



Protocol Number: _____

☐ **Initial Review Submitted Package**

- ☐ Protocol Summary Sheet or Memorandum
- ☐ Original Initial Review Application Form
- ☐ Protocol and Protocol-Related Documents
- ☐ Information for subjects
- ☐ Case Report Forms (CRF)
- ☐ Investigator's CV
- ☐ Investigator's Brochure
- ☐ Informed Consent Form
- ☐ Study budget
- ☐ PI GCP certification
- ☐ others _____

☐ **Resubmission for Re-review Submitted Package**

- ☐ Resubmission or "Correction" Memorandum
- ☐ Revised Protocol Summary Sheet (if submitted initially)
- ☐ Original Initial Review Application Form
- ☐ Protocol and Protocol-Related Documents
- ☐ Information for subjects
- ☐ Case Report Forms (CRF)
- ☐ Investigator's Brochure
- ☐ Informed Consent Form
- ☐ Study budget
- ☐ others _____

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the document or the software package used to prepare the documents.

☐ **Protocol Amendment Submitted Package**

- ☐ Request for Amendment Memorandum
- ☐ Original Amendment Submission Form
- ☐ Protocol and Protocol-Related Documents

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the software package used to prepare the document.

☐ **Annual Continuing Review Package**

- ☐ Request for Annual Continuing Review Memorandum
- ☐ Original Continuing Review Application Form
- ☐ Current Informed Consent Document (last approved by the IEC/IRB)

☐ **Protocol Termination Package**

- ☐ Request for Termination Memorandum

☐ **Original Continuing Review Application Form** (Termination Submissions are contained on this form).

☐ **COMPLETE PACKAGE FOR SUBMISSION**

N.B. THE SUBMISSION WILL NOT BE PROCESSED IF THE PACKAGE IS INCOMPLETE