# Checklist of GCP Essential Documents #3: Post-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.*

# After Completion or Termination of the Trial - After completion or termination of the trial, all of the documents identified in sections 1 and 2 (listed above) should be in the file together with the following documents.

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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** |
| Investigational product(s) accountability at site |  |  |  |
| Documentation of investigational product(s) destruction |  |  |  |
| Completed subject identification code list |  |  |  |
| Audit certificate (if required) |  |  |  |
| Final trial close-out monitoring report |  |  |  |
| Treatment allocation and decoding documentation |  |  |  |
| Final report by investigator/institution to IRB where required, and where applicable, to the regulatory authority(ies)  |  |  |  |
| Clinical study report  |  |  |  |