Form 3.4-02-v001.0

**Protocol Summary**

**Note:** This is a guide. Your protocols may not need all the items. Kindly provide the information whenever appropriate.

* + - * Title of the Protocol
			* Principal Investigator
			* Sponsor
			* Summary
			* Type of Protocol (screening, survey, clinical trial and Phase)
			* Objectives
			* Methodology (synopsis of study design)
			* Anticipated Outcome
			* Inclusion/Exclusion Criteria
			* Withdrawal or discontinuation Criteria
			* Participant recruitment material
			* Modes of Treatment Studied
			* Schedule and Duration of Treatment, if applicable
			* Analysis (methods)
			* Activity plan / Timeline
			* IND Number (if applicable)
			* Efficacy or Evaluation Criteria (Response/Outcome)
			* Safety Parameters Criteria (Toxicity), if applicable