Investigator* |
| **2.3** | Data Flow Diagram *(if separate to protocol)* |
| **2.4** | Template Protocol Deviation Log *(S-1013 Appendix 2)* |
| **2.5** | Current site Protocol Deviation Log |
| **2.6** | CAPA/Serious Breach *notifications and correspondence (if applicable)* |
| **2.7** | Template File Note *(S-1013 Appendix 3)* |
| **2.8** | Site File Note 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)**<br>• Site Sponsor Green Light for the implementation of the amendment<br>• Site R&D/I amendment approval *(Confirmation of Capacity and Capability) (if applicable)*<br>• Evidence of site research team and R&D/I notification of amendment<br>• Copy of the completed amendment tool<br>• Relevant correspondence |
| **5.2** | **Non substantial Amendments (repeat per non-substantial amendment)**<br>• Site Sponsor Green Light/Approval for the implementation of the amendment<br>• Site R&D/I amendment approval *(Confirmation of Capacity and Capability) (if applicable)*<br>• Evidence of site research team R&D/I notification of amendment (ideally stating 35-day implementation date)<br>• Copy of the completed amendment tool<br>• Relevant correspondence |
| **Section 6: Investigator Site Personnel** | |
| **6.1** | Template Delegation of Authority and Signature Log (DoA) *(S-1010 Appendix 2)* |
| **6.2** | Site Delegation of Authority and Signature Log (DoA) |
| **6.3** | Site personnel documents *(covering the duration of involvement with the study)*<br>*The following documents should be filed as relevant per person listed on the DoA;*<br>• Signed and dated research CV *(HRA template recommended)*<br>• Evidence of GCP training<br>• Evidence of consent training *(if applicable)* |

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| | • Evidence of study specific training *e.g. Logs showing protocol training (S-1020 Appendix 1)*<br>• Sponsor SOP read logs *(S-1011 Appendix 3)*<br>• Study Specific SOP read logs (if applicable) |
| **6.4** | Investigator tracking log (A spreadsheet should be maintained which lists all the individuals involved in the study at the site and the dates of relevant training/documents *(S-1015 Appendix 13)* |
| **Section 7: Participant Documentation** | |
| **7.1** | Template Screening Log *(S-1011 Appendix 5)* |
| **7.2** | Site Screening Log(s) *(containing non-identifiable participant data only)* |
| **7.3** | Template Participant Enrolment Log *(S-1011 Appendix 6)* |
| **7.4** | Site Participant Enrolment log *(not to be removed from site)* |
| **Section 8: Informed Consent** | |
| **8.1** | Original Completed Consent Forms |
| **Section 9: Standard Operating Procedures (SOPs)** | |
| **9.1** | Note to file signposting the location of the most current Sponsor SOPs. *e.g. web address/electronic quality management system* |
| **9.2** | Current study specific SOPs *or note to file signposting the location (if applicable)* |
| **9.3** | Superseded study specific SOPs *(if applicable)* |
| **Section 10: Statistics and Analysis** | |
| **10.1** | Procedure for randomisation/code break *(if applicable)* |
| **10.2** | Master Randomisation List or location *e.g. in Sealed Envelope (if applicable)* |
| **10.3** | Evidence of randomisation i.e. envelopes/email/IVRS (unblinded study only) |
| **Section 11: Data Management** | |
| **11.1** | Current CRF Templates |
| **11.2** | Superseded CRF Templates *(if applicable)* |
| **11.3** | File note (or equivalent) providing details of electronic/paper case report form storage/security |
| **11.4** | Any other data management documents *e.g. data management queries/privacy notices* |
| **Section 12: Safety Reporting** | |
| **12.1** | Template Serious Adverse Event (SAE) reporting form *(S-1009 Supporting document 1)* |
| **12.2** | Superseded template Serious Adverse Event (SAE) reporting form(s) *(if applicable)* |
| **12.3** | Site SAE/SAR/SUSAR Tracking Log *(S-1009 Appendix 5)* |
| **12.4** | Site SAE/SAR/SUSAR reports *and associated acknowledgement correspondence* |
| **12.5** | Evidence of site SUSAR notification *(if applicable)* |
| **Section 13: Clinical Laboratory (if applicable)** | |
| **13.1** | Lab Manual/sample processing manual |
| **13.2** | List of all laboratories used |
| **13.3** | Site laboratories Certificates of Accreditation |
| **13.4** | Site laboratories Normal Reference Ranges *(including revisions)* |
| **13.5** | Details of site sample storage facilities/processes |
| **13.6** | Site Sample Shipment Receipt(s)/Tracking Log(s) *(if applicable)* |
| **13.7** | Site Temperature Logs for sample storage |
| **13.8** | Site sample storage instructions |
| **13.9** | Site inventory/destruction log of all samples/specimens |
| **13.10** | Details of local sample storage arrangements for all samples held for future research |
| **Section 14: Monitoring** | |
| **14.1** | Template Monitoring Visit Log |
| **14.2** | Current site Monitoring Visit Log *(if applicable)* |
| **14.3** | Signed site Source Data Agreement *(S-1007 Appendix 4)* |
| **14.4** | Site Initiation Visit (SIV) documentation *e.g. agenda, signed closed SIV report and outstanding actions list, signed SIV log and relevant correspondence (if applicable)* |
| **14.5** | Site Monitoring documentation *e.g. signed closed monitoring visit report(s)/CAPAs and relevant correspondence (if applicable)* |
| **14.6** | Site External Audit documentation *e.g. signed closed monitoring visit report(s)/CAPAs and relevant correspondence (if applicable)* |

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| **14.7** | Site data query management documentation *e.g. copies of internal audits/quality control checks* |
| **14.8** | Site Close out Visit (CoV) documentation *e.g. signed closed COV report and outstanding actions list and relevant correspondence* |
| **Section 15: Financial/Legal** | |
| **15.1** | Site Contracts/Contract Addendums (and any relevant correspondence/documents) *(where applicable)* |
| **15.2** | Study Specific Indemnity *(including updates if applicable)* |
| **15.3** | Sponsor Insurance Certificates *covering the duration of the study* |
| **15.4** | Site signed agreements e.g. OID/mNCA *(including any updates)* |
| **15.5** | Schedule of Events (SoE)/Validated SoECAT *(including any updates)* |
| **15.6** | Site to Participant Identification Centre (PIC) documents *(if applicable)*<br>• PIC site tracker *(S-1015 Appendix 12)*<br>Site to PIC site documents *(repeat per PIC site)*<br>• Site to PIC site(s) Sponsor Green Light<br>• PIC site *Confirmation of Capacity and Capability (if applicable)*<br>• Signed agreement(s) *e.g. site to PIC mNCA*<br>• Relevant Correspondence |
| **15.7** | Misc. financial documents/correspondence |
| **Section 16: Meetings** | |
| **16.1** | Site/Investigator meetings documentation *e.g Meeting agendas, reports, minutes and correspondence* |
| **Section 17: End of Study Reporting** | |
| **17.1** | Signed End of Study Declaration Form |
| **17.2** | Evidence of notification of End of Study to Local R & D/I department |
| **Section 18: Correspondence** | |
| **18.1** | Important correspondence with CI/Sponsor and internal site correspondence |
| **18.2** | Newsletters *(where applicable)* |
| **18.3** | Any other study specific correspondence *(where applicable)* |
| **Section 19: Miscellaneous** | |
| **19.1** | |