*This is a controlled format to ensure uniformity of reports .The actual clinical trial report shall be completed on your official company or institution letter head or official paper.*

A clinical trial protocol should contain the following particulars, as may be appropriate—

1. The name and dosage form of the investigational drug product.
   1. State the name or code number under which the investigational drug product is to be imported and known during the clinical trial. A separate application is required for each clinical trial.
   2. State clearly the pharmaceutical dosage form of the investigational drug product, e.g. tablet, capsule, injection, etc.
2. Identification of the clinical trial
   1. Title of the trial
   2. The clinical trial registration number or code
3. Aim of the clinical trial (a) State the specific objective

(b) Rationale of the clinical trial.

1. Description of the clinical trial design.
   1. Clinical trial design (randomised controlled trial, open-label parallel group, cross-over technique)
   2. Blinding technique (double blind, single blind)
   3. Describe procedure of randomisation
   4. Total number required to achieve the trial objective based on statistical consideration (should be sufficient to allow dropout, variability of effect etc).
2. Description of clinical trial subjects.
   1. Criteria for inclusion and exclusion of potential clinical trial subjects
   2. Process of screening, recruitment and follow up.
3. Treatment profile
   1. Dose – including justification for route of administration, dosage, dosage interval and treatment period for the investigational drug product being tested and the product being used as a control.
   2. Previous, any other treatment that may be given or permitted concomitantly or subsequent therapy, if any. (c) Washout period, where applicable.
4. Parameters of the clinical trial
   1. Indices, variables etc that were selected for measuring parameter under the clinical trial (effect, reaction etc).
   2. Methods of measurements and assessment of observations including details of measuring techniques, assessment, qualification of response, clinical and laboratory tests, pharmacokinetic analysis, etc.
   3. The rationale for choice of indices, variables and their methods of determination, specificity, sensitivity and the precision of the method selected.
5. Operational aspects
   1. Information on the establishment of the trial code where it will be kept and when, how, by whom it can be broken in the event of an emergency.
   2. Measures to be implemented to ensure the safe handling and storage of pharmaceutical products.
6. Adverse event
   1. Methods of recording and reporting adverse events or reactions
   2. Provisions for dealing with complications.
7. Evaluation of results.
   1. Data management procedures
   2. Statistical methods and considerations
   3. Subjects withdrawn from the trial.
8. Name and designations of the principle investigator and investigators.