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