# Checklist of GCP Essential Documents #1: Pre-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.*

# Before the Clinical Phase of the Trial Commences - During this planning stage the following documents should be generated and should be on file before the trial formally starts.

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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 |  |  |  |
| Signed protocol and amendments, if any, and sample case report form (CRF) |  |  |  |
| Information given to trial subject   * Informed consent form   (Including all applicable translations)   * Any other written information * Advertisement for subject recruitment |  |  |  |
| Financial aspects of the trial |  |  |  |
| Insurance statement (where required) |  |  |  |
| Signed agreement between involved parties, e.g.:  - Investigator/institution and sponsor  - Investigator/institution and CRO - Sponsor and CRO - Investigator/institution and authority(ies) (Where required) |  |  |  |
| Dated, documented approval/favorable opinion of IRB of the following:   * Protocol and any amendments * CRF (if applicable) * Informed consent form(s) * Any other written information to be provided to the subject(s) * Advertisement for subject recruitment (if used) * Subject compensation (if any) * Any other documents given approval /favorable opinion |  |  |  |
| IRB composition |  |  |  |
| Regulatory authority(ies) authorization/approval/ notification of protocol (where required) |  |  |  |
| Curriculum vitae and/or other relevant documents evidencing qualifications of investigator(s) and subinvestigators |  |  |  |
| Normal value(s)/range(s) for medical/ laboratory/ technical procedure(s) and/or test(s) included in the protocol |  |  |  |
| Medical/ laboratory/ technical procedures/ tests   * Certification or * Accreditation or * Established quality control and/or external quality assessment or * Other validation (where required) |  |  |  |
| Sample of label(s) attached to investigational product container(s) |  |  |  |
| Instructions for handling of investigational product(s) and trial- related materials (if not included in protocol or Investigator’s Brochure) |  |  |  |
| Shipping records for investigational product(s) and trial-related materials |  |  |  |
| Certificate(s) of analysis of investigational product(s) shipped |  |  |  |
| Decoding procedures for blinded trials |  |  |  |
| Master randomization list |  |  |  |
| Pretrial monitoring report |  |  |  |
| Trial initiation monitoring report |  |  |  |