



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**