# 

# Form 03.1-01-v001.0

# Contents of a Submitted Package

Protocol Number: ………………..

**⬜ Initial Review Submitted Package**

* Protocol Summary Sheet (or Memorandum)
* Original Initial Review Application Form
* Protocol and Protocol-Related Documents

🗖 Information for subjects 🗖 informed consent form

🗖 Case report forms (CRF) 🗖 study budget

🗖 Investigator’s brochure 🗖 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 🗖 informed consent form

🗖 Case report forms (CRF) 🗖 study budget

🗖 Investigator’s brochure 🗖 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/)

**⬜ Protocol Termination Package**

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