# Checklist of GCP Essential Documents #2: During Study

# IRB Protocol #:

# Principal Investigator:

# *Instructions: Complete this checklist to identify the location and delegated authority for each Essential Document required by Good Clinical Practice (GCP). For guidance, please consult the GCP Toolkit of Essential Documents & Regulatory Binder Materials.*

# During the Clinical Conduct of the Trial - In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available.

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| --- | --- | --- | --- |
| **Title of Essential Document** | **Format of Record (Ex. Electronic file, hard copy)** | **Record Location (Electronic shared drive and/or file location, physical binder, room #, etc.)** | **Personnel Responsible** |
| Investigator’s brochure updates |  |  |  |
| Any revisions to:* Protocol/amendment(s) and CRF
* Informed consent form
* Any other written information provided to subjects
* Advertisement for subject recruitment
 |  |  |  |
| Dated, documented approval/favorable opinion of IRB of the following:* Protocol amendment(s)
* Revision(s) of:

Informed consent form; Any other written information to be provided to the subject; Advertisement for subject recruitment (if used); Any other documents given approval/favorable opinion; Continuing review of trial |  |  |  |
| Regulatory authority(ies) authorizations/ approvals/notifications where required for:- Protocol amendment(s) and other documents |  |  |  |
| Curriculum vitae for new investigator(s) and/or subinvestigators |  |  |  |
| Updates to normal value(s)/range(s) for medical laboratory/ technical procedure(s)/test(s) included in the protocol |  |  |  |
| Updates of medical/ laboratory/ technical procedures/tests* Certification or
* Accreditation or
* Established quality control and/or external quality assessment or
* Other validation (where required)
 |  |  |  |
| Documentation of investigational product(s) and trial-related materials shipment |  |  |  |
| Certificate(s) of analysis for new batches of investigational products |  |  |  |
| Monitoring visit reports |  |  |  |
| Relevant communications other than site visits* Letters
* Meeting notes
* Notes of telephone calls
 |  |  |  |
| Signed informed consent forms |  |  |  |
| Source documents |  |  |  |
| Signed, dated, and completed case report forms (CRFs) |  |  |  |
| Documentation of CRF corrections |  |  |  |
| Notification by originating investigator to sponsor of serious adverse events and related reports |  |  |  |
| Notification by sponsor and/or investigator, where applicable, to regulatory authority(ies) and IRB(s) of unexpected serious adverse drug reactions and of other safety information |  |  |  |
| Notification by sponsor to investigators of safety information |  |  |  |
| Interim or annual reports to IRB and authority(ies) |  |  |  |
| Subject screening log |  |  |  |
| Subject identification code list |  |  |  |
| Subject enrollment log |  |  |  |
| Investigational product(s) accountability at the site |  |  |  |
| Signature sheet |  |  |  |
| Record of retained body fluids/tissue samples (if any) |  |  |  |