# ANNEX 1

**AF/01-008/0****1 Contents of a Submitted Package**

Protocol Number:………………..

**⬜ Initial Review Submitted Package**

* Protocol Summary Sheet or Memorandum (ANNEX – AF/03-008/01)
* Application Form for Initial Review: ANNEX – AF/01-008/01
* Protocol and Protocol-Related Documents

 🗖 PI’s address and details 🗖 Study title

🗖 Objectives of the study 🗖 Information sheet of informed consent

🗖 Translated version of informed consent sheet 🗖 informed consent form (ICF)

🗖 Translated version of ICF

🗖 Study budget 🗖 CV of the PI

🗖 Evidence of GCP training (Only in case of clinical trials)

🗖 Research tools (Questionnaire/forms) 🗖 case report forms (CRF) if applicable

🗖 Investigator’s brochure if applicable

🗖 Attachments (Pls. specify) .................................................................................................

🗖 Others……………………

⬜ Resubmission for Re-review Submitted Package

* Resubmission or “Correction” Memorandum
* Revised Protocol Summary Sheet (if submitted initially)
* Application Form for Initial Review: ANNEX – AF/01-008/01
* Protocol and Protocol-Related Documents

🗖 PI’s address and details 🗖 Study title

🗖 Objectives of the study 🗖 Information sheet of informed consent

🗖 Translated version of informed consent sheet 🗖 informed consent form (ICF)

🗖 Translated version of ICF 🗖 study budget

🗖 CV of the PI 🗖 Research tools (Questionnaire/forms)

🗖 Evidence of GCP training (Only in case of clinical trials)

🗖 Case report forms (CRF) if applicable 🗖 investigator’s brochure if applicable

🗖 Attachments (Pls. specify) .................................................................................................

🗖 others……………………

*Note*: *Changes made to the protocol and protocol-related documents shall 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
* Amendment Submission Form: AF/01-014/01
* Protocol and Protocol-Related Documents

*Note*: *Changes made to the protocol and protocol-related documents shall 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
* Continuing Review Application Form: AF/01-015/01
* Current Informed Consent Document (last approved by the IRB)

**⬜ Protocol Termination Package**

* Request for Termination Memorandum
* Continuing Review Application Form (Termination Submissions are contained on this form): AF/01-015/01