# ICH GCP Essential Document Checklist

Study Number: _____ Status: ☐ Pre-Activation; ☐ Active Study; ☐ Closing

Study Type: ☐ Clinical Drug Trial; ☐ Non-Drug Subject Research (ICF); ☐ Non-Drug Research (No ICF)

**Usual Regulatory Binder Items:** Location of Document (if/when applicable) date:

| Regulation Section Number | Document | | Not Applicable | Regulatory Binder | Coordinator Manual | Other Location |
|---|---|---|---|---|---|---|
| **8.3.20** | Subject Screening log | | | | | |
| 5.5.5, **8.3.21** & 8.4.3 | Subject ID code list | | | | | |
| **8.3.22** | Subject enrollment Log | | | | | |
| **8.3.12** | Signed ICFs | | | | | |
| ***8.2.2*** & **8.3.2** | (Signed) Protocol & Amendments | | | | | |
| 5.5.2 | Data Safety Monitoring Plan (if applicable) | | | | | |
| ***8.2.7***, ***8.2.9*** & **8.3.4** | IRB approval | | | | | |
| ***8.2.8*** | IRB Membership Roster | | | | | |
| ***8.2.3*** & **8.3.2** & **8.3.3** | Ongoing approved ICF & subject materials | | | | | |
| ***8.2.9*** & **8.3.4** | **^IND** (1571, 3674, FDA correspondence) | | | | | |
| | Clinicaltrials.gov | | | | | |
| **8.3.19** | Interim/annual IRB reports | | | | | |
| 8.4.4 | Audit certificate (if performed) | | ^Sponsor only | | | |
| 8.4.5 | Final close-out monitor & DSMB reports | | ^Sponsor only | | | |
| 8.4.7 | IRB/FDA closure report(s) | | | | | |
| **8.3.17** | PI to IRB/FDA: SAE reports | | | | | |
| ***8.2.19*** | Pre-Trial Monitor report | | ^Sponsor only | | | |
| ***8.2.20*** | Trial Initiation (SIV) Monitoring Report | | | | | |
| **8.3.10** | Monitoring visit reports | | ^Sponsor only | | | |
| **8.3.11** | Relevant correspondence | | | | | |
| 8.4.8 | Clinical study report (if applicable) | | | | | |
| ***8.2.11*** & **8.3.6** | Lab normal reference ranges (& updates) | | | | | |
| ***8.2.12*** & **8.3.7** | Lab Certificate, CV, ML (& updates) | | | | | |
| ***8.2.1*** & **8.3.1** | Investigator Brochure & Updates | | | | | |
| **8.3.18** | Sponsor to Site: safety & DSMB reports | | | | | |
| ***8.2.10*** & **8.3.5** | CV, ML, FDF of PI & sub-Is | | | | | |
| 4.1.5 | Delegation Log or List | | | | | |
| **8.3.24** | signatures/initials for CRF entry/corrections | | | | | |
| 4.2.4 | Training (Documentation) | | | | | |
| 21CFR312.53c | Completed FDA form 1572 | | | | | |

Place NTF in binder noting 'other location' as necessary.

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Regulatory contact signature Initial review date

***Pre-activation requirements***, **Active study requirements**, Study closure requirements, Other required documents.

# ICH GCP Essential Document Checklist

**Individual Subject Related Items (maintained by coordinator)**

| Section Numbers | Document | | Not Applicable | Regulatory Binder | Coordinator Manual | Other Location |
|---|---|---|---|---|---|---|
| **8.3.20** | Subject Screening log | | | | | |
| **8.3.21** & 8.4.3 | Subject ID code list | | | | | |
| **8.3.22** | Subject enrollment Log | | | | | |
| **8.3.11** | Relevant correspondence | | | | | |
| **8.3.13** | Source documents | | | | | |
| **8.3.14** | Signed/dated completed CRFs | | | | | |
| **8.3.15** | Documentation of CRF corrections | | | | | |
| **8.3.24** | CRF signature & Initials sheet | | | | | |
| **8.3.25** | Record of sample storage | | | | | |
| **8.3.16** | PI to sponsor: SAE reports | | | | | |
| **8.3.17** | PI to IRB/FDA: SAE reports | | | | | |

**Contract items (when applicable)**

| Section Numbers | Document | | Not Applicable | Regulatory Binder | Coordinator Manual | Other Location |
|---|---|---|---|---|---|---|
| | COI information (if applicable) | | | | | |
| ***8.2.4*** | Financial Agreement | | | | | *Contracts |
| ***8.2.5*** | Insurance Statement | | | | | *Contracts |
| ***8.2.6*** | Signed Agreement/Contract | | | | | *Contracts |

*Budget & Contract stored in contracts office; place NTF in binder with contact information.

**Pharmacy Specific Items (when applicable)**

| Section Numbers | Document | | Not Applicable | Regulatory Binder | Coordinator Manual | Other Location |
|---|---|---|---|---|---|---|
| ***8.2.18*** | Master randomization list (if applicable) | | ^Sponsor only | | | *Pharmacy |
| ***8.2.13*** | Sample of IP label | | ^Sponsor only | | | *Pharmacy |
| ***8.2.14*** | IP Manual/instructions | | | | | *Pharmacy |
| ***8.2.15*** & **8.3.8** | IP shipping records | | | | | *Pharmacy |
| ***8.2.16*** & **8.3.9** | IP certification of purity | | ^Sponsor only | | | *Pharmacy |
| ***8.2.17*** & 8.4.6 | Subject allocation/decoding procedures & documents | | ^Sponsor only | | | *Pharmacy |
| **8.3.23** & 8.4.1 & 5.13.2 | IP accountability log, temp logs | | | | | *Pharmacy |
| 8.4.2 | IP destruction records | | | | | *Pharmacy |

*IP & documents (if applicable) maintained by pharmacists/in pharmacy during the study; place NTF in binder.

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Regulatory contact signature Initial review date

***Pre-activation requirements***, **Active study requirements**, Study closure requirements, Other required documents.